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Presidential Documents

Title 3—

The President

Proclamation 9318 of September 10, 2015

National Days of Prayer and Remembrance, 2015

By the President of the United States of America

A Proclamation

Fourteen years ago, the peace of a beautiful morning was broken. The events of September 11, 2001, left a permanent mark on the spirit of every American, and our Nation is forever changed. Nearly 3,000 precious lives were taken, and their loved ones were forced to face an unthinkable grief. As we pay tribute to the innocents we lost and the first responders who put themselves in harm's way—some even giving their own lives for their fellow citizens—we also recognize the families whose love abides, and we reaffirm the truth that resonates in the heart of our Nation: that we will never forget that day.

Guided by a steadfast belief in the power of good over evil, people from every corner of our country came together in the aftermath of the attacks to lift each other up and restore our communities. Bound by a common sense of hope, Americans united across faiths and traditions to reject hate and work together toward a better future.

In memory of those we lost, we resolved to shape a world where events like those of September 11, 2001, could never happen again, and we see this unbreakable spirit live on every day across America. We see it in the courage of first responders who carry the memories of fallen partners with them as they continue safeguarding their communities—prepared to make the same sacrifice for us all. We see it in the gleaming New York City Freedom Tower, which rose high where the buildings once fell. We see it in the example of extraordinary bravery set by the men and women who fought back in the Pennsylvania sky. We see it in the legacy of those killed while serving in the Pentagon, which is reflected in the enduring courage of our troops, veterans, and military families. We see it in the selflessness of all those who sacrificed to bring justice to those responsible, and who continue to defend our liberty. And as a result, we will forever march forward as a stronger people, under God and indivisible, toward a brighter day.

As we solemnly reflect on those taken from us too soon by acts of depravity, let us continue to stand with their loved ones and recommit to forging a tomorrow where the sun sets on an America that knows everlasting freedom, security, and peace.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim Friday, September 11 through Sunday, September 13, 2015, as National Days of Prayer and Remembrance. I ask that the people of the United States honor and remember the victims of September 11, 2001, and their loved ones through prayer, contemplation, memorial services, the visiting of memorials, the ringing of bells, evening candlelight remembrance vigils, and other appropriate ceremonies and activities. I invite people around the world to participate in this commemoration.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of September, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2015–23301
Filed 9–14–15; 8:45 am]
Billing code 3295–F5

Presidential Documents

Proclamation 9319 of September 10, 2015

Patriot Day and National Day of Service and Remembrance, 2015

By the President of the United States of America

A Proclamation

On September 11, 2001, America experienced the worst terrorist attack in her history when nearly 3,000 men, women, and children were taken from us, leaving their families and our Nation with a void that can never be filled. But those who brought hate to our shores and smoke to our skies did not expect our country to emerge stronger, and our beacons of hope and freedom to shine brighter as a result. In the years since, we have stood strong as one people—determined to further embolden our country's character with acts of endurance and strength; rebuilding and resilience; renewal and progress. In remembrance of the innocent victims who lost their lives and in honor of the families they left behind, let us continue to answer these heinous acts by serving our communities, lifting the lives of our fellow citizens, and spreading the hope that others tried to dim that day.

The compassion that rose in the hearts and minds of the American people on September 11 still serves as the ultimate rebuke to the evil of those who attacked us. First responders who risked and gave their lives to rescue others demonstrated the unwavering heroism that defines our great Nation. Volunteers donated time, money, and blood to ensure wounds gave way to healing and recovery. Young people, raised until then in a time of peace, stepped forward to serve and defend us, and meet the threats of our time. And people from across our country and the world joined together in the days that followed to stand up and turn toward one another with open arms, making of a tragedy something the terrorists could never abide—a tribute of hope over fear, and love over hate.

As we reflect on the lives we lost and pay tribute to the families who still live with extraordinary pain, let us resolve to continue embodying the American spirit that no act of terror can ever extinguish. I call on all Americans to observe this National Day of Service and Remembrance with acts of selflessness and charity. In doing so, we prove once again that the power of those who seek to harm and to destroy is never greater than our power to persevere and to build. I encourage everyone to visit www.Serve.gov to learn of the many opportunities available to give back to others and to reaffirm the fundamental truth that we are our brothers' and our sisters' keepers, and that we can forge a brighter future together.

Today, we continue our unfaltering march forward, enduring in the perennial optimism that drives us and brightening the light that the darkness of evil can never overcome. We remember and yearn for the presence of the beautiful lives lost, and we recommit to honoring their memories by shaping the days to come—in as stark a contrast as possible to those who took them from us—with courage, liberty, and love.

By a joint resolution approved December 18, 2001 (Public Law 107–89), the Congress has designated September 11 of each year as ''Patriot Day,'' and by Public Law 111–13, approved April 21, 2009, the Congress has requested the observance of September 11 as an annually recognized ''National Day of Service and Remembrance.''

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim September 11, 2015, as Patriot Day and National Day of Service and Remembrance. I call upon all departments, agencies, and instrumentalities of the United States to display the flag of the United States at half-staff on Patriot Day and National Day of Service and Remembrance in honor of the individuals who lost their lives on September 11, 2001. I invite the Governors of the United States and its Territories and interested organizations and individuals to join in this observance. I call upon the people of the United States to participate in community service in honor of those our Nation lost, to observe this day with appropriate ceremonies and activities, including remembrance services, and to observe a moment of silence beginning at 8:46 a.m. Eastern Daylight Time to honor the innocent victims who perished as a result of the terrorist attacks of September 11, 2001.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of September, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2015–23302
Filed 9–14–15; 8:45 am]
Billing code 3295–F5

Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–1940; Special Conditions No. 25–597–SC]

Special Conditions: Bombardier Aerospace Inc. Model BD–500–1A10 and BD–500–1A11 Airplanes; Flight-Envelope Protection, High Incidence Protection Function

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions, request for comment.

SUMMARY: These special conditions are issued for the Bombardier Aerospace Inc. Model BD–500–1A10 and –A11 airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology and design envisioned in the airworthiness standards for transport-category airplanes. This design feature is a high incidence protection system that limits the angle of attack at which the airplane can be flown during normal low-speed operation. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Bombardier Aerospace Inc. on September 15, 2015. We must receive your comments by October 30, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–1940 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC, 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joe Jacobsen, FAA, Airplane and Flight Crew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2011; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplanes.

In addition, the substance of these special conditions has been subject to the public-comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On December 10, 2009, Bombardier Aerospace Inc. applied for a type certificate for their new Model BD–500-1A10 and –1A11 airplanes. The Model BD–500–1A10 and –1A11 airplanes are swept-wing monoplanes with a pressurized cabin, and share an identical supplier base and significant common design elements. The fuselage is aluminum alloy material, blended double-bubble fuselage, and is sized for nominal five-abreast seating. The powerplant for each airplane model includes two under-wing Pratt and Whitney PW1524G ultra-high bypass, geared turbofan engines. Flight controls are fly-by-wire with two passive/uncoupled side sticks. Avionics include five landscape primary flightdeck displays. The wingspans are 115 feet; heights are 37.75 feet; and length is 114.75 feet for the Model BD–500–1A10, and 127 feet for the Model BD–500–1A11. Passenger capacity is 110 for the Model BD–500–1A10, and 125 for the Model BD–500–1A11. Maximum takeoff weight is 131,000 pounds for the Model BD–500–1A10, and 144,000 pounds for the Model BD–500–1A11. Maximum takeoff thrust is 21,000 pounds for the Model BD–500–1A10, and 23,300 pounds for the Model BD–500–1A11. Range is 3,394 miles, and operating altitude is 41,000 feet, for both airplane models.

Sections specified in these special conditions that address the high incidence protection system will replace common sections found in the applicable sections of Title 14, Code of Federal Regulations (14 CFR) part 25.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Bombardier Aerospace Inc. must show that the Model BD–500-1A10 and –1A11 airplanes meet the applicable provisions of part 25 as amended by Amendments 25–1 through 25–129.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model BD–500–1A10 and –1A11 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model BD–500–1A10 and –1A11 airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36; and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Model BD–500–1A10 and –1A11 airplanes will incorporate the following novel or unusual design feature:

A high incidence protection system that replaces the stall warning system during normal operating conditions, prohibits the airplane from stalling, limits the angle of attack at which the airplane can be flown during normal low speed operation, and that cannot be overridden by the flightcrew. The application of this angle-of-attack limit impacts the stall-speed determination, the stall-characteristics and stall-warning demonstration, and the longitudinal-handling characteristics. The current regulations do not address this type of protection feature.

Discussion

The high incidence protection function prevents the airplane from stalling at low speeds and, therefore, a stall-warning system is not needed during normal flight conditions. If a failure of the high incidence protection function occurs that is not shown to be extremely improbable, stall warning must be provided in a conventional manner. Also, the flight characteristics at the angle of attack for maximum-lift coefficient (C_{Lmax}) must be suitable in the traditional sense.

These special conditions address this novel or unusual design feature on the Bombardier Model BD–500–1A10 and –1A11 airplanes. These special conditions, which include airplane performance requirements, establish a level of safety equivalent to the current regulations for reference stall speeds, stall warning, stall characteristics, and miscellaneous other minimum reference speeds.

These proposed special conditions for the Bombardier Model BD–500–1A10 and –1A11 airplanes present amendments to the appropriate regulations to accommodate the unique features of the high incidence protection function.

Applicability

As discussed above, these special conditions are applicable to the Bombardier Model BD–500–1A10 and –1A11 airplanes. Should Bombardier apply at a later date for a change to the type certificate to include another model incorporating the same or similar novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, the Federal Aviation Administration (FAA) issues the following special conditions as part of the type certification basis for Bombardier Model BD–500–1A10 and –1A11 airplanes.

Flight Envelope Protection: High Incidence Protection System

Special Conditions Part I

Stall Protection and Scheduled Operating Speeds

The following special conditions are in lieu of §§ 25.21(b), 25.103, 25.145(a), 25.145(b)(6), 25.201, 25.203, 25.207, and 25.1323(d).

Foreword

In the following paragraphs, ''in icing conditions'' means with the ice accretions (relative to the relevant flight phase) as defined in 14 CFR part 25, Amendment 121, appendix C.

1. Definitions

These special conditions use terminology that does not appear in 14 CFR part 25:

- *High incidence protection system:* A system that operates directly and automatically on the airplane's flying controls to limit the maximum angle of attack that can be attained to a value below that at which an aerodynamic stall would occur.
- *Alpha limit:* The maximum angle of attack at which the airplane stabilizes with the high incidence protection system operating, and the longitudinal control held on its aft stop.
- V_{min}*:* The minimum steady flight speed in the airplane configuration under consideration with the high incidence protection system operating. See Part I, section 3 of these special conditions.
- V_{min} *1g:* V_{min} corrected to 1g conditions. See Part I, section 3 of these special conditions. It is the minimum calibrated airspeed at which the airplane can develop a lift force normal to the flight path and equal to its weight when at an angle of attack not greater than that determined for V_{min}.

2. Capability and Reliability of the High Incidence Protection System

The applicant must establish the capability and reliability of the high incidence protection system. The applicant may establish this capability and reliability by flight test, simulation, or analysis. The capability and reliability required are:

1. It must not be possible during pilot-induced maneuvers to encounter a stall, and handling characteristics must be acceptable, as required by Part I, section 5 of these special conditions.

2. The airplane must be protected against stalling due to the effects of wind-shears and gusts at low speeds as required by Part I, section 6 of these special conditions.

3. The ability of the high incidence protection system to accommodate any reduction in stalling incidence must be verified in icing conditions.

4. The high incidence protection system must be provided in each abnormal configuration of the high-lift devices that are likely to be used in flight following system failures.

5. The reliability of the system and the effects of failures must be acceptable in accordance with § 25.1309.

3. Minimum Steady Flight Speed and Reference Stall Speed

In lieu of § 25.103, the following applies:

(a) The minimum steady flight speed, V_{min}, is the final stabilized calibrated airspeed obtained when the airplane is decelerated until the longitudinal control is on its stop in such a way that the entry rate does not exceed 1 knot per second.

(b) The minimum steady flight speed, V_{min}, must be determined in icing and non-icing conditions with:

(1) The high incidence protection system operating normally;

(2) Idle thrust and automatic thrust system (if applicable) inhibited;

(3) All combinations of flap settings and landing gear position for which V_{min} is required to be determined;

(4) The weight used when reference stall speed, V_{SR}, is being used as a factor to determine compliance with a required performance standard;

(5) The most unfavorable center of gravity allowable; and

(6) The airplane trimmed for straight flight at a speed achievable by the automatic trim system.

(c) The 1-g minimum steady flight speed, $V_{min}1g$, is the minimum calibrated airspeed at which the airplane can develop a lift force (normal to the flight path) equal to its weight, while at an angle of attack not greater than that at which the minimum steady flight speed of subparagraph (a) was determined. It must be determined in icing and non-icing conditions.

(d) The reference stall speed, V_{SR}, is a calibrated airspeed defined by the applicant. V_{SR} may not be less than a 1g stall speed. V_{SR} must be determined in non-icing conditions and expressed as:

$$V_{SR} \geq \frac{V_{CL_{MAX}}}{\sqrt{n_{zw}}}$$

where—

V_{CLmax} = Calibrated airspeed obtained when the load factor-corrected lift coefficient ($\frac{n_{zw}W}{qS}$) is first a maximum during the maneuver prescribed in paragraph (e)(8) below.

N_{zw} = Load factor normal to the flight path at V_{CLmax}

W = Airplane gross weight;

S = Aerodynamic reference wing area; and

q = Dynamic pressure.

(e) V_{CLmax} is determined in non-icing conditions with:

(1) Engines idling, or, if that resultant thrust causes an appreciable decrease in stall speed, not more than zero thrust at the stall speed;

(2) The airplane in other respects (such as flaps and landing gear) in the condition existing in the test or performance standard in which V_{SR} is being used;

(3) The weight used when V_{SR} is being used as a factor to determine compliance with a required performance standard;

(4) The center of gravity position that results in the highest value of reference stall speed;

(5) The airplane trimmed for straight flight at a speed achievable by the automatic trim system, but not less than 1.13 V_{SR} and not greater than 1.3 V_{SR};

(6) Reserved.

(7) The high incidence protection system adjusted, at the option of the applicant, to allow higher incidence than is possible with the normal production system; and

(8) Starting from the stabilized trim condition, apply the longitudinal control to decelerate the airplane so that the speed reduction does not exceed 1 knot per second.

4. Stall Warning

In lieu of § 25.207, the following apply:

4.1 Normal Operation

If the design meets all conditions of section 2 of these special conditions, then the airplane need not provide stall warning during normal operation. The conditions of section 2 provide safety equivalent to § 25.207, ''Stall warning,'' so the provision of an additional, unique warning device for normal operations is not required.

4.2 High Incidence Protection System Failure

For any failure of the high incidence protection system that the applicant cannot show to be extremely improbable, and that result in the capability of the system no longer satisfying any part of section 2 of these

special conditions, the design must provide stall warning that protects against encountering unacceptable stall characteristics and against encountering stall.

(a) This stall warning, with the flaps and landing gear in any normal position, must be clear and distinctive to the pilot and meet the requirements specified in paragraphs (d) and (e), below.

(b) The design must also provide this stall warning in each abnormal configuration of the high-lift devices that is likely to be used in flight following system failures.

(c) The design may furnish this stall warning either through the inherent aerodynamic qualities of the airplane or by a device that will give clearly distinguishable indications under all expected conditions of flight. However, a visual stall-warning device that requires the attention of the crew within the flightdeck is not acceptable by itself. If a warning device is used, it must provide a warning in each of the airplane configurations prescribed in paragraph (a), above, and for the conditions prescribed in paragraphs (d) and (e), below.

(d) In non-icing conditions, stall warning must provide sufficient margin to prevent encountering unacceptable stall characteristics and encountering stall in the following conditions:

(1) In power-off straight deceleration not exceeding 1 knot per second to a speed 5 knots or 5 percent calibrated airspeed, whichever is greater, below the warning onset.

(2) In turning flight, stall deceleration at entry rates up to 3 knots per second when recovery is initiated not less than 1 second after the warning onset.

(e) In icing conditions, stall warning must provide sufficient margin to prevent encountering unacceptable characteristics and encountering stall, in power-off straight and turning flight decelerations not exceeding 1 knot per second, when the pilot starts a recovery maneuver not less than three seconds after the onset of stall warning.

(f) An airplane is considered stalled when the behavior of the airplane gives the pilot a clear and distinctive indication of an acceptable nature that the airplane is stalled. Acceptable indications of a stall, occurring either individually or in combination, are:

(1) A nose-down pitch that cannot be readily arrested;

(2) Buffeting, of a magnitude and severity that is a strong and effective deterrent to further speed reduction;

(3) The pitch control reaches the aft stop, and no further increase in pitch attitude occurs when the control is held full aft for a short time before recovery is initiated.

(g) An airplane exhibits unacceptable characteristics during straight or turning flight decelerations if it is not always possible to produce and to correct roll and yaw by unreversed use of aileron and rudder controls, or abnormal nose-up pitching occurs.

5. Handling Characteristics at High Incidence

In lieu of §§ 25.201 and 25.203, the following apply:

5.1 High Incidence Handling Demonstration

In lieu of § 25.201:

(a) Maneuvers to the limit of the longitudinal control, in the nose-up pitch, must be demonstrated in straight flight and in 30-degree banked turns with:

(1) The high incidence protection system operating normally;

(2) Initial power conditions of:

i. Power off; and

ii. The power necessary to maintain level flight at 1.5 V_{SR1}, where V_{SR1} is the reference stall speed with flaps in approach position, the landing gear retracted, and maximum landing weight.

(3) None.

(4) Flaps, landing gear, and deceleration devices in any likely combination of positions;

(5) Representative weights within the range for which certification is requested; and

(6) The airplane trimmed for straight flight at a speed achievable by the automatic trim system.

(b) The following procedures must be used to show compliance in non-icing and icing conditions:

(1) Starting at a speed sufficiently above the minimum steady flight speed to ensure that a steady rate of speed reduction can be established, apply the longitudinal control so that the speed reduction does not exceed 1 knot per second until the control reaches the stop;

(2) The longitudinal control must be maintained at the stop until the airplane has reached a stabilized flight condition and must then be recovered by normal recovery techniques;

(3) Maneuvers with increased deceleration rates:

(i) In non-icing conditions, the requirements must also be met with increased rates of entry to the incidence limit, up to the maximum rate achievable; and

(ii) In icing conditions, with the anti-ice system working normally, the requirements must also be met with increased rates of entry to the incidence limit, up to 3 knots per second.

(4) Maneuver with ice accretion prior to operation of the normal anti-ice system. With the ice accretion prior to operation of the normal anti-ice system, the requirements must also be met in deceleration at 1 knot per second up to full back stick.

5.2 Characteristics in High Incidence Maneuvers

In lieu of § 25.203:

In icing and non-icing conditions:

(a) Throughout maneuvers with a rate of deceleration of not more than 1 knot per second, both in straight flight and in 30-degree banked turns, the airplane's characteristics must be as follows:

(1) There must not be any abnormal nose-up pitching.

(2) There must not be any uncommanded nose-down pitching, which would be indicative of stall. However, reasonable attitude changes associated with stabilizing the incidence at Alpha limit as the longitudinal control reaches the stop would be acceptable.

(3) There must not be any uncommanded lateral or directional motion, and the pilot must retain good lateral and directional control, by conventional use of the controls, throughout the maneuver.

(4) The airplane must not exhibit buffeting of a magnitude and severity that would act as a deterrent from completing the maneuver specified in paragraph 5.1(a).

(b) In maneuvers with increased rates of deceleration, some degradation of characteristics is acceptable, associated with a transient excursion beyond the stabilized Alpha limit. However, the airplane must not exhibit dangerous characteristics or characteristics that would deter the pilot from holding the longitudinal control on the stop for a period of time appropriate to the maneuver.

(c) It must always be possible to reduce incidence by conventional use of the controls.

(d) The rate at which the airplane can be maneuvered from trim speeds associated with scheduled operating speeds such as V_2 and $V_{REF,}$ up to Alpha limit, must not be unduly damped or be significantly slower than can be achieved on conventionally controlled transport airplanes.

5.3 Characteristics Up to Maximum Lift Angle of Attack

In lieu of § 25.201:

(a) In non-icing conditions:

Maneuvers with a rate of deceleration of not more than 1 knot per second, up

to the angle of attack at which V_{CLmax} was obtained, as defined in section 3, ''Minimum Steady Flight Speed and Reference Stall Speed,'' must be demonstrated in straight flight and in 30-degree banked turns in the following configurations:

(1) The high incidence protection deactivated or adjusted, at the option of the applicant, to allow higher incidence than is possible with the normal production system;

(2) Automatic thrust-increase system inhibited (if applicable);

(3) Engines idling;

(4) Flaps and landing gear in any likely combination of positions; and

(5) The airplane trimmed for straight flight at a speed achievable by the automatic trim system.

(b) In icing conditions:

Maneuvers with a rate of deceleration of not more than 1 knot per second, up to the maximum angle of attack reached during maneuvers from paragraph 5.1(b)(3)(ii), must be demonstrated in straight flight with:

(1) The high incidence protection deactivated or adjusted, at the option of the applicant, to allow higher incidence than is possible with the normal production system;

(2) Automatic thrust-increase system inhibited (if applicable);

(3) Engines idling;

(4) Flaps and landing gear in any likely combination of positions; and

(5) The airplane trimmed for straight flight at a speed achievable by the automatic trim system.

(c) During the maneuvers used to show compliance with paragraphs (a) and (b), above, the airplane must not exhibit dangerous characteristics, and it must always be possible to reduce the angle of attack by conventional use of the controls. The pilot must retain good lateral and directional control, by conventional use of the controls, throughout the maneuver.

6. Atmospheric Disturbances

Operation of the high incidence protection system must not adversely affect airplane control during expected levels of atmospheric disturbances, nor impede the application of recovery procedures in case of wind-shear. This must be demonstrated in non-icing and icing conditions.

7. Proof of Compliance

In lieu of § 25.21(b), ''[Reserved],'' the design must meet the following requirement:

(b) The flying qualities must be evaluated at the most unfavorable center-of-gravity position.

8. Sections 25.145(a), 25.145(b)(6), and 25.1323(d)

The design must meet the following modified requirements:

- For § 25.145(a), add ''V_{min}'' in lieu of ''stall identification.''
- For § 25.145(b)(6), add ''V_{min}'' in lieu of ''V_{SW}.''
- For § 25.1323(d), add ''From 1.23 V_{SR} to V_{min} . . .,'' in lieu of ''1.23 V_{SR} to stall warning speed . . .,'' and, ''. . . speeds below V_{min} . . .'' in lieu of ''. . . speeds below stall warning. . . .''

Special Conditions Part II—Credit for Robust Envelope Protection in Icing Conditions

The following special conditions are in lieu of the specified paragraphs of §§ 25.103, 25.105, 25.107, 25.121, 25.123, 25.125, 25.143, and 25.207.

1. In lieu of § 25.103, define the stall speed as provided in Part I of these special conditions.

2. In lieu of § 25.105(a)(2)(i), the following applies:

(i) The V_2 speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the takeoff configuration, or apply 25.105(a)(2)(ii) unchanged.

3. In lieu of § 25.107(c) and (g), the following apply, with additional sections (c′) and (g′):

(c) In non-icing conditions, V_2, in terms of calibrated airspeed, must be selected by the applicant to provide at least the gradient of climb required by § 25.121(b), but may not be less than—

(1) V_{2MIN};

(2) V_R plus the speed increment attained (in accordance with § 25.111(c)(2)) before reaching a height of 35 feet above the takeoff surface; and

(3) A speed that provides the maneuvering capability specified in § 25.143(h).

(c′) In icing conditions with the ''takeoff ice'' accretion defined in part 25, appendix C, V_2 may not be less than—

(1) The V_2 speed determined in non-icing conditions; and

(2) A speed that provides the maneuvering capability specified in § 25.143(h).

(g) In non-icing conditions, V_{FTO}, in terms of calibrated airspeed, must be selected by the applicant to provide at least the gradient of climb required by § 25.121(c), but may not be less than—

(1) 1.18 V_{SR}; and

(2) A speed that provides the maneuvering capability specified in § 25.143(h).

(g′) In icing conditions with the ''final takeoff ice'' accretion defined in part 25, appendix C, V_{FTO} may not be less than—

(1) The V_{FTO} speed determined in non-icing conditions.

(2) A speed that provides the maneuvering capability specified in § 25.143(h).

4. In lieu of §§ 25.121(b)(2)(ii)(A), 25.121(c)(2)(ii)(A), and 25.121(d)(2)(ii), the following apply:

In lieu of § 25.121(b)(2)(ii)(A):

(A) The V_2 speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the takeoff configuration; or

In lieu of § 25.121(c)(2)(ii)(A):

(A) The V_{FTO} speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the en-route configuration; or

In lieu of § 25.121(d)(2)(ii):

(d)(2) The requirements of subparagraph (d)(1) of this paragraph must be met:

(ii) In icing conditions with the approach ice accretion defined in 14 CFR part 25, appendix C, in a configuration corresponding to the normal all-engines-operating procedure in which $V_{min}1g$ for this configuration does not exceed 110 percent of the $V_{min}1g$ for the related all-engines-operating landing configuration in icing, with a climb speed established with normal landing procedures, but not more than 1.4 V_{SR} (V_{SR} determined in non-icing conditions).

5. In lieu of § 25.123(b)(2)(i), the following applies:

(i) The minimum en-route speed scheduled in non-icing conditions does not provide the maneuvering capability specified in § 25.143(h) for the en-route configuration, or

6. In lieu of § 25.125(b)(2)(ii)(B) and § 25.125(b)(2)(ii)(C), the following applies:

(B) A speed that provides the maneuvering capability specified in § 25.143(h) with the approach ice accretion defined in 14 CFR part 25, appendix C.

7. In lieu of § 25.143(j)(2)(i), the following applies:

(i) The airplane is controllable in a pull-up maneuver up to 1.5 g load factor or lower if limited by angle-of-attack protection.

8. In lieu of § 25.207, ''Stall warning,'' to read as the requirements defined in these special conditions Part I, section 4.

Issued in Renton, Washington, on September 1, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–23101 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2014–1075; Special Conditions No. 25–599–SC]

Special Conditions: Dassault Aviation Model Falcon 5X Airplane, Pilot-Compartment View Through Hydrophobic Windshield Coatings in Lieu of Windshield Wipers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comment.

SUMMARY: These special conditions are issued for the Dassault Model Falcon 5X airplane. This airplane will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is hydrophobic windshield coatings in lieu of windshield wipers. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Dassault Aviation on September 15, 2015. We must receive your comments by October 30, 2015.

ADDRESSES: Send comments identified by docket number FAA–2014–1075 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Bob Hettman, ANM–112, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2683; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplane(s).

In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On July 1, 2012, Dassault Aviation applied for a type certificate for their new Model Falcon 5X airplane.

The Model Falcon 5X airplane is a large, transport-category airplane to be operated in private/corporate transportation with a maximum of 19 passengers. The airplane incorporates a low, swept-wing design with winglets; twin rear-fuselage-mounted engines; and the newest generation of Dassault Aviation's EASy flightdeck.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.17, Dassault Aviation must show that the Model Falcon 5X airplane meets the applicable provisions of part 25, as amended by Amendments 25–1 through 25–136.

The certification basis includes certain special conditions, exemptions, or later amended sections of the applicable part that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model Falcon 5X airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model Falcon 5X airplane must comply with the fuel-vent and exhaust-emission requirements of part 34, and the noise-certification requirements of part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Features

The Dassault Model Falcon 5X airplane will incorporate the following novel or unusual design feature:

The airplane flightdeck design incorporates a hydrophobic windshield coating that, during precipitation, provides an adequate outside view from the pilot compartment. Sole reliance on such a coating, without windshield wipers, constitutes a novel or unusual design feature for which the applicable airworthiness regulations do not contain adequate or appropriate safety

standards. Therefore, special conditions are required to provide a level of safety equivalent to that established by the regulations.

Discussion

Section 25.773(b)(1) requires a means to maintain a clear portion of the windshield for both pilots operating a transport-category airplane to have a sufficiently extensive view along the flight path during precipitation conditions. The regulations require this means to maintain such an area of clear vision during heavy-rain precipitation at airplane speeds up to 1.5 V_{SR1}.

This requirement has existed in principle since 1953 in part 4b of the ''Civil Air Regulations'' (CAR). Section 4b.351(b)(1) required that ''Means shall be provided for maintaining a sufficient portion of the windshield clear so that both pilots are afforded a sufficiently extensive view along the flight path in all normal flight attitudes of the airplane. Such means shall be designed to function under the following conditions without continuous attention on the part of the crew: (i) In heavy rain at speeds up to 1.6 V_{S1}, flaps retracted.''

Effective December 26, 2002, Amendment 25–108 changed the speed for effectiveness of the means to maintain an area of clear vision from up to 1.6 V_{S1} to 1.5 V_{SR1} to accommodate the redefinition of the reference stall speed from the minimum speed in the stall, V_{S1}, to greater than or equal to the 1g stall speed, V_{SR1}. As noted in the preamble to the final rule for that amendment, the reduced factor of 1.5 on V_{SR1} is to maintain approximately the same speed as the 1.6 factor on V_{S1}.

The requirement that the means to maintain a clear area of forward vision must function at high speeds and high precipitation rates is based on the use of windshield wipers as the means to maintain an adequate area of clear vision in precipitation conditions. The requirement in 14 CFR 121.313(b) and 125.213(b) to provide ''. . . a windshield wiper or equivalent for each pilot station . . .'' has remained unchanged since at least 1953.

The effectiveness of windshield wipers to maintain an area of clear vision normally degrades as airspeed and precipitation rates increase. It is assumed that because high speeds and high precipitation rates represent limiting conditions for windshield wipers, they will also be effective at lower speeds and precipitation levels. Accordingly, § 25.773(b)(1)(i) does not require maintenance of a clear area of forward vision at lower speeds or lower precipitation rates.

A forced airflow blown directly over the windshield has also been used to maintain an area of clear vision in precipitation. The limiting conditions for this technology are comparable to those for windshield wipers. Accordingly, introduction of this technology did not present a need for special conditions to maintain the level of safety embodied in the existing regulations.

Hydrophobic windshield coatings may depend to some degree on airflow to maintain a clear-vision area. The heavy rain and high speed conditions specified in the current rule do not necessarily represent the limiting condition for this new technology. For example, airflow over the windshield, which may be necessary to remove moisture from the windshield, may not be adequate to maintain a sufficiently clear-vision area of the windshield in low-speed flight or during surface operations. Alternatively, airflow over the windshield may be disturbed during such critical times as the approach to land, where the airplane is at a higher-than-normal pitch attitude. In these cases, areas of airflow disturbance or separation on the windshield could cause failure to maintain a clear-vision area on the windshield.

In addition to potentially depending on airflow to function effectively, hydrophobic coatings may also be dependent on water-droplet size for effective precipitation removal. For example, precipitation in the form of a light mist may not be sufficient for the coating's properties to result in maintaining a clear area of vision.

The current regulations identify speed and precipitation rate requirements that represent limiting conditions for windshield wipers and blowers, but not for hydrophobic coatings. Likewise, it is necessary to issue special conditions to maintain the level of safety represented by the current regulations.

These special conditions provide an appropriate safety standard for the hydrophobic-coating technology as the means to maintain a clear area of vision by requiring the coating to be effective at low speeds and low precipitation rates, as well as at the higher speeds and precipitation rates identified in the current regulation. These special conditions are the only new or changed requirements relative to those in § 25.773(b)(1) at Amendment 25–108.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Dassault Falcon 5X airplane. Should Dassault apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Dassault Falcon 5X airplane. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type-certification basis for Dassault Falcon 5X airplanes.

The airplane must have a means to maintain a clear portion of the windshield, during precipitation conditions, enough for both pilots to have a sufficiently extensive view along the ground or flight path in normal taxi and flight attitudes of the airplane. This means must be designed to function, without continuous attention on the part of the flightcrew, in conditions from light misting precipitation to heavy rain, at speeds from fully stopped in still air, to 1.5 V_{SR1} with lift and drag devices retracted.

Issued in Renton, Washington, on September 9, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–23099 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–1483; Special Conditions No. 25–598–SC]

Special Conditions: Gulfstream Aerospace Corporation Model GVII–G500 Airplanes; Limit Engine Torque Loads

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Gulfstream Model GVII–G500 airplane. These airplanes have a novel or unusual design feature as compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature includes engine size and the potential torque loads imposed by sudden engine stoppage. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is September 15, 2015. We must receive your comments by October 30, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–1483 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Walt Sippel, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2774; facsimile 425–227–1232.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for, prior public comment on these special conditions are impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplane.

In addition, the substance of these special conditions has been subject to the public-comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On March 29, 2012, Gulfstream Aerospace Corporation applied for a type certificate for their new Model GVII–G500 airplane.

The GVII airplane is a large-cabin business jet with seating for 19 passengers. It incorporates a low, swept-wing design with winglets and a T-tail. The Model GVII–G500 airplane is powered by two aft-fuselage-mounted Pratt & Whitney turbofan engines. Avionics will include four primary display units and multiple touchscreen controllers. The flight-control system is a three-axis fly-by-wire system controlled by active control/coupled side sticks.

The Model GVII–G500 airplane wingspan is approximately 87 ft with a length of just over 91 ft. Maximum takeoff weight will be approximately 76,850 lbs and maximum takeoff thrust will be approximately 15,135 lbs. Maximum range will be approximately 5,000 nm and maximum operating altitude will be 51,000 ft.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.17, Gulfstream Aerospace Corporation must show that the Model GVII–500 airplane meets the applicable provisions of part 25, as amended by Amendments 25–1 through 25–137 thereto.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model GVII–G500 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model GVII–G500 airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34 and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of

the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Model GVII–G500 airplane will incorporate the following novel or unusual design features: Large-bypass engines capable of larger and more complex dynamic loads than were envisioned when the 14 CFR 25.361(b) rule was developed in 1957, thereby requiring issuance of special conditions to establish appropriate design standards for the Model GVII–G500 airplane.

Discussion

The limit engine torque load imposed by sudden engine stoppage due to malfunction or structural failure (such as a compressor jamming) has been a specific requirement for transport-category airplanes since 1957. In the past, the design torque loads associated with typical failure scenarios have been estimated by the engine manufacturer and were provided to the airframe manufacturer as limit loads. These limit loads were considered simple, pure-torque static loads.

It is evident from service history that the engine-failure events that tend to cause the most severe loads are fan-blade failures, and these events occur much less frequently than the typical ''limit'' load condition.

To maintain the level of safety envisioned by § 25.361(b), more comprehensive criteria are required for the new generation of high-bypass engines. These special conditions distinguish between the more common engine-failure events and those rare events resulting from structural failures. The more-common events are regarded as static torque limit load conditions. The more-severe events resulting from extreme engine-failure conditions (such as loss of a full fan blade at redline speed) are regarded as full dynamic load conditions. These are considered ultimate loads, and include all transient loads associated with the event. An additional safety factor is applied to the more-critical airframe supporting structure.

Applicability

As discussed above, these special conditions are applicable to the Model GVII–G500 airplane. Should Gulfstream Aerospace apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplane. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Gulfstream Aerospace Corporation Model GVII–G500 airplane.

In lieu of § 25.361(b) the following special conditions apply:

1. For turbine engine installations, the engine mounts, pylons, and adjacent supporting airframe structure must be designed to withstand 1g level flight loads acting simultaneously with the maximum limit torque loads imposed by each of the following:

a. Sudden engine deceleration due to a malfunction that could result in a temporary loss of power or thrust, and

b. The maximum acceleration of the engine.

2. For auxiliary power unit (APU) installations, the power unit mounts and adjacent supporting airframe structure must be designed to withstand 1g level-flight loads acting simultaneously with the maximum limit torque loads imposed by each of the following:

a. Sudden APU deceleration due to malfunction or structural failure; and

b. The maximum acceleration of the APU.

3. For engine supporting structure, an ultimate loading condition must be considered that combines 1g flight loads with the transient dynamic loads resulting from:

a. The loss of any fan, compressor, or turbine blade; and separately,

b. Where applicable to a specific engine design, any other engine structural failure that results in higher loads.

4. The ultimate loads developed from the conditions specified in special conditions 3(a) and 3(b), above, are to be multiplied by a factor of 1.0 when applied to engine mounts and pylons, and multiplied by a factor of 1.25 when applied to adjacent supporting airframe structure.

5. Any permanent deformation that results from the conditions specified in special condition 3, above, must not prevent continued safe flight and landing.

Issued in Renton, Washington, on September 1, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–23100 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0926; Directorate Identifier 2014–NM–121–AD; Amendment 39–18263; AD 2015–18–05]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 97–07–14, for certain Airbus Model A320–111, –211, and –231 airplanes. AD 97–07–14 required modification of an area on the front spar of the wing center section by installing shims and new fasteners to reinforce pressure floor fittings. This new AD continues to require modifying the rib flange on the front spar of the wing center section by installing shims and new fasteners to reinforce pressure floor fittings; and requires repetitive high frequency eddy current inspections for cracking of the radius of the rib flanges and vertical stiffener at frame 36, a rototest inspection for cracking of the fastener holes of the rib flanges, repair if needed, and adding additional airplanes to the applicability. This AD was prompted by the need for repetitive inspections on airplanes on which the modification of the rib flange on the front spar of the wing center section has been done. We are issuing this AD to prevent fatigue cracking on the rib flange area of the front spar of the wing center section, which can reduce the structural integrity of fuselage frame 36 and the wing center section.

DATES: This AD becomes effective October 20, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 20, 2015.

The Director of the Federal Register approved the incorporation by reference

of a certain other publication listed in this AD as of May 12, 1997 (62 FR 16473, April 7, 1997).

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0926;* or in person at the Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0926.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997). AD 97–07–14 applied to certain Airbus Model A320–111, –211, and –231 airplanes. The NPRM published in the **Federal Register** on April 24, 2015 (80 FR 22943).

Since we issued AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997), we have determined the need for repetitive inspections on airplanes on which Airbus Modification 20976 (modification of the rib flange on the front spar of the wing center section) was done in production, or was done using Airbus Service Bulletin A320–57–1013, dated April 12, 1989; or Airbus Service Bulletin A320–57–1013, Revision 1, dated September 29, 1992.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0053, dated March 7, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition on certain Airbus Model A320–211 and –231 airplanes. The MCAI states:

> During full scale fatigue tests on the Airbus A320 test specimen, cracks were found in the rib flange on the front spar side perpendicular to vertical posts at frame (FR) 36. It was determined that similar cracks could develop on certain in-service aeroplanes.
>
> This condition, if not detected and corrected, could affect the wing structural integrity.
>
> To reduce the risk of crack initiation, two modifications for aeroplanes in production and one modification for in-service aeroplanes were developed by Airbus: Prior to [manufacturer serial number] MSN 0085, the adaptation modification (Mod) 20976 was applied in production, consisting in installing shims under the fasteners linking the rib flange, the lower corner, the front spar and its vertical stiffener; from MSN 0085 onwards, the serial Mod 20908 was applied in production, consisting in installing reinforced lower surface rib flanges at front spar level.
>
> Airbus issued Service Bulletin (SB) A320–57–1013 for affected in-service aeroplanes, and [Directorate General for Civil Aviation] DGAC France issued AD [F–19]95–098–066 [dated May 24, 1995, which corresponds to FAA AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997), *http://ad.easa.europa.eu/ad/F-1995-098-066*] to require installation of shims under the fasteners linking the rib flange, the lower corner, the front spar and its vertical stiffener.
>
> Following a recent analysis, Airbus identified the need for repetitive [HFEC and rototest] inspections for aeroplanes on which Airbus SB A320–57–1013 or production Mod 20976 has been embodied.
>
> For the reason described above, this [EASA] AD retains the requirements of DGAC France AD [F–19]95–098–066, [dated May 24, 1995, which corresponds to FAA AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997), *http://ad.easa.europa.eu/ad/F-1995-098-066*], which is superseded, and requires repetitive [HFEC and rototest] inspections of the center wing lower ribs at FR 36 and, depending on findings, accomplishment of a repair.
>
> After EASA issued PAD 14–013, it was discovered that additional work [removal of shims and fasteners on the rib flange on the front spar side and doing an HFEC inspection for cracking of the radius of the rib flanges and a rototest inspection for cracking of the fastener holes during each inspection] to be included in Revision 01 of Airbus SB A320–57–1175, is required to accomplish the inspections. This Final [EASA] AD has been amended accordingly.

Airplanes having MSNs 001, 009, and 015 were not included in the applicability of AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997). EASA AD 2014–0053, dated March 7, 2014, expanded the applicability to all airplanes having manufacturer serial numbers up to MSN 0084 inclusive. We included paragraph (h) of this AD to require the modification for the airplanes having MSNs 001, 009, and 015. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0926-0002.*

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (80 FR 22943, April 24, 2015) or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 22943, April 24, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 22943, April 24, 2015).

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320–57–1175, Revision 01, including Appendix 01, dated May 28, 2014. The service information describes procedures for repetitive high frequency eddy current inspections for cracking of the radius of the rib flanges and vertical stiffener at frame 36, a rototest inspection for cracking of the fastener holes of the rib flanges, and repair. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Explanation of ''RC'' Procedures and Tests in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which procedures and tests in the service information are required for compliance with an AD. Differentiating these procedures and tests from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help

provide consistent judgment in AD compliance. The procedures and tests identified as Required for Compliance (RC) in any service information have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

As specified in a NOTE under the Accomplishment Instructions of the specified service information, procedures and tests that are identified as RC in any service information must be done to comply with the AD. However, procedures and tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an alternative method of compliance (AMOC), provided the procedures and tests identified as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to procedures or tests identified as RC will require approval of an AMOC.

Costs of Compliance

We estimate that this AD affects 11 airplanes of U.S. registry.

The actions required by AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997), and retained in this AD take about 13 work-hours per product, at an average labor rate of $85 per work-hour. Required parts cost about $576 per product. Based on these figures, the estimated cost of the actions that were required by AD 97–07–14 is $1,681 per product.

We also estimate that it will take about 45 work-hours per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $1,600 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $59,675, or $5,425 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov/#!docketDetail;D=FAA-2015-0926;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997), and adding the following new AD:

2015–18–05 Airbus: Amendment 39–18263. Docket No. FAA–2015–0926; Directorate Identifier 2014–NM–121–AD.

(a) Effective Date

This AD becomes effective October 20, 2015.

(b) Affected ADs

This AD replaces AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997).

(c) Applicability

This AD applies to Airbus Model A320–211 and -231 airplanes, certificated in any category, all manufacturer serial numbers (MSN) up to MSN 0084 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by the determination that repetitive inspections are needed on airplanes on which the modification of the rib flange on the front spar of the wing center section has been done. We are issuing this AD to prevent fatigue cracking on the rib flange area of the front spar of the wing center section, which can reduce the structural integrity of fuselage frame 36 and the wing center section.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Modification

This paragraph restates the requirements of paragraph (a) of AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997). For airplanes with manufacturer serial numbers (MSN) 005 through 008 inclusive, MSNs 010 through 014 inclusive, and MSNs 016 through 042 inclusive: Prior to the accumulation of 16,000 total landings, or within 3 months after May 12, 1997 (the effective date of AD 97–07–14), whichever occurs later, modify the rib flange on the front spar of the wing center section by installing shims and new fasteners to reinforce pressure floor fittings, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–57–1013, Revision 1, dated September 29, 1992.

(h) New Requirement of This AD: Modification for Airplanes With MSNs 001, 009, and 015

Prior to the accumulation of 16,000 total landings since first flight, or within 30 days after the effective date of this AD, whichever occurs later, modify the rib flange on the front spar of the wing center section by installing shims and new fasteners to reinforce pressure floor fittings, in

accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–57–1013, Revision 1, dated September 29, 1992.

(i) New Requirement of This AD: Repetitive Inspections

Within the applicable compliance times specified in paragraphs (i)(1) and (i)(2) of this AD, do a high frequency eddy current (HFEC) inspection for cracking of the radius of the rib flanges and vertical stiffener at frame 36, and do a rototest inspection for cracking of the fastener holes of the rib flanges and vertical stiffener, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–57–1175, Revision 01, including Appendix 01, dated May 28, 2014. During each inspection, remove the shims and fasteners on the rib flange on the front spar side and do an HFEC inspection for cracking of the radius of the rib flanges and a rototest inspection for cracking of the fastener holes. If no cracking is found, oversize the holes of the rib flange and the holes of the shims, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–57–1175, Revision 01, including Appendix 01, dated May 28, 2014. Repeat the inspections thereafter at intervals not to exceed 32,500 flight cycles or 65,000 flight hours, whichever occurs first.

(1) For airplanes having Airbus Modification 20976 embodied: At the later of the times specified in paragraphs (i)(1)(i) or (i)(1)(ii) of this AD.

(i) Before exceeding 47,800 flight cycles or 95,600 flight hours, whichever occurs first, since the airplane's first flight.

(ii) Within 850 flight cycles or 1,700 flight hours, whichever occurs first, after the effective date of this AD.

(2) For airplanes on which the modification of the front spar of the wing center section was accomplished using Airbus Service Bulletin A320–57–1013, Revision 1, dated September 29, 1992: At the later of the times specified in paragraphs (i)(2)(i) or (i)(2)(ii) of this AD.

(i) Before exceeding 10,700 flight cycles or 21,500 flight hours, whichever occurs first, after the modification of the rib flange on the front spar of the wing center section was done using Airbus Service Bulletin A320–57–1013, Revision 1, dated September 29, 1992.

(ii) Within 850 flight cycles or 1,700 flight hours, whichever occurs first, after the effective date of this AD.

(j) Repair

If, during any inspection required by paragraph (i) of this AD, any cracking is found, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(k) Credit for Previous Actions

This paragraph restates the requirements of Note 2 of paragraph (g) of AD 97–07–14, Amendment 39–9988 (62 FR 16473, April 7, 1997): This paragraph provides credit for the modification of the rib flange required by paragraph (g) of this AD, if those actions were performed before May 12, 1997 (the effective date of AD 97–07–14), using Airbus Service Bulletin A320–57–1013, dated April 12, 1989, which is not incorporated by reference in this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j) of this AD, if the service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures and tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(m) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0053, dated March 7, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0926.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (n)(5) and (n)(6) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on October 20, 2015.

(i) Airbus Service Bulletin A320–57–1175, Revision 01, including Appendix 01, dated May 28, 2014.

(ii) Reserved.

(4) The following service information was approved for IBR on May 12, 1997 (62 FR 16473, April 7, 1997).

(i) Airbus Service Bulletin A320–57–1013, Revision 1, dated September 29, 1992.

Note 1 to paragraph (n)(4)(i): Airbus Service Bulletin A320–57–1013, Revision 1, dated September 29, 1992, contains the following list of effective pages: Pages 1 through 3 show revision level 1, dated September 29, 1992; pages 4 through 11 are from the original issue, dated April 12, 1989.

(ii) Reserved.

(5) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on September 2, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–22924 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0363; Directorate Identifier 2014–NE–08–AD; Amendment 39–18252; AD 2015–17–19]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Rolls-Royce plc (RR) RB211 Trent 768–60, 772–60, and 772B–60 turbofan engines. This AD was prompted by fuel leaks caused by damage to the fan case low-pressure (LP) fuel tube. This AD requires inspection of the fan case LP fuel tubes and associated clips and the fuel oil heat exchanger (FOHE) mounts and associated hardware. We are issuing this AD to prevent failure of the fan case LP fuel tube, which could lead to an in-flight engine shutdown, loss of thrust control, and damage to the airplane.

DATES: This AD is effective October 20, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 20, 2015.

ADDRESSES: For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* Web site: *https://www.aeromanager.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0363.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0363; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Wego Wang, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7134; fax: 781–238–7199; email: *wego.wang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to all RR RB211 Trent 768–60, 772–60, and 772B–60 turbofan engines. The SNPRM published in the **Federal Register** on April 21, 2015 (80 FR 22137). We preceded the SNPRM with a notice of proposed rulemaking (NPRM) that published in the **Federal Register** on July 3, 2014 (79 FR 37965). The NPRM proposed to require inspection of the fan case LP fuel tubes and associated clips and the FOHE mounts and associated hardware. The NPRM was prompted by fuel leaks caused by damage to the fan case LP fuel tube. We are issuing this AD to prevent failure of the fan case LP fuel tube, which could lead to an in-flight engine shutdown, loss of thrust control, and damage to the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–73–AH522, Revision 2, dated July 18, 2014; and RR Alert NMSB No. RB.211–73–AH837, dated September 9, 2014. This service information describes procedures for inspecting, and replacing if required, the fan case LP fuel tube and clips and the FOHE mounts and hardware. This service information is reasonably available because the interested parties have access to it through their normal course of business or see **ADDRESSES** for other ways to access this service information.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the SNPRM (80 FR 22137, April 21, 2015).

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this AD as proposed.

Costs of Compliance

We estimate that this AD affects about 50 engines installed on airplanes of U.S. registry. We also estimate that it will take about 6 hours per engine to comply with this AD. The average labor rate is $85 per hour. We also estimate that 25 of the engines will fail the inspection required by this AD. Required parts cost about $4,031 per engine. Based on these figures, we estimate the cost of this AD on U.S. operators to be $126,275.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2015–17–19 Rolls-Royce plc: Amendment 39–18252; Docket No. FAA–2014–0363; Directorate Identifier 2014–NE–08–AD.

(a) Effective Date

This AD is effective October 20, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Rolls-Royce plc (RR) RB211 Trent 768–60, 772–60, and 772B–60 turbofan engines, if fitted with fuel tube, part number (P/N) FW53576, which was incorporated through RR production modification 73–F343 or which were modified in service in accordance with RR Service Bulletin (SB) No. RB.211–73–F343, Revision 4, dated May 26, 2011.

(d) Reason

This AD was prompted by fuel leaks caused by damage to the fan case low-pressure (LP) fuel tube. We are issuing this AD to prevent failure of the fan case LP fuel tube, which could lead to an in-flight engine shutdown, loss of thrust control, and damage to the airplane.

(e) Actions and Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Within 800 flight hours (FH) after the effective date of this AD, and thereafter at intervals not to exceed 800 FH, inspect the clip at the uppermost fan case LP fuel tube clip position, CP4881, and support bracket, P/N FW26692. Use Accomplishment Instructions, paragraph 3.A, of RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–73–AH837, dated September 9, 2014, or paragraph 3.A. or 3.B. of RR Alert NMSB No. RB.211–73–AH522, Revision 2, dated July 18, 2014, to do the inspection.

(i) If the clip at the uppermost clip position, CP4881, fails inspection, replace the clip with a part eligible for installation and, before further flight, inspect the fan case LP fuel tube, P/N FW53576, for fretting, and clips for cracks or failure, according to Accomplishment Instructions, paragraph 3.A. of RR Alert NMSB No. RB.211–73–AH837, dated September 9, 2014, or paragraph 3.A. or 3.B. of RR Alert NMSB No. RB.211–73–AH522, Revision 2, dated July 18, 2014.

(ii) If the support bracket, P/N FW26692, fails inspection, replace the bracket before further flight with a part eligible for installation and inspect the fan case LP fuel tube, P/N FW53576, and clips for cracks or failure.

(2) Within 4,000 FH since new or 800 FH, whichever occurs later, after the effective date of this AD, and thereafter at intervals not to exceed 4,000 FH, inspect the fan case LP fuel tube, P/N FW53576, and clips, and the fuel oil heat exchanger (FOHE) mounts and hardware, for damage, wear, or fretting. Use paragraph 3.A. or 3.B., Accomplishment Instructions, of RR Alert NMSB No. RB.211–73–AH522, Revision 2, dated July 18, 2014, to do the inspection.

(i) If the fan case LP fuel tube, P/N FW53576, fails inspection, before further flight, replace the fuel tube and clips with parts eligible for installation.

(ii) If any FOHE mount or hardware shows signs of damage, wear, or fretting, replace the damaged part before further flight with a part eligible for installation.

(3) At each shop visit after the effective date of this AD, inspect the fan case LP fuel tubes, P/Ns FW26589, FW36335, FW26587, FW53577, and FW53576, and clips, and the FOHE mounts and hardware, for damage, wear, or fretting. Use paragraphs 3.B.(1) and 3.B.(2) of RR Alert NMSB No. RB.211–73–AH522, Revision 2, dated July 18, 2014, to do the inspection.

(i) If any fan case LP fuel tube fails inspection, replace the fuel tube and clips before further flight with parts eligible for installation.

(ii) If any FOHE mount or hardware shows signs of damage, wear, or fretting, replace the damaged part before further flight with a part eligible for installation.

(4) If you replace any fan case LP fuel tube, clip, or FOHE mount or hardware as a result of the inspections in paragraphs (e)(1), (e)(2), or (e)(3) of this AD, you must still continue to perform the repetitive inspections in paragraphs (e)(1), (e)(2), and (e)(3) of this AD.

(5) Any reports requested in the Alert NMSB accomplishment instructions referenced in paragraphs (e)(1), (e)(2), and (e)(3) of this AD are not required by this AD.

(f) Credit for Previous Actions

If, before the effective date of this AD, you performed the inspections and corrective actions required by paragraph (e) of this AD using RR NMSB No. RB.211–73–G848, Revision 3, dated June 12, 2014; or RR Alert NMSB No. RB.211–73–AH837, dated September 9, 2014; or paragraph 3.A. or 3.B. of RR Alert NMSB No. RB.211–73–AH522, Revision 2, dated July 18, 2014; or earlier versions, you met the inspection requirements in paragraph (e) of this AD.

(g) Definitions

For the purposes of this AD:

(1) An ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges, except that the separation of engine flanges solely for the purposes of transportation without subsequent engine maintenance is not an engine shop visit.

(2) The fan case LP fuel tubes and clips, and the FOHE mounts and hardware, are eligible for installation if they have passed the inspection requirements of paragraphs (e)(1), (e)(2), and (e)(3) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE–AD–AMOC@faa.gov.*

(i) Related Information

(1) For more information about this AD, contact Wego Wang, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7134; fax: 781–238–7199; email: *wego.wang@faa.gov*.

(2) Refer to MCAI European Aviation Safety Agency AD 2014–0243R1, dated December 10, 2014 for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2014-0363-0004*.

(3) RR NMSB No. RB.211–73–G848, Revision 3, dated June 12, 2014; RR Alert NMSB No. RB.211–73–AH837, dated September 9, 2014; and RR Alert NMSB No. RB.211–73–AH522, Revision 2, dated July 18, 2014, or earlier versions, which are not incorporated by reference in this AD, can be obtained from RR, using the contact information in paragraph (j)(3) of this AD.

(4) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Rolls-Royce plc (RR) Alert Non-Modification Service Bulletin (NMSB) No. RB.211–73–AH522, Revision 2, dated July 18, 2014.

(ii) RR NMSB No. RB.211–73–AH837, dated September 9, 2014.

(3) For RR service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE24 8BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* Internet: *https://www.aeromanager.com*.

(4) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Burlington, Massachusetts, on August 20, 2015.

Colleen M. D'Alessandro,

Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–21458 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0277; Directorate Identifier 2015–NE–05–AD; Amendment 39–18262; AD 2015–18–04]

RIN 2120–AA64

Airworthiness Directives; CFM International S.A. Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain CFM International S.A. (CFM) CFM56–7B and CFM56–3 turbofan engines. This AD was prompted by a report of an uncommanded in-flight shutdown (IFSD) on a CFM CFM56–7B engine following rupture of the 73-tooth gearshaft located in the engine accessory gearbox (AGB). This AD requires AGB/transfer gearbox (TGB) magnetic chip detector (MCD) inspection of the affected gearshafts until removal. We are issuing this AD to prevent failure of certain engine AGB gearshafts, which could lead to failure of one or more engines, loss of thrust control, and damage to the airplane.

DATES: This AD is effective October 20, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 20, 2015.

ADDRESSES: For service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877–432–3272; fax: 877–432–3329; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0277.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0277; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kyle Gustafson, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7183; fax: 781–238–7199; email: *kyle.gustafson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain CFM CFM56–7B series turbofan engines. The NPRM published in the **Federal Register** on May 1, 2015 (80 FR 24856). The NPRM was prompted by a report of an uncommanded IFSD on a CFM CFM56–7B engine following rupture of the 73-tooth gearshaft located in the engine AGB. The NPRM proposed to require MCD inspection of the affected gearshafts until removal.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (80 FR 24856, May 1, 2015) and the FAA's response to each comment.

Request To Add CFM56–3 Engines to Applicability

CFM requested that we add CFM56–3 engines to this AD, as the CFM56–3 engines share the same 73-tooth and 41-tooth gearshafts as the CFM56–7B engines.

We agree. We revised the applicability of this AD by adding CFM56–3 engines.

Request To Clarify Discussion of IFSDs

CFM commented that the NPRM (80 FR 24856, May 1, 2015) incorrectly indicated that multiple instances of uncommanded IFSDs occurred on CFM56–7B engines following rupture of the 73-tooth gearshaft when only one IFSD actually occurred. CFM requested that this AD be revised to reflect that only one IFSD occurred following rupture of the 73-tooth gearshaft.

We agree. We revised the Summary, Discussion, and Unsafe Condition sections of this final rule to reflect the occurrence of one IFSD following rupture of the 73-tooth gearshaft in the CFM56–7B's AGB.

Request To Clarify Inspection Requirement

CFM commented that the NPRM (80 FR 24856, May 1, 2015) did not clearly specify that the MCD inspection is of the AGB/TGB.

We agree. We revised the Summary and the Compliance sections of this final rule to reflect that the required inspection is an ''AGB/TGB MCD inspection.''

Request To Clarify Relevant Service Information

CFM requested that we specify in the Relevant Service Information section of the NPRM (80 FR 24856, May 1, 2015) that the referenced service bulletins (SBs) describe the procedures for removal of the affected 73-tooth and 41-tooth gearshafts and also list the affected gearshafts by serial number (S/N).

We disagree. This AD does not include a ''Relevant Service Information'' section. We are, however, incorporating this SB by reference and it is available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0277. We did not change this AD.

Request To Clarify Proposed AD Requirements

CFM commented that the Proposed AD Requirements section should be revised to be consistent with the compliance and mandatory terminating action paragraphs in this AD.

We disagree. This AD incorporates changes produced as a result of the comments received, as permitted by the Administrative Procedures Act (APA) (Pub. L. 79–404, 5 U.S.C. 551, *et. seq.*). To take the action the commenter suggests would be contrary to the APA. We did not change this AD.

Request To Allow Use of Later Revisions to SBs

CFM requested that we include a provision in this AD to allow for use of later revisions to CFM SB No. CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014, and SB No. CFM56–7B S/B 72–0965, dated December 16, 2014.

We disagree. We do not know the content of future revisions of SBs and, therefore, cannot approve them before publication. We did not change this AD.

Request To Revise Description of Laboratory Analysis

CFM requested we change the wording in the Compliance section of this AD from ''particles lab analysis'' to ''laboratory analysis.''

We agree. The term ''laboratory analysis'' is more accurate. We revised the term ''particles lab analysis'' to read ''laboratory analysis'' in the Compliance section of this AD.

Request To Include Serial Numbers of Affected Gearshafts

CFM requested that we include the S/Ns of the affected 73-tooth and 41-tooth gearshafts in this AD instead of referencing the SBs. CFM indicated that CFM56–3 operators may not have access to the CFM56–7B SBs.

We disagree. Operators have access to CFM SB No. CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014, in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–0277, or by requesting the SB from CFM. We did not change this AD.

Request To Limit Applicability by Engine Serial Number

Sun Country Airlines requested that the Applicability of this AD be limited to CFM56–7B engines with engine S/Ns listed in Appendix A of CFM SB No. CFM56–7B S/B 72–0964 and CFM56–7B engines that have the 73-tooth gearshafts listed in Appendix B of CFM SB No. CFM56–7B S/B 72–0964 installed post-production. Sun Country Airlines noted that the applicability of the NPRM (80 FR 24856, May 1, 2015) could be misconstrued to mean to include all CFM56–7B engines unless it is proven that they do not have the affected 73-tooth or 41-toth gearshafts.

We disagree. CFM identified the affected population of gearshafts by gearshaft S/N and by the engine S/N on which it was installed. However, an affected gearshaft may now be installed on an engine with an S/N not listed in Appendix A. To address the latter population, those engines with a gearshaft that has been installed on an unknown engine, we identified the affected population of 73-tooth and 41-tooth gearshafts by gearshaft part number and S/N. We did not change this AD.

Request To Clarify That Applicability Is by Gearshaft Serial Number

Delta Air Lines (Delta) requested that we clarify that the applicability of the AD is by gearshaft S/N rather than by engine S/N.

We agree. We revised the Applicability paragraph of this AD to read: ''This AD applies to all CFM International S.A. (CFM) CFM56–7B and CFM56–3 engines with a 73-tooth or 41-tooth gearshaft installed in the accessory gearbox (AGB), that has a gearshaft serial number in Appendix A or Appendix B of CFM Service Bulletin (SB) No. CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014.''

Request To Verify Affected Gearshafts Have Been Removed From Service and Reduce the Scope of Applicability

Delta requested that we verify which gearshafts have been removed from service per the proposed requirements of the NPRM (80 FR 24856, May 1, 2015). Delta further asked that we reduce the applicability to only those affected gearshafts that remain in service.

We disagree. This AD will ensure that all affected gearshafts are removed from service and that gearshafts already removed from service are not returned to service. We did not change this AD.

Support for the NPRM

The Boeing Company and an anonymous commenter expressed support for the NPRM (80 FR 24856, May 1, 2015) as proposed.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed CFM SB No. CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014. The service information describes procedures for removal of affected 73-tooth and 41-tooth gearshafts. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

Costs of Compliance

We estimate that this AD will affect about 67 engines installed on airplanes of U.S. registry. We also estimate that it will take about 1 hour per engine to do the inspection and 8 hours per engine to replace each affected gearshaft. We estimate thirty-six 73-tooth gearshafts and forty 41-tooth gearshafts will need replacement at a cost of $12,480 and $7,680 per part, respectively. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $813,855.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2015–18–04 CFM International S.A.: Amendment 39–18262; Docket No. FAA–2015–0277; Directorate Identifier 2015–NE–05–AD.

(a) Effective Date

This AD is effective October 20, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to CFM International S.A. (CFM) CFM56–7B and CFM56–3 engines with a 73-tooth or 41-tooth gearshaft installed in the accessory gearbox (AGB), that has a gearshaft serial number in Appendix A or Appendix B of CFM Service Bulletin (SB) No. CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014.

(d) Unsafe Condition

This AD was prompted by a report of an uncommanded in-flight shutdown on a CFM CFM56–7B engine following rupture of the 73-tooth gearshaft located in the engine AGB. We are issuing this AD to prevent failure of certain AGB gearshafts, which could lead to failure of one or more engines, loss of thrust control, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Initial AGB/Transfer Gearbox (TGB)/ Magnetic Chip Detector (MCD) Inspection and Analysis

(i) For affected 73-tooth gearshafts, perform an AGB/TGB MCD inspection within 250 flight hours (FHs) since last inspection, within 25 FHs from the effective date of this AD, or when the gearshaft accumulates 3,000 FHs since new, whichever comes later.

(ii) For affected 41-tooth gearshafts, perform an AGB/TGB MCD inspection within 250 FHs since last inspection, within 25 FHs from the effective date of this AD, or when the gearshaft accumulates 6,000 FHs since new, whichever comes later.

(iii) If any magnetic particles, including fuzz, are seen, determine with laboratory analysis if the particles are 73-tooth or 41-tooth gearshaft material.

(iv) If the particles are 73-tooth or 41-tooth gearshaft material, remove the affected gearshaft(s) within 75 FHs since the AGB/ TGB MCD inspection.

(2) Repetitive AGB/TGB MCD Inspection and Analysis

(i) For affected 73-tooth gearshafts, perform an AGB/TGB MCD inspection and laboratory analysis within every 500 FHs since the last AGB/TGB MCD inspection until affected gearshaft is removed.

(ii) For affected 41-tooth gearshafts, perform an AGB/TGB MCD inspection and laboratory analysis within every 500 FHs since the last AGB/TGB MCD inspection until affected gearshaft is removed.

(iii) If any magnetic particles, including fuzz, are seen, determine with laboratory analysis if the particles are 73-tooth or 41-tooth gearshaft material.

(iv) If the particles are 73-tooth or 41-tooth gearshaft material, remove the affected gearshaft(s) within 75 FHs since the AGB/ TGB MCD inspection.

(f) Mandatory Terminating Action

(1) Remove the affected 73-tooth gearshaft prior to the gearshaft accumulating 6,000 FHs since new or within 50 FHs after the effective date of this AD, whichever comes later.

(2) Remove the affected 41-tooth gearshaft prior to the gearshaft accumulating 9,000 FHs since new or within 50 FHs after the effective date of this AD, whichever comes later.

(g) Installation Prohibition

After the effective date of this AD, do not install an affected gearshaft into an AGB.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(i) Related Information

For more information about this AD, contact Kyle Gustafson, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7183; fax: 781–238–7199; email: *kyle.gustafson@faa.gov.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on October 20, 2015.

(i) CFM International Service Bulletin No. CFM56–7B S/B 72–0964, Revision 1, dated December 15, 2014.

(ii) Reserved.

(4) For CFM service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877–432–3272; fax: 877–432–3329; email: *aviation.fleetsupport@ge.com.*

(5) You may view this service information at FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(6) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on August 28, 2015.

Ann C. Mollica,

Acting Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–22598 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0504]

RIN 0910–AH12

Administrative Destruction of Certain Drugs Refused Admission to the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is implementing its authority to destroy a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), by issuing a rule that provides to the owner or consignee notice and an opportunity to appear and introduce testimony to the Agency prior to destruction. This regulation is authorized by amendments made to the FD&C Act by the Food and Drug Administration Safety and Innovation Act (FDASIA). Implementation of this authority will allow FDA to better protect the public health by providing an administrative process for the destruction of certain refused drugs, thus increasing the integrity of the drug supply chain.

DATES: This rule is effective October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4338, Silver Spring, MD 20993–0002, 301–796–3324, *FDASIAImplementationORA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

Implementation of FDA's administrative destruction authority will better protect the integrity of the

drug supply chain by providing a disincentive for the importation of drugs that are adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act (21 U.S.C. 355) (unapproved drugs) and reducing the likelihood of such drugs being refused admission and subsequently offered for reimportation. In 2012, Congress amended section 801(a) of the FD&C Act (21 U.S.C. 381(a)) to provide FDA with the authority to destroy a refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) without providing the owner or consignee with the opportunity to export the drug. Congress directed FDA to issue regulations that provide the drug's owner or consignee with notice and an opportunity to present testimony to the Agency prior to the drug's destruction (section 708 of FDASIA). The final rule provides the owner or consignee of a drug that has been refused admission into the United States, and that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) with: (1) Written notice that FDA intends to destroy the drug and (2) an opportunity to present testimony to the Agency before the drug is destroyed.

FDA is issuing this final rule under section 801(a) of the FD&C Act.

Summary of the Major Provisions

The final rule implements the authority of FDA to destroy a drug after providing the owner or consignee of a drug that has been refused admission into the United States under section 801(a) of the FD&C Act, and that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) with: (1) Written notice that FDA intends to destroy the drug and (2) an opportunity to present testimony to the Agency before the drug is destroyed.

FDA is amending part 1 (21 CFR part 1) by expanding the scope of § 1.94 (21 CFR 1.94) to include administrative destruction. Currently this provision provides the owner or consignee of an FDA-regulated product offered for import into the United States with notice and opportunity to present testimony to the Agency prior to refusal of admission of the product. The final rule expands the scope of § 1.94 to also provide an owner or consignee with notice and opportunity to present testimony to the Agency prior to the destruction of certain refused drugs.

Section 708 of FDASIA and the final rule allow FDA to provide two separate notices and hearings—one for refusal of admission and one for destruction of a refused drug product—or to combine both notices and hearings into one notice and proceeding. Whether the determinations occur separately or in one combined proceeding, the determination of refusal and the determination regarding destruction of a drug will be made separately by the Agency as the findings are separate and distinct.

Costs and Benefits

The primary public health benefit from adoption of the rule would be the value of the illnesses and deaths avoided because FDA destroyed a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that posed a public health risk. This benefit accrues whenever the Agency's other enforcement tools would not have prevented a drug, including a biological product, which does not comply with the requirements of the FD&C Act (violative drug) from entering the U.S. market. The estimated primary costs of the final rule include the additional costs to destroy a violative drug and the one-time costs of updating the FDA Operational and Administrative System for Import Support (OASIS), making appropriate revisions to Chapter 9 of the FDA Regulatory Procedures Manual (RPM) and the Agency's internal import operations guidelines, and training for FDA personnel. FDA estimates the quantifiable net annual effect of the final rule to range between a cost of $54,325 and a cost savings of $901,950 for an estimated 15,100 destructions each year. The Agency estimates that it will also incur one-time costs of $531,670.

I. Background and Legal Authority

In the **Federal Register** of May 6, 2014 (79 FR 25758), FDA proposed a rule to implement its new authority under section 708 of FDASIA to destroy a refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). As discussed in the preamble to the proposed rule, President Obama signed FDASIA (Pub. L. 112–144) into law on July 9, 2012. Title VII of FDASIA provides FDA with important new authorities to help the Agency better protect the integrity of the drug supply chain. One of those new authorities is provided in section 708 of FDASIA, which amends section 801(a) of the FD&C Act, to provide FDA with the authority to use an administrative procedure to destroy a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that was not brought into compliance as described in section 801(b) of the FD&C Act and was refused admission into the United States. Section 708 of FDASIA authorizes FDA to use this new administrative procedure without offering the owner or consignee the opportunity to export the drug. The statute further provides that FDA will store and, as applicable, dispose of the drug that the Agency intends to destroy. The drug's owner or consignee is liable for FDA's storage and disposal costs under section 801(c) of the FD&C Act.

Section 708 of FDASIA directs FDA to issue regulations that provide the owner or consignee of a drug designated by the Agency for administrative destruction with notice and an opportunity to introduce testimony to the Agency prior to the destruction of the drug. The provision further states that this process may be combined with the notice and opportunity to appear before FDA and introduce testimony on the admissibility of the drug under section 801(a) of the FD&C Act, as long as appropriate notice is provided to the owner or consignee.

II. Overview of the Final Rule Including Changes to the Proposed Rule

FDA is amending part 1 to implement the administrative destruction of refused drugs. The amendment to part 1 consists of amendments to § 1.94, including two technical changes to § 1.94(b) where ''his'' is now changed to ''his or her'' and ''act'' is now changed to ''Federal Food, Drug, and Cosmetic Act'' in the final rule. No changes have been made to the proposed regulation and, therefore, FDA is finalizing the implementing regulation as proposed.

III. Comments on the Proposed Rule

FDA received 22 comments in the public docket for the May 6, 2014, proposed rule by the close of the comment period, July 7, 2014, each containing one or more comments. One comment was received in the public docket on July 8, 2014, 1 day after the docket closed. These comments were submitted by consumers, consumer advocacy groups, industry and trade organizations, industry, and a member of Congress. One comment consisted of a ''placeholder'' and did not contain any substantive remarks.

After considering the comments responsive to the proposed rule, the Agency is not making any changes to the regulatory language included in the proposed rule.

This section contains summaries of the relevant portions of the responsive comments and the Agency's responses to those comments. To make it easier to

identify the comments and our responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before our response. We have numbered each comment and response to help distinguish between different types of comments. Similar comments are grouped together under the same number. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

The Agency also received some general comments that were not responsive to the content of the rule, and therefore were not considered in its final development. Some of these comments, however, are summarized in this section and the Agency responded to those comments to provide clarity for the public and industry on the Agency's implementation of its administrative destruction authority under section 708 of FDASIA.

A. Notice and Hearing Process

Two comments suggested that FDA modify the notice and hearing process in the proposed rule.

(Comment 1) One comment asserted that the procedure set forth in § 1.94 appears to apply only to large commercial drug imports, not drugs offered for import by individuals, and that FDA should create a separate administrative hearing process for individuals.

(Response 1) The proposed rule amends § 1.94 to add administrative destruction of certain drugs to the current administrative hearing process for refusal of admission of an FDA-regulated product. The current rule applies to all imports regardless of how they enter the United States, *e.g.,* via a commercial port or an International Mail Facility (IMF), and regardless of who seeks to import the drug. As amended by this final rule, § 1.94 will provide an administrative hearing process to any owner or consignee of a refused drug with a value of $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that FDA intends to destroy whether that owner or consignee is an individual owner or consignee or a commercial importer. There is, therefore, no need to establish a separate administrative hearing process for individuals whose drugs have been refused and designated for administrative destruction.

(Comment 2) One comment stated that FDA should provide clarity for consumers regarding how they can introduce testimony to the Agency to challenge the administrative destruction of drugs they attempted to import but which were refused admission. The comment suggested that FDA allow testimony to be submitted by an affected owner or consignee through an online platform, email, regular mail, or facsimile and that the Agency include a supplemental document in the notice that instructs consumers on how to provide testimony to FDA to prevent administrative destruction of their drugs.

(Response 2) As described in Chapter 9 of the RPM, the type of administrative hearing under § 1.94 may vary from a series of telephone conversations to a more formal procedure. Introduction of testimony by the owner or consignee for Agency review and consideration can take many forms, including a telephone conversation, a facsimile, or mail, and does not have to be introduced in person. However, an in-person hearing will be scheduled if requested by the owner or consignee. (*http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf*). Current Agency procedures also allow such testimony to be submitted by the owner or consignee by email. Under the final rule, owners or consignees will have the same options for submitting testimony in opposition to the destruction of their drugs. Given the variety of options historically available to owners and consignees for submission of testimony, which will continue under the final rule, FDA does not believe that a dedicated online platform for submission of testimony is currently needed. If circumstances change in the future, FDA will consider whether such a system is appropriate.

FDA recognizes that an owner or consignee importing a drug for his/her own personal use may need information about the administrative hearing process when that drug has been detained by FDA for administrative destruction. Accordingly, the Agency will provide information on the administrative hearing process under § 1.94, as amended in this rule, by providing an insert in the Agency's notice of detention or by establishing a Web page on the FDA Web site containing information about the administrative destruction process including ways to submit testimony to the Agency in opposition to the destruction of a drug. FDA will also consider issuing guidance or other explanatory materials, as appropriate.

B. Drugs Subject to Administrative Destruction by FDA

Two comments requested clarity regarding what drugs will be destroyed by FDA under section 708 of FDASIA.

(Comment 3) Two commenters requested clarity on when a refused drug will be destroyed under section 708 of FDASIA and when the Agency will give the owner or consignee the option to destroy or export a refused drug.

(Response 3) Currently, owners or consignees of drugs that have been refused admission into the United States under section 801(a) of the FD&C Act have the option to destroy or export those drugs. Drugs imported via an IMF that have been refused admission are sent back to the United States Postal Service (USPS) for export. After implementation of section 708 of FDASIA, FDA anticipates that owners or consignees will still have the option to destroy or export a refused drug in at least two situations. First, only a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) is subject to administrative destruction under section 708 of FDASIA. Owners or consignees of a drug valued over the current $2,500 threshold that has been refused admission will still have the option to destroy or export that drug unless the drug has been imported via an IMF. For a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission, section 708 of FDASIA allows FDA to destroy the drug without providing the owner or consignee with the opportunity to destroy or export the drug.

The second situation where owners or consignees will still have the option to destroy or export a refused drug is when FDA refuses admission to a drug, including a biological product, that is subject to destruction under section 708 of FDASIA, but the Agency is not able to make a determination that the drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act. As stated in the proposed rule, FDA intends to administratively destroy a drug only where the Agency has made a determination that the drug is adulterated, misbranded, or is an unapproved drug. There may be situations where the Agency refuses admission to a drug that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) because it appears to be an adulterated, misbranded, or unapproved

drug but the Agency does not have sufficient information to make a determination that the drug is, in fact, an adulterated, misbranded, or unapproved drug. Under those circumstances, the owner or consignee will be given the opportunity to destroy or export that refused drug. If such a drug has come into the United States via an IMF, however, FDA will generally return the drug to the USPS for export.

C. Storage and Destruction Costs of Drugs Designated for Destruction

Section 708 of FDASIA provides that FDA will store and, as applicable, dispose of a drug where the Agency has made the determination to destroy that drug. The drug's owner or consignee is liable for FDA's storage and disposal costs under section 801(c) of the FD&C Act.

(Comment 4) One comment asked when FDA will take physical possession of drugs designated for destruction at express courier facilities and expressed concern about the possibility of extended storage time for these drugs at the expense of the express courier. The commenter also requested clarification regarding whether an express courier could be held liable for the costs of storage and destruction of a refused drug under section 801(c) of the FD&C Act.

(Response 4) If FDA designates a drug for possible destruction that has been offered for import into the United States via an express courier, FDA intends to take physical possession of that drug when the Agency has made the determination to destroy the drug. The Agency expects that by combining the notice and introduction of testimony on destruction with the notice and introduction of testimony on refusal of admission, any additional storage time at an express courier due to implementation of section 708 of FDASIA will be minimal.

An express courier is not liable for the storage or destruction costs under section 801(c) of the FD&C Act unless that courier is also the owner or consignee of a destroyed drug, which would be unusual. As stated in the proposed rule, if a drug is sent by international mail, FDA generally considers the addressee of the parcel to be the owner or consignee of the drug.

(Comment 5) One commenter requested that FDA clearly define and outline the storage and destruction costs to consumers under section 801(c) of the FD&C Act and that the Agency provide offsets to those costs for consumers unable to pay due to financial stress.

(Response 5) FDA generally does not intend to pursue recovery of storage and destruction costs under section 801(c) of the FD&C Act against individual consumers who seek to import a drug for their own personal use that is then refused and destroyed by the Agency under section 708 of FDASIA.

D. General Comments

The final rule provides the owner or consignee of a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that is refused admission into the United States with: (1) Written notice that FDA intends to destroy the drug and (2) an opportunity to present testimony to the Agency before the drug is destroyed.

(Comment 6) Many comments made general remarks expressing support or opposition to the authority granted to FDA by section 708 of FDASIA to administratively destroy certain refused drugs and did not focus on the rule or a particular section of the rule.

One comment supported the administrative destruction of certain refused drugs while several comments expressed concern about the potential impact of administrative destruction on a consumer's access to foreign drugs. These comments cited a patient's inability to comply with a drug treatment plan as a consequence of that lack of access. One comment requested that FDA change its current Personal Importation Policy to allow importation of any drug from a ''safe'' foreign pharmacy or for which there is a ''valid'' prescription. The comment further requested that FDA define the term ''safe personal drug import'' in the final rule.

(Response 6) As required for implementation of section 708 of FDASIA, the final rule provides appropriate due process to the owner or consignee of a drug that has been refused admission under section 801(a) of the FD&C Act, and that FDA intends to destroy. The new authority granted to FDA by section 708 of FDASIA to administratively destroy a drug applies only after the Agency has made the final decision to refuse admission to the drug. This new authority, therefore, does not affect a consumer's access to a foreign drug because consumers have no access to a refused drug under the FD&C Act. The final rule does not modify FDA's current policy with respect to personal importation of drugs.

(Comment 7) One comment suggested that implementation of section 708 of FDASIA could adversely affect the supply of low-value excipients and other drug components potentially leading to a drug shortage. The commenter suggested that FDA closely coordinate with manufacturers to limit the impact on the drug supply chain when the Agency exercises its authority to destroy low-value excipients or other drug components. The commenter further suggested that FDA's Drug Shortages Task Force monitor and publicly report on the effects of section 708 of FDASIA on the drug supply in the United States.

(Response 7) Excipients and other components of a drug are defined as drugs under section 201(g)(1) of the FD&C Act. An excipient or other drug component is therefore subject to administrative destruction under section 708 of FDASIA if that excipient or drug component offered for import is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) and is refused admission. FDA does not expect that administrative destruction of refused excipients or other drug components will lead to shortages of medically necessary drugs. The majority of excipients and drug components are imported into the United States as commercial entries. Currently, where excipients or drug components are refused admission, they are exported or destroyed. Refused excipients or other drug components, therefore, are not currently available for drug manufacturing in the United States. The Agency's exercise of administrative destruction will not affect a manufacturer's access to these refused excipients or other drug components and, therefore, will not contribute to shortages of drugs manufactured in the United States.

(Comment 8) One comment asserted that FDA only quantified the benefits but not the costs of the proposed rule which, according to the comment, should include the societal costs attributable to a patient's lack of access to an imported drug that does not pose a public health risk, and that patient's non-adherence to a medical plan that includes such drug.

(Response 8) In the proposed rule, FDA estimated both the costs and the benefits of the implementation of section 708 of FDASIA and the result was a quantifiable net annual social benefit. The detailed analysis of the estimated economic impact as provided in Ref. 10 in the proposed rule can be found at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm#.*

The preliminary Regulatory Impact Analysis did not include any costs attributable to lack of access to an imported drug by a patient as this is not a cost attributable to administrative destruction. Currently, drugs that are

refused admission are destroyed or exported by the importer or, in the case of international mail, returned to the USPS for export. Consequently, patients do not have access to those drugs. Only refused drugs are subject to administrative destruction under section 708 of FDASIA and, therefore, implementation of this authority does not result in a quantifiable cost to be included in the regulatory impact analysis of the implementation of section 708.

(Comment 9) A number of comments requested that FDA flag shipments in Customs and Border Protection's Automated Commercial System (ACS) or the Automated Commercial Environment (ACE) system, which is expected to replace ACS by December 2016, when a drug is destroyed. Another comment suggested that FDA establish a public database listing drugs destroyed by FDA under the authority of section 708 of FDASIA.

(Response 9) These comments relate to the Agency's operations implementing the final rule and, as FDA stated in the proposed rule, the Agency plans to specify the operational details of its process for destruction by guidance, operating guidelines, or similar means.

IV. Analysis of Impacts (Summary of the Final Regulatory Impact Analysis)

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the small number of expected destructions each year and the very small value per event, the Agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The primary public health benefit from adoption of the rule will be the value of the illnesses or deaths avoided because the Agency destroyed a refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that posed a public health risk. Additionally, the final rule may benefit firms through increases in sales, brand value, and investment in research and development if the destroyed drug is a counterfeit or an otherwise falsified version of an approved drug. The threat of destruction may also have a deterrent effect resulting in a reduction in the amount of violative drugs shipped into the United States in the future. These benefits accrue whenever the Agency's other enforcement tools would not have prevented a violative drug from entering the U.S. market. The current procedure whereby a drug refused admission might be exported does not ensure that the drug would not be imported into the United States in the future. These benefits are not quantified.

The estimated primary costs to FDA include the additional costs incurred by FDA to destroy a refused drug as opposed to the costs related to exportation of the drug and the one-time costs of updating OASIS, revising Chapter 9 of the RPM and other internal import operations guidelines, and training for FDA personnel. Our estimates of the primary costs assume that all refused drugs valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) would be destroyed (estimated 15,100 destructions performed each year), that FDA would contract the act of destruction out to another government agency or private firm, and the notice and hearing process for destruction will be combined with the current FDA notice and hearing process for refusal of drugs. The assumption that FDA will destroy all refused drugs represents an upper bound and may not always hold. If FDA chooses to destroy less than all of the refused drugs, all annual costs will decrease but the one-time costs will stay the same.

Based on an assumed 15,100 administrative destructions performed each year, the Agency estimates the quantifiable net annual effect of the final rule to be between a cost of $54,325 and a cost savings of $901,950, in addition to one-time costs of $531,670. Annualized over 20 years, the final rule is estimated to produce a net effect ranging from a cost of $89,021 to a cost savings of $867,254 at a 3 percent discount rate and a cost of $101,228 to a cost savings of $855,047 at a 7 percent discount rate. The present discounted value of the quantifiable net effect over 20 years ranges from a cost of $1,324,403 to a cost savings of $12,902,554 at a 3 percent discount rate and a cost of $1,072,408 to a cost savings of $9,058,383 at a 7 percent discount rate.

Our estimates do not include net benefits of the final rule because we have not quantified the potential health benefits of reducing the probability that a refused drug will be imported into the United States in the future. However, because the final rule likely represents a cost savings and the health benefits, though not quantified, will be positive even if one violative drug that would have caused an adverse event is destroyed rather than entering the U.S. market, the net benefits of the rule are likely positive.

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. U.S. Federal Government Agencies will bear the costs of the final rule with FDA bearing most of the cost as the Agency is responsible under section 708 of FDASIA for implementation of the rule and for the costs of storage and destruction. Therefore we certify that this final rule will not have a significant economic impact on a substantial number of small entities. This analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

The full discussion of economic impacts, which includes a list of changes made in the final regulatory impact analysis, is available in Docket No. FDA–2014–N–0504 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/*

EconomicAnalyses/default.htm# (Ref. 1).

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)(ii)). Therefore, clearance by the Office of Management and Budget is not required under the Paperwork Reduction Act of 1995.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this Reference section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Final Unfunded Mandates Reform Act Analysis for Administrative Destruction of Certain Drugs Refused Admission to the United States, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*#.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Revise § 1.94 to read as follows:

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission, or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his or her intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing on refusal of admission, the district director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director may give the owner or consignee a single written notice that provides the notice on refusal of admission and the notice on destruction of an article described in paragraph (a) of this section. The district director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

Dated: September 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23124 Filed 9–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 22

[Public Notice: 9269]

RIN 1400–AD71

Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates—Passport and Citizenship Services Fee Changes; Correction

AGENCY: Department of State.

ACTION: Interim final rule; correction.

SUMMARY: The Department of State published an interim final rule on September 8, 2015, amending the Schedule of Fees for Consular Services (Schedule) for certain passport fees and citizenship services fees. The document contained an incorrect effective date for a portion of the rule. This document corrects the rule.

DATES: The effective date of the amendments to § 22.1, Items 2.(a), 2.(b), and 2.(g), published in the **Federal Register** on September 8, 2015 (80 FR 53704), is corrected to September 26, 2015.

FOR FURTHER INFORMATION CONTACT: Jill Warning, Special Assistant, Office of the Comptroller, Bureau of Consular Affairs, Department of State; phone: 202–485–6681, telefax: 202–485–6826; email: *fees@state.gov.*

SUPPLEMENTARY INFORMATION: The Department of State published an interim final rule on September 8, 2015 (80 FR 53704); this document corrects the effective date for one portion of the rulemaking. The other dates applicable to the rulemaking, as well as the duration of the public comment period, are unchanged.

Corrections

In FR Rule Doc. 2015–22054, in the **Federal Register** of September 8, 2015 (80 FR 53704), the following corrections are made:

1. On page 53704 in the second column, the first sentence of the **DATES** section is corrected to read: ''Section 22.1, Items 2.(a), 2.(b), and 2.(g) of this rule become effective on September 26, 2015.''

2. On page 53709, in the third column, amendatory instruction 2a is corrected to read:

''a. Revising Items 2.(a), (b), and (g), effective September 26, 2015; and''

Dated: September 9, 2015.

David T. Donahue,

Acting Assistant Secretary of State for Consular Affairs, U.S. Department of State.

[FR Doc. 2015–23140 Filed 9–14–15; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9737]

RIN 1545–BK96

Controlled Group Regulation Examples

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final rules with revisions to examples that illustrate the controlled group rules applicable to regulated investment companies (RICs). The revised examples illustrate how the controlled group rules affect the RIC asset diversification tests.

DATES: *Effective Date:* These regulations are effective on September 15, 2015.

Applicability Dates: For dates of applicability, see §§ 1.851–3(b), 1.851–5(b).

FOR FURTHER INFORMATION CONTACT: Julanne Allen or Susan Baker of the Office of Associate Chief Counsel (Financial Institutions and Products) at (202) 317–6945 (Julanne Allen) or (202) 317–7053 (Susan Baker) (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR, part 1) relating to the application of the controlled group rules under section 851(c) to RICs.

To qualify as a RIC, a taxpayer must meet asset diversification tests pursuant to which, at the close of each quarter of the RIC's taxable year, not more than 25 percent of the value of the taxpayer's total assets may be invested in (i) the securities (other than Government securities or the securities of other RICs) of any one issuer; (ii) the securities (other than the securities of other RICs) of two or more issuers that the taxpayer controls and that are determined, under regulations prescribed by the Secretary, to be engaged in the same or similar trades or businesses or related trades or businesses; or (iii) the securities of one or more qualified publicly traded partnerships (as defined in section 851(h)) (the 25 percent tests). *See* section 851(b)(3)(B).

Section 851(c) provides special rules applicable to the asset diversification requirements of section 851(b)(3), including the 25 percent tests. The controlled group rules in section 851(c)(1) provide that, when ascertaining the value of a taxpayer's investment in the securities of an issuer for purposes of determining whether the 25 percent tests have been met, the taxpayer's proper proportion of any investment in the securities of such issuer that are held by a member of the taxpayer's ''controlled group'' must be aggregated with the taxpayer's investment in such issuer, as determined under regulations.

Section 851(c)(3) defines a controlled group as one or more chains of corporations connected through stock ownership with the taxpayer if (i) 20 percent or more of the total combined voting power of all classes of stock entitled to vote of each of the corporations (except the taxpayer) is owned directly by one or more of the other corporations, and (ii) the taxpayer owns directly at least 20 percent or more of the total combined voting power of all classes of stock entitled to vote of at least one of the other corporations.

On August 2, 2013, the Treasury Department and the IRS published in the **Federal Register** a notice of proposed rulemaking (REG–114122–12 at 78 FR 46851) (NPRM). The proposed regulations would revise certain examples in § 1.851–5 to clarify that a RIC and its controlled subsidiary are a controlled group even if the group consists of only that RIC and its subsidiary.

No public hearing was requested or held. Written comments responding to the NPRM were received. The written comments are available for public inspection at *http://www.regulations.gov* or upon request. After consideration of all the comments, these final regulations adopt the provisions of the proposed regulations with certain clarifications. The comments and clarifications are discussed in this preamble.

Summary of Comments and Explanation of Revisions

Comments received in response to the NPRM's request for comments addressed three general categories of issues: (1) application of the proposed changes to a parent RIC investing in the stock of subsidiary RICs (a Fund of Funds structure); (2) application of the proposed changes to a RIC's indirect investment in qualified publicly traded partnerships, as defined in section 851(h) (QPTPs); and (3) clarification of existing regulatory language implementing the controlled group rules of section 851(c).

1. Fund of Funds

Commenters recognized that the changes to the examples in § 1.851–5 apply to structures in which the investments of a RIC (Upper RIC) include stock of one or more subsidiary RICs (Lower RICs). Commenters noted that there may be uncertainty in determining whether an Upper RIC satisfies its 25 percent tests when what might otherwise be a quarter-end violation by the Lower RIC is saved from being a violation by one or both of the relief provisions in section 851(d)(1) (sometimes called the ''market value exception'' and the ''30-day cure provision'') or when the Upper RIC and a Lower RIC have different quarter end testing dates.

To resolve this uncertainty, commenters urged the Treasury Department and the IRS either to provide a safe harbor for Fund of Funds structures or to exempt these structures from the controlled group rules. Commenters noted that securities of RICs are listed as qualifying assets for purposes of the ''good asset'' 50 percent test of section 851(b)(3)(A) and are correspondingly excluded from the categories of assets listed in the 25 percent tests set forth in sections 851(b)(3)(B)(i) and (ii). In response to these requests, the Treasury Department and the IRS are issuing Revenue Procedure 2015–45 (2015–39 IRB dated September 28, 2015), which describes conditions under which the IRS will treat an Upper RIC that invests in one or more Lower RICs as satisfying the 25 percent tests and provides procedures to lessen the burden of demonstrating compliance with the 25 percent tests, applying the market value exception and the 30-day cure provision, and dealing with different quarter-end testing dates.

2. QPTPs

Comments were received both on the revised language in *Example 1* and on proposed *Example 7.* Example 7 illustrates the application of the controlled group rules to a RIC's indirect investment in securities of QPTPs.

In 2004, Congress enacted section 851(b)(2)(B), which facilitated

investment by RICs in equity interests of QPTPs by providing that net income from an interest in a QPTP would be treated as qualifying income under the RIC income test set forth in section 851(b)(2) without regard to the character of the income earned by the QPTP. Congress provided for this new ability of RICs to invest in QPTPs to improve QPTP access to U.S. capital markets.[1]

At the same time, however, Congress enacted section 851(b)(3)(B)(iii), which limits a RIC's investment in securities of one or more QPTPs to not more than 25 percent of the value of the RIC's assets. The Ways and Means Committee report explained the rationale for this limitation by stating:

> [T]he Committee bill requires that present-law limitations on ownership and composition of assets of mutual funds apply to any investment in a publicly traded partnership by a mutual fund. The Committee believes that these limitations will serve to limit the use of mutual funds as conduits for avoidance of unrelated business income tax or withholding rules [for effectively connected income] that would otherwise apply with respect to publicly traded partnership income.

H.R. Rep. No. 108–548, pt. 1 at 152 (2004). Commenters relied on this legislative history in support of their position that the section 851(b)(3)(B)(iii) QPTP test (which focuses on a RIC's holdings of securities of a category of issuers) is fundamentally different from the section 851(b)(3)(B)(i) and (ii) tests (which focus on a RIC's holdings of securities of particular issuers). These commenters contended that an interest in a QPTP should not be subject to the clarified controlled group rules in the NPRM when the interest in the QPTP is held by a corporation that is not a RIC.

The Treasury Department and the IRS do not find this argument sufficiently persuasive to overcome the plain language of section 851(c) regarding the application of the controlled group rules. Pursuant to its introductory language, section 851(c) applies generally ''[f]or purposes of subsection 851(b)(3),'' and pursuant to section 851(c)(1), the look-through rule for controlled group members applies specifically ''for purposes of subparagraph (B)'' of section 851(b)(3), in each case without distinguishing between the various 25 percent tests. Moreover, the Treasury Department and the IRS note that Congress, in the same legislation in which it enacted section 851(b)(3)(B)(iii), had the opportunity to amend these rules in the manner urged by the commenters. In that legislation, Congress made other changes to conform section 851(c) to the changes relating to QPTPs by redesignating former section 851(c)(5) as section 851(c)(6) and adding a new section 851(c)(5), which defines the term ''outstanding voting securities of such issuer'' to include equity securities of QPTPs. Congress made no changes, however, to limit the application of the section 851(c) controlled group rules to solely the 25 percent tests under section 851(b)(3)(i) and (ii).

Thus, the Treasury Department and the IRS believe, consistent with the statutory language, that the controlled group rules should apply to section 851(b)(3)(B)(iii) because (1) Congress specifically provided that a RIC's investment in QPTP securities should be limited to 25 percent of the RIC's total asset value; (2) the controlled group rules of section 851(c) by their terms apply to all of section 851(b)(3), including section 851(b)(3)(B)(iii); and (3) Congress did not carve out section 851(b)(3)(B)(iii) when it updated section 851(c).

3. Clarifying regulatory language

Some practitioners have interpreted section 851(c)(3) to require the presence of at least two levels of controlled entities for a controlled group to exist and have relied on certain of the examples in the existing regulations to support this interpretation. These final regulations clarify, through revisions to the existing examples, that as few as two corporations are enough to constitute a controlled group if the ownership requirements of section 851(c)(3) are met.

The Treasury Department and the IRS believe that the interpretation of the controlled group rules reflected in these final regulations is consistent with both the statutory language of section 851(c)(3) and the well-established interpretation of analogous Code provisions. For example, for purposes of the consolidated return rules, the IRS has consistently treated a parent and its directly owned subsidiary as ''affiliated'' within the meaning of section 1504(a)(1). Similarly, in limiting certain tax benefits for affiliated corporations, the IRS treats a parent and its subsidiary as a ''controlled group'' under section 1563, which uses language similar to section 1504(a). *See* section 1563(a)(1) and § 1.1563–1(a)(2)(ii),

Example 1. The interpretation reflected in these final regulations is also consistent with the purpose of section 851(c)(3), which is to aggregate the investments of a RIC's related corporations for purposes of determining whether the RIC satisfies its 25 percent tests.

As stated in the preamble to the NPRM, the Treasury Department and the IRS believe that the language in the examples in the existing regulations was intended merely to simplify the description of certain fact patterns and not to articulate a legal interpretation that is inconsistent with the statutory language of section 851(c) and the construction of substantially similar language elsewhere in the Code.

Commenters noted that § 1.851–3 states that ''[i]n determining the value of the taxpayer's investment in the securities of *any one* issuer, for the purposes of subparagraph (B) of section 851(b)[(3)], there shall be included its proper proportion of the investment of any other corporation, a member of a controlled group, in the securities of such issuer'' (emphasis added). Commenters cited the phrase ''any one issuer'' in support of the proposition that the controlled group rules should not be applied for purposes of section 851(b)(3)(B)(iii), which addresses not the value of a RIC's direct and indirect holdings of securities of any single issuer but rather a RIC's aggregate direct and indirect holdings of securities of a category of issuers (that is, QPTPs). While the Treasury Department and the IRS do not believe that the use of ''any one issuer'' in § 1.851–3 bears the weight these commenters attribute to it, in order to respond to the comment and more closely align § 1.851–3 with the statutory language of section 851(c)(1), these final regulations update the language of § 1.851–3 by changing ''any one issuer'' to ''an issuer.''

Commenters similarly maintained that because section 851(c)(1) refers to use of the controlled group rules ''in ascertaining the value of the taxpayer's investment in the securities of *an issuer''* (emphasis added), the rules should not apply for purposes of a limitation that applies to holdings of securities in a category of issuers, such as the section 851(b)(3)(B)(iii) limitation on investment in QPTPs. The Treasury Department and the IRS do not agree with this reading of the statute. As noted above, the controlled group rules expressly apply for purposes of section 851(b)(3)(B) without qualification. The

[1] ''The Congress understood that . . .[p]ublicly traded partnerships with specified types of income are not treated as corporations, however, for the reason that if the income is from sources that are commonly considered to be passive investments, then there is less reason to treat the publicly traded partnership as a corporation. The Congress understood that these types of publicly traded partnerships may have improved access to capital markets if their interests were permitted investments of mutual funds. Therefore, the Act treats publicly traded partnership interests as permitted investments for mutual funds ('RICs').'' Joint Committee on Taxation, General Explanation of Tax Legislation Enacted in the 108th Congress at 249 (JCS–5–05), May 2005 (footnote omitted).

Treasury Department and the IRS believe that the more natural reading of the statutory language is that, in assessing compliance with section 851(b)(3), a RIC applies the controlled group rules to determine its indirect holdings in each individual issuer (including each QPTP), and the RIC then aggregates its direct and indirect holdings in each individual issuer for purposes of applying the test in section 851(b)(3)(B)(i); aggregates its direct and indirect holdings of securities of issuers engaged in the same or similar trades or businesses or related trades or businesses for purposes of applying the test in section 851(b)(3)(ii); and aggregates its direct and indirect holdings of securities of issuers that are QPTPs for purposes of applying the test in section 851(b)(3)(iii).

Finally, commenters suggested that operative rules should be set forth in substantive rules in addition to being demonstrated in the examples. They urged the Treasury Department and the IRS to provide regulatory text setting forth general rules, with the examples in § 1.851–5 demonstrating the application of those rules. The Treasury Department and the IRS believe that the revised examples are intended to, and do, make sufficiently clear how the statutory rules are to be interpreted and applied, and accordingly no changes are being made in response to this comment.

Applicability Date

The final regulations apply to quarters that begin on or after *December 14, 2015.* Under section 851(d)(1), whether a taxpayer loses status as a RIC in one quarter may depend on whether the taxpayer satisfied section 851(b)(3) and (c) at the close of one or more prior quarters. For purposes of applying the first sentence of section 851(d)(1) to a quarter that begins on or after March 14, 2016, these final regulations apply in determining whether the taxpayer met the requirements of section 851(b)(3) and (c) at the close of prior quarters.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses. No comments were received.

Drafting Information

The principal author of these regulations is Julanne Allen, Office of Associate Chief Counsel (Financial Institutions and Products). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Sections 1.851–3 and 1.851–5 are also issued under 26 U.S.C. 851(c).

* * * * *

■ **Par. 2.** Section 1.851–3 is revised to read as follows:

§ 1.851–3 Rules applicable to section 851(b)(3).

(a) *In general.* In determining the value of the taxpayer's investment in the securities of an issuer, for purposes of subparagraph (B) of section 851(b)(3), there shall be included its proper proportion of the investment of any other corporation, a member of a controlled group, in the securities of such issuer. *See Example 4* in § 1.851–5. For purposes of §§ 1.851–2, 1.851–4, 1.851–5, and 1.851–6, the terms ''controls,'' ''controlled group,'' and ''value'' have the meaning assigned to them by section 851(c). All other terms used in these sections have the same meaning as when used in the Investment Company Act of 1940 (15 U.S.C., chapter 2D), as amended.

(b) *Effective/applicability dates.* The rules of this section apply to quarters that begin on or after December 14, 2015. For purposes of applying the first sentence of section 851(d)(1) to a quarter that begins on or after March 14, 2016, the rules of this section apply in determining whether the taxpayer met the requirements of section 851(b)(3) and (c) at the close of prior quarters.

■ **Par. 3.** Section 1.851–5 is revised to read as follows:

§ 1.851–5 Examples.

(a) *Examples.* The provisions of section 851 may be illustrated by the following examples:

Example 1. (i) Investment Company W at the close of its first quarter of its taxable year has its assets invested as follows:

	Percent
Cash	5
Government securities	10
Securities of regulated investment companies	20
Securities of Corporation A	10
Securities of Corporation B	15
Securities of Corporation C	20
Securities of various corporations (not exceeding 5 percent of its assets in any one company)	20
Total	100

(ii) Investment Company W owns all of the voting stock of Corporations A and B, 15 percent of the voting stock of Corporation C, and less than 10 percent of the voting stock of regulated investment companies and various other corporations. Neither Corporation A nor Corporation B owns:

(A) 20 percent or more of the voting stock of any other corporation;

(B) Securities issued by Corporation C; or

(C) Securities issued by any of the regulated investment companies or various corporations whose securities are owned by Investment Company W. Except for Corporation A and Corporation B, none of the corporations (including the regulated investment companies) is a member of a controlled group with Investment Company W.

(iii) Investment Company W meets the requirements under section 851(b)(3) at the end of its first quarter. It complies with subparagraph (A) of section 851(b)(3) because it has 55 percent of its assets invested as provided in that subparagraph. It complies with subparagraph (B) of section 851(b)(3) because it does not have more than 25 percent of its assets invested in the securities of any one issuer, of two or more issuers that it controls, or of one or more qualified publicly traded partnerships (as defined in section 851(h)).

Example 2. (i) Investment Company V at the close of a particular quarter of the taxable year has its assets invested as follows:

	Percent
Cash	10
Government securities	35
Securities of Corporation A	7
Securities of Corporation B	12
Securities of Corporation C	15
Securities of Corporation D	21
Total	100

(ii) Investment Company V fails to meet the requirements of subparagraph (A) of section

851(b)(3) since its assets invested in Corporations A, B, C, and D exceed in each case 5 percent of the value of the total assets of the company at the close of the particular quarter.

Example 3. (i) Investment Company X at the close of a particular quarter of the taxable year has its assets invested as follows:

	Percent
Cash and Government securities	20
Securities of Corporation A	5
Securities of Corporation B	10
Securities of Corporation C	25
Securities of various corporations (not exceeding 5 percent of its assets in any one company)	40
Total	100

(ii) Investment Company X owns more than 20 percent of the voting power of Corporations B and C and less than 10 percent of the voting power of all of the other corporations. Corporation B manufactures radios and Corporation C acts as its distributor and also distributes radios for other companies. Investment Company X fails to meet the requirements of subparagraph (B) of section 851(b)(3) since it has 35 percent of its assets invested in the securities of two issuers which it controls and which are engaged in related trades or businesses.

Example 4. (i) Investment Company Y at the close of a particular quarter of its taxable year has its assets invested as follows:

	Percent
Cash and Government securities	15
Securities of Corporation K (a regulated investment company)	30
Securities of Corporation A	10
Securities of Corporation B	20
Securities of various corporations (not exceeding 5 percent of its assets in any one company)	25
Total	100

(ii) Corporation K has 20 percent of its assets invested in Corporation L, and Corporation L has 40 percent of its assets invested in Corporation B. Corporation A also has 30 percent of its assets invested in Corporation B. Investment Company Y owns more than 20 percent of the voting power of Corporations A and K. Corporation K owns more than 20 percent of the voting power of Corporation L.

(iii) At the end of that quarter, Investment Company Y is disqualified under subparagraph (B)(i) of section 851(b)(3) because, after applying section 851(c)(1), more than 25 percent of the value of Investment Company Y's total assets is invested in the securities of Corporation B. This result is shown by the following calculation:

	Percent
Percentage of assets invested directly in Corporation B	20.0
Percentage invested indirectly through K and L (30% × 20% × 40%)	2.4
Percentage invested indirectly through A (10% × 30%)	3.0
Total percentage of assets of Investment Company Y invested in Corporation B	25.4

Example 5. Investment Company Z, which keeps its books and makes its returns on the basis of the calendar year, at the close of the first quarter of 2016 meets the requirements of section 851(b)(3) and has 20 percent of its assets invested in Corporation A. Later during the taxable year it makes distributions to its shareholders and because of such distributions, it finds at the close of the taxable year that it has more than 25 percent of its remaining assets invested in Corporation A. Investment Company Z does not lose its status as a regulated investment company for the taxable year 2016 because of such distributions, nor will it lose its status as a regulated investment company for any subsequent year solely as a result of such distributions. *See* section 851(d)(1).

Example 6. Investment Company Q, which keeps its books and makes its returns on the basis of the calendar year, at the close of the first quarter of 2016 meets the requirements of section 851(b)(3) and has 20 percent of its assets invested in Corporation P. At the close of the taxable year 2016, it finds that it has more than 25 percent of its assets invested in Corporation P. This situation results entirely from fluctuations in the market values of the securities in Investment Company Q's portfolio and is not due in whole or in part to the acquisition of any security or other property. Investment Company Q does not lose its status as a regulated investment company for the taxable year 2016 because of such fluctuations in the market values of the securities in its portfolio, nor will it lose its status as a regulated investment company for any subsequent year solely as a result of such market value fluctuations. *See* section 851(d)(1).

Example 7. (i) Investment Company T at the close of a particular quarter of its taxable year has its assets invested as follows:

	Percent
Cash and Government securities	40
Securities of Corporation A	20
Securities of various qualified publicly traded partnerships (within the meaning of sections 851(b)(3) and 851(h))	15
Securities of various corporations (not exceeding 5 percent of its assets in any one company)	25
Total	100

(ii) Investment Company T owns more than 20 percent of the voting power of Corporation A and less than 10 percent of the voting power of all of the other corporations. Corporation A has 80 percent of its assets invested in qualified publicly traded partnerships.

(iii) Investment Company T is disqualified under subparagraph (B)(iii) of section 851(b)(3), because, after applying section 851(c)(1), more than 25 percent of the value of Investment Company T's total assets is invested in the securities of one or more qualified publicly traded partnerships. This result is shown by the following calculation:

	Percent
Percentage of assets invested directly in qualified publicly traded partnerships	15.0
Percentage invested in qualified publicly traded partnerships indirectly through A (20% × 80%)	16.0
Total percentage of assets of Investment Company T invested in qualified publicly traded partnerships	31.0

(b) *Effective/applicability dates.* The rules of this section apply to quarters that begin on or after December 14, 2015. For purposes of applying the first sentence of section 851(d)(1) to a quarter that begins on or after March 14, 2016, the rules of this section apply in determining whether the taxpayer met the requirements of section 851(b)(3) and (c) at the close of prior quarters.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: September 2, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2015–23137 Filed 9–14–15; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 24 and 70

[Docket No. TTB–2015–0013; T.D. TTB–130]

RIN 1513–AB92

Return of Wine to Bonded Premises

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is revising the wine regulations governing the return of wine to bonded wine premises in response to two statutory changes. First, to incorporate a provision contained in the Taxpayer Relief Act of 1997, TTB is removing a regulatory requirement that wine returned to bond must be

unmerchantable. Second, to incorporate a provision contained in the Internal Revenue Service Restructuring and Reform Act of 1998, TTB is revising the regulations to clarify that the refund or credit of excise tax applies to any wine removed from a bonded wine cellar and subsequently returned to bond. The current regulatory text states that a refund or credit of tax is available only for wine produced in the United States.

DATES: This rule is effective on October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Jennifer Berry, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Rulings Division; telephone 202–453–1039, ext. 275.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Chapter 51 of the Internal Revenue Code of 1986, as amended (IRC), 26 U.S.C. chapter 51, sets forth excise tax collection and related provisions pertaining to, among other things, the production and importation of wine. Under 26 U.S.C. 5041(a), a Federal excise tax is imposed on all wine in bond in, produced in, or imported, into the United States, and such tax is determined at the time the wine is removed for consumption or sale. As a general matter, the tax is determined or paid at the time the product is removed from bonded premises in accordance with 26 U.S.C. 5041(a). Tax on imported wine, however, is imposed when the product is imported into the United States, and is generally determined or paid when the product is removed from bonded premises or from customs custody for consumption or sale in accordance with relevant statutory provisions and Treasury regulations and orders.

Section 5361 of the IRC (26 U.S.C. 5361) provides that taxpaid wine may be returned to bonded wine premises, and section 5044(a) of the IRC (26 U.S.C. 5044(a)) states that, under regulations prescribed by the Secretary of the Treasury, when wine is removed from a bonded wine cellar and subsequently returned to bond, then: (1) If tax on wine returned to bond has been paid (taxpaid wine), that tax shall be refunded or credited, without interest, to the proprietor of the bonded wine cellar to which the wine is delivered; and (2) if tax on wine returned to bond has not been paid, the person liable for the tax may be relieved of liability.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers chapter 51 of the IRC pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Current Regulatory Requirements

Regulations implementing the provisions of chapter 51 of the IRC pertaining to the establishment and operation of wine premises are contained in 27 CFR part 24. Provisions regarding the return of wine to bonded premises are contained in 27 CFR 24.295. Section 24.295(a) states that when taxpaid wine produced in the United States has been removed from bonded premises and subsequently found to be unmerchantable, such wine may be returned to a bonded wine premises for reconditioning, reformulation, or destruction. When such wine is returned to bond, the tax paid on such wine may be refunded or credited without interest to the proprietor of the bonded premises to which the wine was delivered if a claim pursuant to 27 CFR part 70, subpart G has or will not be made. In the case of untaxpaid domestic wine that was removed from bonded premises and then found to be unmerchantable, the person liable for the tax may be relieved of that liability when such wine is returned to bond. Claims for relief, credit, or refund may be filed pursuant to § 24.66.

Section 24.66 (27 CFR 24.66) currently provides that a claim for credit or refund, or relief from liability, of tax on unmerchantable U.S. wine returned to bond will be filed with the appropriate TTB officer within six months after the date of the return of the wine to bond. A single claim may not be filed under this section for a quantity on which the credit or refund of tax would be less than $25. However, this limitation does not apply to any returned wine on which the six- month period for filing a claim will expire.

Statutory Changes and Conforming Regulatory Amendments

Public Law 105–34

Section 1416 of the Taxpayer Relief Act of 1997, Public Law 105–34, 111 Stat. 788, amended section 5044 of the IRC to remove a previous requirement that wine returned to bond must be unmerchantable. Accordingly, TTB is amending its regulatory provisions to conform the regulations to the statute by removing the word ''unmerchantable'' from where it appears in §§ 24.66(a), 24.295, and 24.312, and from the undesignated center heading that precedes § 24.295. TTB is also removing the definition of unmerchantable wine from 27 CFR 24.10 since that definition is no longer relevant with respect to the part 24 regulations. In addition, TTB is removing the word ''unmerchantable'' in the four instances where it appears in Part 70, Procedure and Administration (see §§ 70.411(c)(10), 70.413(c)(2)(ii) (removing the phrase ''as unmerchantable''), 70.413(d)(2), and 70.414(d)(3)).

Public Law 105–206

Section 6014(b)(2) of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206, 112 Stat. 685, amended section 5044 of the IRC by removing a prior requirement that wine returned to bond must have been produced in the United States and instead required only that the wine first have been removed from a bonded wine cellar. To conform the regulations to the statute, TTB is removing references to ''United States'' or ''produced in the United States'' when it modifies the term ''wine'' in §§ 24.66(a) and 24.295, respectively. TTB is also removing the word ''domestic'' in the two instances where it modifies ''wine'' in part 70, Procedure and Administration (see §§ 70.413(d)(2) and 70.414(d)(3)).

OMB Information Collection Control Numbers

In addition, TTB is removing obsolete references to Office of Management and Budget (OMB) control numbers for information collection requests used by the former Bureau of Alcohol, Tobacco and Firearms (ATF) and replacing them with the OMB control numbers assigned to TTB. Specifically, in the second parenthetical statement at the end of § 24.66, OMB control number ''1512–0492'' is updated to ''1513–0030''; in the second parenthetical statement at the end of § 24.295, OMB control numbers ''1512–0216,'' ''1512–0298,'' and ''1512–0492'' are updated to ''1513–0053,'' ''1513–0115,'' and ''1513–0030'' respectively; in the second parenthetical statement at the end of § 24.312, OMB control number ''1512–0298'' is updated to ''1513–0115''; and in the first parenthetical statement at the end of § 70.413, OMB control number ''1512–0141'' is updated to ''1513–0030.'' The changes to these OMB control numbers are technical in nature and do not change any TTB information collection or recordkeeping requirement.

Inapplicability of Prior Notice and Comment

TTB is issuing this final rule without prior notice and comment pursuant to authority under section 4(a) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)). This provision authorizes an agency to issue a rule without prior notice and comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' TTB finds that prior notice and comment for this rule is unnecessary because the rule is limited to conforming TTB regulations to statutory amendments that TTB lacks discretion to change.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Accordingly, a regulatory flexibility analysis is not required. Pursuant to section 7805(f) of the IRC, TTB submitted this final rule to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact of the regulations, and no comments were received.

Paperwork Reduction Act

The collections of information in the regulations contained in this final rule have been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), and assigned control numbers 1513–0030, 1513–0053, and 1513–0115. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. There is no new collection of information imposed by this final rule.

Executive Order 12866

This final rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, it requires no regulatory assessment.

Drafting Information

Jennifer Berry of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this document.

List of Subjects

27 CFR Part 24

Administrative practice and procedure, Claims, Electronic fund transfers, Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavorings, Surety bonds, Vinegar, Warehouses, Wine.

27 CFR Part 70

Administrative practice and procedure, Claims, Excise taxes, Freedom of information, Law enforcement, Penalties, Reporting and recordkeeping requirements, Surety bonds.

Amendments to the Regulations

For the reasons discussed in the preamble, TTB amends 27 CFR, chapter I, parts 24 and 70 as set forth below:

PART 24—WINE

■ 1. The authority citation for 27 CFR part 24 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5121, 5122–5124, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356, 5357, 5361, 5362, 5364–5373, 5381–5388, 5391, 5392, 5511, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

§ 24.10 [Amended]

■ 2. Section 24.10 is amended by removing the definition of ''Unmerchantable wine''.

§ 24.66 [Amended]

■ 3. In § 24.66:

■ a. The first sentence of paragraph (a) is amended by removing the words ''unmerchantable United States''; and

■ b. The second parenthetical phrase at the end of the section is amended by removing the Office of Management and Budget control number ''1512–0492'' and adding, in its place, the number ''1513–0030''.

Subpart N—[Amended]

■ 4. In subpart N, the undesignated center heading located before § 24.295 is revised to read as follows:

Return of Wine to Bond

■ 5. In § 24.295:

■ a. The section heading and paragraph (a) are revised;

■ b. The first sentences of paragraph (b) and paragraph (c) are amended by removing the word ''unmerchantable'';

■ c. Paragraph (b) is amended by removing the term ''United States'' where it occurs in two instances; and

■ d. The second parenthetical phrase at the end of the section is amended by removing the Office of Management and Budget control numbers ''1512–0216, 1512–0298, and 1512–0492'' and adding, in their place, the numbers ''1513–0053, 1513–0115, and 1513–0030''.

The revisions read as follows:

§ 24.295 Return of wine to bond.

(a) *General.* Wine, domestic or imported, which has been taxpaid and removed from bonded wine premises, may be received by the proprietor of a bonded wine premises for return to bond. The proprietor may, when such taxpaid wine is returned to bond, make a claim for refund or credit, without interest. However, tax will not be refunded or credited for any wine for which a claim has been or will be made under 27 CFR part 70, subpart G. If the tax has been determined but not paid, the person liable for the tax may, when such wine is returned to bond, be relieved of the liability. Claims for refund or credit, or relief from tax paid or determined on wine returned to bond, are filed in accordance with § 24.66.

* * * * *

■ 6. In § 24.312:

■ a. The section heading is revised, and the introductory text is amended by removing the word ''unmerchantable''; and

■ b. The second parenthetical phrase at the end of the section is amended by removing the Office of Management and Budget control number ''1512–0298'' and adding, in its place, the number ''1513–0115''.

The revision reads as follows:

§ 24.312 Wine returned to bond record.

* * * * *

PART 70—PROCEDURE AND ADMINISTRATION

■ 7. The authority citation for part 70 continues to read as follows:

Authority: 5 U.S.C. 301 and 552; 26 U.S.C. 4181, 4182, 5123, 5203, 5207, 5275, 5367, 5415, 5504, 5555, 5684(a), 5741, 5761(b), 5802, 6020, 6021, 6064, 6102, 6155, 6159, 6201, 6203, 6204, 6301, 6303, 6311, 6313, 6314, 6321, 6323, 6325, 6326, 6331–6343, 6401–6404, 6407, 6416, 6423, 6501–6503, 6511, 6513, 6514, 6532, 6601, 6602, 6611, 6621, 6622, 6651, 6653, 6656–6658, 6665, 6671, 6672, 6701, 6723, 6801, 6862, 6863, 6901, 7011, 7101, 7102, 7121, 7122, 7207, 7209, 7214, 7304, 7401, 7403, 7406, 7423, 7424, 7425, 7426, 7429, 7430, 7432, 7502, 7503, 7505, 7506, 7513, 7601–7606, 7608–7610, 7622, 7623, 7653, 7805.

§ 70.411 [Amended]

■ 8. Section 70.411 is amended by removing the word ''unmerchantable'' from paragraph (c)(10).

§ 70.413 [Amended]

■ 9. In § 70.413:
■ a. Paragraph (c)(2)(ii) is amended by removing the words ''as unmerchantable,'';
■ b. Paragraph (d)(2) is amended by removing the words ''unmerchantable domestic''; and
■ c. The first parenthetical phrase at the end of the section is amended by removing the Office of Management and Budget control number ''1512–0141'' and adding, in its place, the number ''1513–0030''.

§ 70.414 [Amended]

■ 10. Section 70.414 is amended by removing the words ''unmerchantable domestic'' from paragraph (d)(3).

Signed: June 11, 2015.

John J. Manfreda,

Administrator.

Approved: June 19, 2015.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 2015–23132 Filed 9–14–15; 8:45 am]

BILLING CODE 4810–31–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Allocation of Assets in Single-Employer Plans; Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under the benefit payments regulation for valuation dates in October 2015 and interest assumptions under the asset allocation regulation for valuation dates in the fourth quarter of 2015. The interest assumptions are used for valuing and paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective October 1, 2015.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@PBGC.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulations on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) and Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulations are also published on PBGC's Web site (*http://www.pbgc.gov*).

The interest assumptions in Appendix B to Part 4044 are used to value benefits for allocation purposes under ERISA section 4044. PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the asset allocation regulation are updated quarterly; assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for October 2015 and updates the asset allocation interest assumptions for the fourth quarter (October through December) of 2015.

The fourth quarter 2015 interest assumptions under the allocation regulation will be 2.46 percent for the first 20 years following the valuation date and 2.98 percent thereafter. In comparison with the interest assumptions in effect for the third quarter of 2015, these interest assumptions represent no change in the select period (the period during which the select rate (the initial rate) applies), an increase of 0.14 percent in the select rate, and an increase of 0.68 percent in the ultimate rate (the final rate).

The October 2015 interest assumptions under the benefit payments regulation will be 1.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for September 2015, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits under plans with valuation dates during October 2015, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 264, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
264	10–1–15	11–1–15	1.25	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 264, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
264	10–1–15	11–1–15	1.25	4.00	4.00	4.00	7	8

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 4. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 5. In appendix B to part 4044, a new entry for October–December 2015, as set forth below, is added to the table.

Appendix B to Part 4044—Interest Rates Used to Value Benefits

* * * * *

For valuation dates occurring in the month—	The values of i_t are:					
	i_t	for t =	i_t	for t =	i_t	for t =
*	*	*	*	*	*	*
October–December 2015	0.0246	1–20	0.0298	>20	N/A	N/A

Issued in Washington, DC, on this 10th day of September 2015.

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2015–23231 Filed 9–14–15; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2006–HA–0207]

RIN 0720–AB15

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); TRICARE Reserve Select; TRICARE Dental Program; Early Eligibility for TRICARE for Certain Reserve Component Members

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: TRICARE Reserve Select (TRS) is a premium-based TRICARE health plan available for purchase worldwide by qualified members of the Ready Reserve and by qualified survivors of TRS members. TRICARE Dental Program (TDP) is a premium-based TRICARE dental plan available for purchase worldwide by qualified Service members. This final rule revises requirements and procedures for the TRS program to specify the appropriate actuarial basis for calculating premiums in addition to making other minor clarifying administrative changes. For a member who is involuntarily separated from the Selected Reserve under other than adverse conditions this final rule provides a time-limited exception that allows TRS coverage in effect to continue for up to 180 days after the date on which the member is separated from the Selected Reserve and TDP coverage in effect to continue for no less than 180 days after the separation date. It also expands early TRICARE eligibility for certain Reserve Component members from a maximum of 90 days to a maximum of 180 days prior to activation in support of a contingency operation for more than 30 days.

DATES: This rule is effective October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Brian Smith, Defense Health Agency, TRICARE Health Plan Division, telephone (703) 681–0039.

Questions regarding payment of specific claims under the TRICARE allowable charge method should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

A. Overview

An interim final rule was published in the **Federal Register** on August 20, 2007 (72 FR 46380). That interim final rule addressed provisions of the National Defense Authorization Act for Fiscal Year 2007 (NDAA–07) (Pub. L. 109–364),which expanded eligibility for the TRICARE Reserve Select program to include all Selected Reservists except those individuals either enrolled or

eligible to enroll in the Federal Employees Health Benefits program.

Before finalizing the interim final rule, a proposed rule was published in the **Federal Register** on August 27, 2014 (79 FR 51127). The proposed rule addressed provisions of the National Defense Authorization Act for Fiscal Year 2009 (NDAA–09) (Pub. L. 110–417), the National Defense Authorization Act for Fiscal Year 2010 (NDAA–10) (Pub. L. 111–84), and the National Defense Authorization Act for Fiscal Year 2013 (NDAA–13) (Pub. L. 112–239). First, section 704 of NDAA–09 specifies that the appropriate actuarial basis for calculating premiums for TRS shall utilize the actual cost of providing benefits to members and their dependents during preceding calendar years. Second, section 702 of NDAA–10 expands early eligibility for Reserve Component members issued delayed-effective-date active duty orders from a maximum of 90 days to a maximum of 180 days prior to activation in support of a contingency for more than 30 days. Third, for a member who is involuntarily separated from the Selected Reserve under other than adverse conditions as characterized by the Secretary concerned, section 701 of NDAA–13 provides a time-limited exception that allows TRS coverage already in effect at time of separation to continue for up to 180 days after the date on which the member is separated from the Selected Reserve and TDP coverage already in effect at time of separation to continue for no less than 180 days after the separation date. This exception expires December 31, 2018. Finally, the proposed rule addressed additional administrative clarifications to 32 CFR 199.24, which implements TRS.

This final rule addresses and finalizes the provisions in both the interim final rule and the proposed rule.

B. Public Comments

An interim final rule was published in the **Federal Register** on August 20, 2007 and we received 4 comments (one comment was a duplicate submission). A proposed rule was published in the **Federal Register** on August 27, 2014 and we received 1 comment. We thank those who provided comments. Specific matters raised by those who submitted comments are summarized below.

II. Provisions of the Rule Regarding Early TRICARE Eligibility

1. *Provisions of Proposed Rule.* Section 199.3(b)(5) implements section 702 of NDAA–10, which specifies that Reserve Component members issued delayed-effective-date orders for service in support of a contingency operation, and their family members, are eligible for TRICARE on the date the orders are issued, up to a maximum of 180 days prior to the date on which the period of active duty of more than 30 consecutive days is to begin. Previously, members and their family members could become eligible for TRICARE up to a maximum of 90 days prior to the date on which the period of active duty in support of a contingency operation of more than 30 consecutive days is to begin.

2. *Analysis of Major Public Comments.* No public comments were received relating to this section of the rule.

3. *Provisions of the Final Rule.* The final rule is consistent with the proposed rule.

III. Provisions of the Rule Regarding the TRICARE Dental Program

A summary of the relevant proposed rule provision is presented, followed by an analysis of major public comments, and by a summary of the final rule provisions.

1. *Provisions of Proposed Final Rule.* So that the existing provisions of § 199.13(c)(3)(ii)(E)(*2*) would not be confused with the new paragraph described below, we proposed to clarify that the continued coverage described in this paragraph is actually survivor coverage. We also proposed to reinsert the provision that the government will pay both the government and the beneficiary's portion of the premium share during the three-year period of continued survivor enrollment, which was inadvertently deleted by a previous amendment to the regulation.

We proposed to add new § 199.13(c)(3)(ii)(E)(*5*) that implements the provisions in section 701 of NDAA–13 concerning TDP. A time-limited exception is added to the general rule that TDP coverage shall terminate for members who no longer qualify for TDP. This exception specifies that if a member is involuntarily separated from the Selected Reserve under other than adverse conditions, as characterized by the Secretary concerned, and TDP coverage was in effect for the member and/or the family on the last day of his or her membership in the Selected Reserve, the TDP coverage that was in effect, whether member coverage and/or family coverage, may terminate no earlier than 180 days after the date on which the member is separated from the Selected Reserve. This exception expires December 31, 2018.

2. *Analysis of Major Public Comments.* No public comments were received relating to this section of the rule.

3. *Provisions of the Final Rule.* The final rule is consistent with the proposed rule.

IV. Provisions of the Rule Regarding the TRICARE Reserve Select Program

Many of our proposed clarifications update the rules for TRS (§ 199.24) and, as appropriate, bring the rules in closer alignment and sequencing with the very similar TRICARE Retired Reserve program (§ 199.25).

A. Establishment of the TRICARE Reserve Select Program (§ 199.24(a))

1. *Provisions of Interim Final Rule.* This paragraph describes the nature, purpose, statutory basis, scope, and major features of TRICARE Reserve Select, a premium-based medical coverage program that was made available worldwide to certain members of the Selected Reserve and their family members. TRICARE Reserve Select is authorized by 10 U.S.C. 1076d.

2. *Provisions of the Proposed Rule.* We proposed to remove the existing terminology at § 199.24(a)(4) and to redesignate § 199.24(a)(5) as § 199.24(a)(4). We proposed to clarify that certain special programs established in 32 CFR part 199 are not available to members covered under TRS (§ 199.24(a)(4)(i)(B)).

We proposed to clarify the wording for submitting an initial payment of the appropriate premium along with the request to purchase coverage (§ 199.24(a)(4)(iii)) and to make it consistent throughout this section. We proposed to clarify that both the member and the member's covered family members are provided access priority for care in military treatment facilities on the same basis as active duty service members' dependents who are not enrolled in TRICARE Prime (§ 199.24(a)(4)(iv)).

3. *Analysis of Major Public Comments.* No public comments were received relating to this section of the rule.

4. *Provisions of the Final Rule.* The final rule is consistent with the interim final rule and the proposed rule.

B. Qualifications for TRICARE Reserve Select Coverage (§ 199.24(b))

1. *Provisions of Interim Final Rule.* In the interim final rule, paragraph (b) addressed *TRICARE Reserve Select premiums* (§ 199.24(b)). It continued that members are charged premiums for coverage under TRICARE Reserve Select that represent 28 percent of the total annual premium amount that the Assistant Secretary of Defense, Health Affairs (ASD(HA)) determines on an appropriate actuarial basis as being

appropriate for coverage under the TRICARE Standard (and Extra) benefit for the TRICARE Reserve Select eligible population. Premiums are to be paid monthly, except as otherwise established as part of the administrative implementation of TRICARE Reserve Select.

Annual rates for the first year TRICARE Reserve Select was offered (2005) were based on the calendar year annual premiums for the Blue Cross and Blue Shield Standard Service Benefit Plan under the Federal Employees Health Benefits Program, a nationwide plan closely resembling TRICARE Standard (and Extra) coverage, with an adjustment based on estimated differences in covered populations, as determined by the ASD(HA).

Based on an analysis of demographic differences between Blue Cross and Blue Shield members and beneficiaries eligible for TRICARE Reserve Select, the adjustment amount in calendar year 2005 represented a 32 percent reduction from the Blue Cross and Blue Shield annual premium for member-only coverage and represented an 8 percent reduction from the Blue Cross and Blue Shield annual premium for member and family coverage. (The difference in the percentage reductions between member only and member and family premiums is due to the disproportionately high number of high cost, single, elderly retiree federal employees covered by Blue Cross and Blue Shield member-only coverage).

TRICARE Reserve Select monthly premium rates are established and updated annually, on a calendar year basis, to maintain an appropriate relationship with the annual changes in Blue Cross and Blue Shield premiums, or by other adjustment methodology determined to be appropriate by the ASD(HA) for each of the two types of coverage, member-only coverage and member and family coverage, on a calendar year basis. The monthly rate for each month of a calendar year is one twelfth of the annual rate for that calendar year.

In addition to these annual premium changes, premium adjustments may also be made prospectively for any calendar year to reflect any significant program changes or any actual experience in the costs of administering the TRICARE Reserve Select Program.

A surviving family member of a Reserve Component service member who qualified for TRICARE Reserve Select coverage as described in paragraph (c)(3) of this section will pay premium rates as follows. The premium amount shall be at the member-only rate if there is only one surviving family member to be covered by TRICARE Reserve Select and at the member and family rate if there are two or more survivors to be covered.

2. *Provisions of the Proposed Rule.* We proposed to redesignate § 199.24(c) as § 199.24(b) so that it precedes the section on *TRICARE Reserve Select premiums* for clarity and maintains parallel sequencing with § 199.25.

Section 10144(b) of title 10, U.S.C. provides that the Secretary concerned may designate a category of members within the Individual Ready Reserve (IRR) of each Reserve Component who are subject to being ordered to active duty involuntarily in accordance with section 12304 of title 10, U.S.C. We proposed to clarify that since a member of the IRR who has volunteered to serve in such mobilization category is eligible for benefits (other than pay and training) as are normally available to members of the Selected Reserve, these members may also qualify for TRS (§ 199.24(b)(1)(i)).

We proposed to clarify the exclusion involving the Federal Employees Health Benefits (FEHB) program. Section 199.24(b)(1)(ii) specifies that an otherwise qualified member of the Ready Reserve qualifies to purchase TRS coverage if the member is not enrolled in, or eligible to enroll in, a health benefits plan under chapter 89 of title 5, U.S.C. That statute has been implemented under part 890 of title 5, CFR as the ''Federal Employees Health Benefits'' program. For purposes of the FEHB program, the terms ''enrolled,'' ''enroll'' and ''enrollee'' are defined in § 890.101 of title 5, CFR. We proposed to clarify that the member (or certain involuntarily separated former member) no longer qualifies for TRS coverage when the member has been eligible for active coverage in a health benefits plan under the FEHB program for more than 60 days (§ 199.24(b)(1)(ii)). This affords the member sufficient time to make arrangements for health coverage other than TRS and avoid any days without having health coverage being in force.

We proposed to clarify that qualification for TRS survivor coverage applies regardless of type of coverage in effect on the day of the TRS member's death (§ 199.24(b)(2)).

3. *Analysis of Major Public Comments.* One commenter suggested that we eliminate the exclusion regarding the FEHB program rather than clarify it.

Response. The exclusion is statutory; the Department of Defense has no authority to eliminate it.

4. *Provisions of the Final Rule.* Note in the proposed rule that we proposed to redesignate paragraph (c) as paragraph (b) so that the section on *Qualifications for TRICARE Reserve Select coverage* would precede the section on *TRICARE Reserve Select premiums* for clarity purposes and to maintain consistent sequencing with § 199.25. Then we proposed to replace the content in the section on *Eligibility for (qualifying to purchase) TRICARE Reserve Select coverage* that appeared in the interim final rule in its entirety with the newly revised section on *Qualifications for TRICARE Reserve Select coverage.* Therefore, the final rule is consistent with the proposed rule.

C. TRICARE Reserve Select Premiums (§ 199.24(c))

1. *Provisions of Interim Final Rule.* In the interim final rule, § 199.24(c) addressed *Eligibility for (qualifying to purchase) TRICARE Reserve Select coverage.* It reflected the statutory conditions under which members of a Reserve component may qualify to purchase TRICARE Reserve Select coverage.

2. *Provisions of the Proposed Rule.* We proposed to redesignate § 199.24(b) as § 199.24(c) so that it follows the section on *Qualifications for TRICARE Reserve Select coverage* for clarity purposes and maintains consistent sequencing with § 199.25. We also proposed to clarify that the Director, Healthcare Operations in the Defense Health Agency may establish procedures for administrative implementation related to premiums (§ 199.24(c)).

Section 199.24(c)(1) implements section 704 of NDAA–09, which requires that monthly premiums be determined by utilizing the actual reported cost of providing benefits to TRS members and their dependents during preceding calendar years. Section 704 of NDAA–09 specified that actual TRS cost data from calendar years 2006 and 2007 be utilized in the determination of premium rates for calendar year 2009. This established pattern has been followed to determine premium rates for all calendar years starting with 2009 (§ 199.24(c)(1)). Further, we proposed to amend § 199.24(c) by deleting all former provisions involving the relationship between premium rates for TRS and premium rates for the Blue Cross and Blue Shield Standard Service Benefit Plan under the Federal Employees Health Benefits program.

3. *Analysis of Major Public Comments.* Three military service organizations commented on the methodology described in the interim final rule to be used for annual TRS premium updates that was based on

annual changes in premiums in the Blue Cross/Blue Shield plan offered nationwide by the Federal Employees Health Benefits program. Rather than applying the same percentage increases to TRS premiums that were observed in the federal Blue Cross/Blue Shield nationwide plan, each commenting organization requested that the annual TRS premium increases not exceed the percentage increase in military basic pay.

Response. Section 704 of NDAA–09 added 10 U.S.C. 1076 d(d)(3)(B) to specify that the appropriate actuarial basis for calculating premiums for TRS shall utilize the actual cost of providing benefits to members and their dependents during preceding calendar years. The final rule is consistent with this statutory requirement.

4. *Provisions of the Final Rule.* Note in the proposed rule that we proposed to redesignate paragraph (b) as paragraph (c) so that the section on *TRICARE Reserve Select premiums* would follow the section on *Qualifications for TRICARE Reserve Select coverage* for clarity purposes and to maintain consistent sequencing with § 199.25). Then we proposed to replace the content on *TRICARE Reserve Select premiums* that appeared in the interim final rule in its entirety with the newly revised section on *TRICARE Reserve Select premiums* in order to implement section 704 of NDAA–09. That had the effect of removing all of the former provisions involving the relationship between premium rates for TRS and premium rates for the Blue Cross and Blue Shield Standard Service Benefit Plan under the Federal Employees Health Benefits program will appear in the amended § 199.24(c). The final rule is consistent with the proposed rule.

D. Procedures (§ 199.24(d))

1. Provisions of Interim Final Rule

The interim final rule addressed procedures for TRS coverage.

2. *Provisions of the Proposed Rule.* We proposed to clarify that the Director, Healthcare Operations in the Defense Health Agency may establish procedures for TRS (§ 199.24(d)).

We proposed to clarify that either reserve members or survivors qualified under § 199.24(b) may follow applicable procedures throughout this section regarding TRS coverage. We proposed to clarify the rule about immediate family members who may be included in family coverage under TRS (§ 199.24(d)(1)), which is further supported by the proposed definition for immediate family member included in § 199.24(g).

We proposed to clarify continuation coverage by removing the previous requirement that the member had to be the sponsor of the other TRICARE coverage in order to qualify for continuation coverage (§ 199.24(d)(1)(i)). In circumstances when the spouse of the Reserve Component member is the sponsor for purposes of the other TRICARE coverage, it would be clear that the qualified member would be able to purchase TRS coverage with an effective date immediately following the date of termination of coverage under another TRICARE program regardless whether it was the Reserve Component member or the spouse who was the sponsor of the other TRICARE coverage.

We proposed rules to implement the provisions in section 701 of NDAA–13 concerning TRS coverage (§ 199.24(d)(3)(i)). Similar to the TDP, this provision would apply to members involuntarily separated from the Selected Reserve if, and only if, the member was covered by TRS on the last day of his or her membership in the Selected Reserve. However, the termination date of TRS is characterized slightly differently from the TDP provision because TRS may terminate up to 180 days after the date on which the member is separated from the Selected Reserve. This delayed termination exception applies regardless of type of TRS coverage actually in effect at the time. This exception expires December 31, 2018.

We proposed to clarify the rule that procedures may be established for TRS coverage to be suspended for up to one year followed by final termination for members or qualified survivors if they fail to make premium payments in accordance with established procedures or otherwise if they request suspension/termination of coverage (§ 199.24(d)(3)). Suspension/termination of coverage for the TRS member/survivor will result in suspension/termination of coverage for the member's/survivor's family members in TRS, except as described in § 199.24 (d)(1)(iv). We also proposed to clarify that procedures may be established for the suspension to be lifted upon request before final termination is applied.

3. *Analysis of Major Public Comments.* No public comments were received relating to this section of the rule.

4. *Provisions of the Final Rule.* The final rule is consistent with the interim final rule and the proposed rule.

E. Preemption of State Laws (§ 199.24(e))

1. *Provisions of Interim Final Rule.* In the interim final rule, paragraph (e) addressed *Relationship to Continued Health Care Benefits Program (CHCBP)* (§ 199.24(e)). Based on a statutory amendment concerning CHCBP, the Final Rule published September 16, 2011 (76 FR 57637–57641) removed paragraph (e) in its entirety and replaced it with the placeholder (e) *Reserved* to maintain numerical sequencing.

3. *Provisions of the Proposed Rule.* We proposed to remove the previous § 199.24(e) *Reserved* and redesignate § 199.24(f) as § 199.24(e). No other changes are proposed this section.

4. *Analysis of Major Public Comments.* No public comments were received relating to this section of the rule.

5. *Provisions of the Final Rule.* The final rule is consistent with the proposed rule.

F. Administration (§ 199.25(f))

1. *Provisions of Interim Final Rule.* In the interim final rule, paragraph (f) addressed *Preemption of State laws* (§ 199.25(f)).

2. *Provisions of the Proposed Rule.* We proposed to redesignate § 199.24(g) as § 199.24(f). We proposed to clarify this provision by removing the phrase, ''based on extraordinary circumstances'' as a limitation on authority to grant exceptions to requirements of the section and to clarify that the Director, Healthcare Operations in the Defense Health Agency has authority to grant such exceptions and establish administrative rules and procedures for TRS.

3. *Analysis of Major Public Comments.* No public comments were received relating to this section of the rule.

4. *Provisions of the Final Rule.* The final rule is consistent with the proposed rule.

G. Terminology (§ 199.25(g))

1. *Provisions of Interim Final Rule.* In the interim final rule, paragraph (g) addressed *Administration* (§ 199.25(g)).

2. *Provisions of the Proposed Rule.* We proposed to redesignate paragraph (g) as paragraph (f) and to add a new paragraph (g) regarding terminology. This would also remove the terminology under § 199.25(a)(4).

3. *Analysis of Major Public Comments.* No public comments were received relating to this section of the rule.

4. *Provisions of the Final Rule.* The final rule is consistent with the proposed rule.

V. Costs

Fiscal year 2014 through 2019 costs are anticipated to be $7,735,728.00:

Fiscal year	Government cost
2014	$1,296,884
2015	1,373,929
2016	1,455,633
2017	1,542,277
2018	1,634,096
2019	432,909
Total FY14–FY19	7,735,728

VI. Regulatory Procedures

Executive Orders 12866 and 13563 require certain regulatory assessments for any significant regulatory action that would result in an annual effect on the economy of $100 million or more, or have other substantial impacts. The Congressional Review Act establishes certain procedures for major rules, defined as those with similar major impacts. The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation that would have significant impact on a substantial number of small entities. This final rule is not subject to any of these requirements because it will not have any of these substantial impacts. However, this rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511).

We have examined the impact(s) of the final rule under Executive Order 13132 and it does not have policies that have federalism implications that will have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The preemption provisions in the rule conform to law and long-established TRICARE policy. Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Handicapped, Health insurance, Military personnel.

Accordingly, the interim final rule published at 72 FR 46380 on August 20, 2007, amending 32 CFR part 199 is adopted as a final rule with the following changes:

PART 199—[AMENDED]

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Amend § 199.3 by revising paragraph (b)(5)(iii)(B) to read as follows:

§ 199.3 Eligibility.

* * * * *

(b) * * *

(5) * * *

(iii) * * *

(B) 180 days before the date on which the period of active duty is to begin.

* * * * *

■ 3. Amend § 199.13 by revising paragraph (c)(3)(ii)(E)(*2*) introductory text and adding paragraph (c)(3)(ii)(E)(*5*) to read as follows:

§ 199.13 TRICARE Dental Program.

* * * * *

(c) * * *

(3) * * *

(ii) * * *

(E) * * *

(*2*) *Survivor eligibility.* Eligible dependents of active duty members who die while on active duty for a period of more than 30 days and eligible dependents of members of the Ready Reserve (*i.e.,* Selected Reserve or Individual Ready Reserve, as specified in 10 U.S.C. 10143 and 10144(b) respectively) who die, shall be eligible for survivor enrollment in the TDP. During the period of survivor enrollment, the government will pay both the government and the eligible dependent's portion of the premium share. This survivor enrollment shall be up to (3) three years from the date of the member's death, except that, in the case of a dependent of the deceased who is described in 10 U.S.C. 1072(2)(D) or (I), the period of survivor enrollment shall be the longer of the following periods beginning on the date of the member's death:

* * * * *

(*5*) TRICARE Dental Program coverage shall terminate for members who no longer qualify for the TRICARE Dental Program as specified in paragraph (c)(2) of this section, with one exception. If a member is involuntarily separated from the Selected Reserve under other than adverse conditions, as characterized by the Secretary concerned, and TRICARE Dental Program coverage is in effect for the member and/or the family on the last day of his or her membership in the Selected Reserve; then the TRICARE Dental Program coverage that was actually in effect may terminate no earlier than 180 days after the date on which the member is separated from the Selected Reserve. This exception expires December 31, 2018.

* * * * *

■ 4. Amend § 199.24 as follows.

■ a. Remove paragraph (a)(4).

■ b. Redesignate paragraph (a)(5) as paragraph (a)(4).

■ c. Revise newly redesignated paragraphs (a)(4)(i)(B), (a)(4)(iii), and (a)(4)(iv).

■ d. Redesignate paragraphs (b) and (c) as paragraphs (c) and (b), respectively.

■ e. Revise newly redesignated paragraphs (b) and (c).

■ f. Revise paragraph (d).

■ g. Redesignate paragraphs (f) and (g) as paragraphs (e) and (f), respectively.

■ h. Revise newly redesignated paragraph (f).

■ i. Add new paragraph (g).

The revisions and additions read as follows:

§ 199.24 TRICARE Reserve Select.

(a) * * *

(4) * * *

(i) * * *

(B) Certain special programs established in 32 CFR part 199 are not available to members covered under TRICARE Reserve Select. These include the Extended Care Health Option (§ 199.5), the Special Supplemental Food Program (see § 199.23), and the Supplemental Health Care Program (§ 199.16), except when referred by a Military Treatment Facility (MTF) provider for incidental consults and the MTF provider maintains clinical control over the episode of care. The TRICARE Dental Program (§ 199.13) is independent of this program and is otherwise available to all members of the Selected Reserve and their eligible family members whether or not they purchase TRICARE Reserve Select coverage. The Continued Health Care Benefits Program (§ 199.20) is also independent of this program and is otherwise available to all members who qualify.

* * * * *

(iii) *Procedures.* Under TRICARE Reserve Select, Reserve Component members who fulfilled all of the statutory qualifications may purchase either the member-only type of coverage or the member-and-family type of coverage by submitting a completed request in the appropriate format along with an initial payment of the applicable premium. Rules and procedures for purchasing coverage and paying applicable premiums are prescribed in this section.

(iv) *Benefits.* When their coverage becomes effective, TRICARE Reserve

Select beneficiaries receive the TRICARE Standard (and Extra) benefit including access to military treatment facility services and pharmacies, as described in §§ 199.17 and 199.21. TRICARE Reserve Select coverage features the deductible and cost share provisions of the TRICARE Standard (and Extra) plan applicable to active duty family members for both the member and the member's covered family members (paragraph (a)(4)(iv) of this section). Both the member and the member's covered family members are provided access priority for care in military treatment facilities on the same basis as active duty service members' dependents who are not enrolled in TRICARE Prime as described in § 199.17(d)(1)(i)(D).

(b) *Qualifications for TRICARE Reserve Select coverage*—(1) *Ready Reserve member.* A Ready Reserve member qualifies to purchase TRICARE Reserve Select coverage if the Service member meets both the following criteria:

(i) Is a member of the Selected Reserve of the Ready Reserve of the Armed Forces, or a member of the Individual Ready Reserve of the Armed Forces who has volunteered to be ordered to active duty pursuant to the provisions of 10 U.S.C. 12304 in accordance with section 10 U.S.C. 10144(b); and

(ii) Is not enrolled in, or eligible to enroll in, a health benefits plan under 5 U.S.C. chapter 89. That statute has been implemented under 5 CFR part 890 as the Federal Employees Health Benefits (FEHB) program. For purposes of the FEHB program, the terms ''enrolled,'' ''enroll'' and ''enrollee'' are defined in 5 CFR 890.101. Further, the member (or certain former member involuntarily separated) no longer qualifies for TRICARE Reserve Select when the member (or former member) has been eligible for coverage to be effective in a health benefits plan under the FEHB program for more than 60 days.

(2) *TRICARE Reserve Select survivor.* If a qualified Service member dies while in a period of TRICARE Reserve Select coverage, the immediate family member(s) of such member is qualified to purchase new or continue existing TRICARE Reserve Select coverage for up to six months beyond the date of the member's death as long as they meet the definition of immediate family members as specified in paragraph (g)(2) of this section. This applies regardless of type of coverage in effect on the day of the TRICARE Reserve Select member's death.

(c) *TRICARE Reserve Select premiums.* Members are charged premiums for coverage under TRICARE Reserve Select that represent 28 percent of the total annual premium amount that the Director, Defense Health Agency determines on an appropriate actuarial basis as being appropriate for coverage under the TRICARE Standard (and Extra) benefit for the TRICARE Reserve Select eligible population. Premiums are to be paid monthly, except as otherwise provided through administrative implementation, pursuant to procedures established by the Director, Healthcare Operations in the Defense Health Agency. The monthly rate for each month of a calendar year is one-twelfth of the annual rate for that calendar year.

(1) *Annual establishment of rates.* TRICARE Reserve Select monthly premium rates shall be established and updated annually on a calendar year basis for each of the two types of coverage, member-only and member-and-family as described in paragraph (d)(1) of this section. Starting with calendar year 2009, the appropriate actuarial basis for purposes of this paragraph (c) shall be determined for each calendar year by utilizing the actual reported cost of providing benefits under this section to members and their dependents during the calendar years preceding such calendar year. Reported actual TRS cost data from calendar years 2006 and 2007 was used to determine premium rates for calendar year 2009. This established pattern will be followed to determine premium rates for all calendar years subsequent to 2009.

(2) *Premium adjustments.* In addition to the determinations described in paragraph (c)(1) of this section, premium adjustments may be made prospectively for any calendar year to reflect any significant program changes or any actual experience in the costs of administering TRICARE Reserve Select.

(3) *Survivor premiums.* A surviving family member of a Reserve Component service member who qualified for TRICARE Reserve Select coverage as described in paragraph (b)(2) of this section will pay premium rates as follows. The premium amount shall be at the member-only rate if there is only one surviving family member to be covered by TRICARE Reserve Select and at the member and family rate if there are two or more survivors to be covered.

(d) *Procedures.* The Director, Healthcare Operations in the Defense Health Agency, may establish procedures for the following.

(1) *Purchasing coverage.* Procedures may be established for a qualified member to purchase one of two types of coverage: Member-only coverage or member and family coverage. Immediate family members of a qualified member as specified in paragraph (g)(2) of this section may be included in such family coverage. To purchase either type of TRICARE Reserve Select coverage for effective dates of coverage described below, members and survivors qualified under either paragraph (b)(1) or (2) of this section must submit a request in the appropriate format, along with an initial payment of the applicable premium required by paragraph (c) of this section in accordance with established procedures.

(i) *Continuation coverage.* Procedures may be established for a qualified member or qualified survivor to purchase TRICARE Reserve Select coverage with an effective date immediately following the date of termination of coverage under another TRICARE program.

(ii) *Qualifying life event.* Procedures may be established for a qualified member or qualified survivor to purchase TRICARE Reserve Select coverage on the occasion of a qualifying life event that changes the immediate family composition (*e.g.,* birth, adoption, divorce, etc.) that is eligible for coverage under TRICARE Reserve Select. The effective date for TRICARE Reserve Select coverage will coincide with the date of the qualifying life event. It is the responsibility of the member to provide personnel officials with the necessary evidence required to substantiate the change in immediate family composition. Personnel officials will update DEERS in the usual manner. Appropriate action will be taken upon receipt of the completed request in the appropriate format along with an initial payment of the applicable premium in accordance with established procedures.

(iii) *Open enrollment.* Procedures may be established for a qualified member to purchase TRICARE Reserve Select coverage at any time. The effective date of coverage will coincide with the first day of a month.

(iv) *Survivor coverage under TRICARE Reserve Select.* Procedures may be established for a surviving family member of a Reserve Component service member who qualified for TRICARE Reserve Select coverage as described in paragraph (b)(2) of this section to purchase new TRICARE Reserve Select coverage or continue existing TRICARE Reserve Select coverage for up to six months beyond the date of the member's death. The effective date of coverage will be the day following the date of the member's death.

(2) *Changing type of coverage.* Procedures may be established for TRICARE Reserve Select members to request to change type of coverage during open enrollment as described in paragraph (d)(1)(iii) of this section or on the occasion of a qualifying life event that changes immediate family composition as described in paragraph (d)(1)(ii) of this section by submitting a completed request in the appropriate format.

(3) *Suspension and termination.* Suspension/termination of coverage for the TRS member/survivor will result in suspension/termination of coverage for the member's/survivor's family members in TRICARE Reserve Select, except as described in paragraph (d)(1)(iv) of this section. Procedures may be established for coverage to be suspended or terminated as follows.

(i) Coverage shall terminate when members or survivors no longer qualify for TRICARE Reserve Select as specified in paragraph (b) of this section, with one exception. If a member is involuntarily separated from the Selected Reserve under other than adverse conditions, as characterized by the Secretary concerned, and is covered by TRICARE Reserve Select on the last day of his or her membership in the Selected Reserve, then TRICARE Reserve Select coverage may terminate up to 180 days after the date on which the member was separated from the Selected Reserve. This applies regardless of type of coverage. This exception expires December 31, 2018.

(ii) Coverage may terminate for members, former members, and survivors who gain coverage under another TRICARE program.

(iii) Coverage may be suspended and finally terminated for members/survivors who fail to make premium payments in accordance with established procedures.

(iv) Coverage may be suspended and finally terminated for members/survivors upon request at any time by submitting a completed request in the appropriate format in accordance with established procedures.

(v) Under paragraph (d)(3)(iii) or (iv) of this section, TRICARE Reserve Select coverage may first be suspended for a period of up to one year followed by final termination. Procedures may be established for the suspension to be lifted upon request before final termination is applied.

(4) *Processing.* Upon receipt of a completed request in the appropriate format, enrollment actions will be processed into DEERS in accordance with established procedures.

(5) *Periodic revision.* Periodically, certain features, rules or procedures of TRICARE Reserve Select may be revised. If such revisions will have a significant effect on members' or survivors' costs or access to care, members or survivors may be given the opportunity to change their type of coverage or terminate coverage coincident with the revisions.

* * * * *

(f) *Administration.* The Director, Healthcare Operations in the Defense Health Agency may establish other rules and procedures for the effective administration of TRICARE Reserve Select, and may authorize exceptions to requirements of this section, if permitted by law.

(g) *Terminology.* The following terms are applicable to the TRICARE Reserve Select program.

(1) *Coverage.* This term means the medical benefits covered under the TRICARE Standard or Extra programs as further outlined in other sections of 32 CFR part 199 whether delivered in military treatment facilities or purchased from civilian sources.

(2) *Immediate family member.* This term means spouse (except former spouses) as defined in § 199.3(b)(2)(i), or child as defined in § 199.3(b)(2)(ii).

(3) *Qualified member.* This term means a member who has satisfied all the criteria that must be met before the member is authorized for TRS coverage.

(4) *Qualified survivor.* This term means an immediate family member who has satisfied all the criteria that must be met before the survivor is authorized for TRS coverage.

Dated: September 4, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–22815 Filed 9–14–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0873]

Drawbridge Operation Regulation; Snake River, Burbank, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Burlington Northern Santa Fe (BNSF) Railway Bridge across the Snake River, mile 1.5, at Burbank, WA. The deviation is necessary to accommodate maintenance to replace movable rail joints. This deviation allows the bridge to remain in the closed-to-navigation position during maintenance activities.

DATES: This deviation is effective from 7 a.m. on September 28, 2015 until 7 p.m. on October 1, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0873] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: BNSF has requested that the BNSF Snake River Bridge across the Snake River, mile 1.5, remain in the closed-to-navigation position to vessel traffic to perform railroad bridge maintenance. During this maintenance period, movable rail joints will be replaced at both ends of the lift span. The BNSF Snake River Bridge, mile 1.5, provides 14.1 feet of vertical clearance above Columbia River Datum 0.0 while in the closed position. The normal operating schedule for the BNSF Snake River Bridge 3.08 operates in accordance with 33 CFR 117.1058, and is automated and is normally maintained in the fully open-to-navigation position.

The deviation allows the lift span of the BNSF Snake River Bridge across the Snake River, mile 1.5, to remain in the closed-to-navigation position, and need not open for maritime traffic from 7 a.m. to 3 p.m. on September 28, 2015; from 7 a.m. to 7 p.m. on September 29, 2015; from 7 a.m. to 3 p.m. on September 30, 2015; and from 7 a.m. to 7 p.m. on October 1, 2015. During the active maintenance, BNSF will lower the lift span in closed-to-navigation position. Waterway usage on this part of the

Snake River includes vessels ranging from commercial tug and tow vessels to recreational pleasure craft including cabin cruisers and sailing vessels.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The span will be able to open for maritime emergencies, but any time lost to emergency openings will necessitate a time extension added to the approved dates. No immediate alternate route for vessels to pass is available on this part of the river. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 8, 2015.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2015–23141 Filed 9–14–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0002]

RIN 1625–AA11

Regulated Navigation Area, Kill Van Kull and Newark Bay; Bayonne, NJ, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The United States Coast Guard is establishing a Regulated Navigation Area (RNA) on the navigable waters of Kill Van Kull and Newark Bay surrounding the Bayonne Bridge. In response to a planned Bayonne Bridge construction project, this rule will establish a speed restriction in the waters surrounding the Bayonne Bridge. This rule will allow the Coast Guard to prohibit vessel traffic through the RNA when necessary to safeguard people and vessels from the hazards associated with bridge construction.

DATES: This rule is effective from October 15, 2015 until December 31, 2017.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2014–0002]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact BMC Craig Lapiejko, Coast Guard First District Waterways Management Branch, telephone (617) 223–8381, email *craig.d.lapiejko@uscg.mil;* or Mr. Jeff Yunker, Coast Guard Sector New York Waterways Management Division, U.S. Coast Guard; telephone 718–354–4195, email *jeff.m.yunker@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
NPRM Notice of Proposed Rulemaking
FR **Federal Register**

A. Regulatory History and Information

On January 9, 2015, we published a NPRM entitled Regulated Navigation Area, Kill Van Kull and Newark Bay; Bayonne, NJ, NY in the **Federal Register**. We received no comments on the proposed rule.

No public meeting was requested and none was held.

B. Basis and Purpose

Under the Ports and Waterways Safety Act, the Coast Guard has the authority to establish Regulated Navigation Areas in defined water areas that are hazardous or in which hazardous conditions are determined to exist. See 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; and Department of Homeland Security Delegation No. 0170.1.

The purpose of this rulemaking is to ensure the safety of vessels and workers from hazards associated with construction on the Bayonne Bridge. The current Bayonne Bridge was built in 1931 and carries the NY/NJ Route 440. The Port Authority New York/New Jersey (PANYNJ) has contracted Skanska-Koch Inc. and Kiewit Infrastructure for this project.

Construction operations are sensitive to water movement, and wake from passing vessels could pose significant risk of injury or death to construction workers. In order to minimize such unexpected or uncontrolled movement of water, the RNA will limit vessel speed and wake of all vessels operating in the vicinity of the bridge construction zone. This will be achieved by implementing a five (5) knot speed limit and ''NO WAKE'' zone in the vicinity of the construction as well as providing a means to suspend all vessel traffic for emergent situations that pose imminent threat to waterway users in the area.

After consulting with PANYNJ, Skanska-Koch Inc., and Kiewit Infrastructure, the Coast Guard has determined that certain aspects of the construction project can only be completed in the channel and will require closing the waterway. For instance, barges are expected to be used at times while portions of the bridge are being raised and the barges' presence might limit maneuverability in the waterway. Also, the Coast Guard anticipates that crane and cutting operations may create the potential for falling debris into the waterway. It is expected that the construction efforts that might require waterway closures will not take place until the summer of 2016.

C. Discussion of Comments, Changes and the Final Rule

No comments were received concerning this rule. Due to schedule delays, the overall timeline of the project has changed. Waterway closures are now expected during the summer of 2016. Completion of the entire project is now slated for 2017.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those

Orders. The Coast Guard expects the economic impact of this rule to be minimal as this RNA will not necessarily prohibit vessel traffic in the affected waterways. Rather, this RNA will primarily establish a speed and wake restriction along the waters surrounding the Bayonne Bridge. There may be times that the Coast Guard will prohibit vessel traffic through the RNA, but such closures are expected to take place during off peak hours. Moreover, even when the Coast Guard generally prohibits vessel traffic through the RNA, specific vessels may still obtain permission to transit through the RNA. Additionally, the Coast Guard will provide the public with advanced notification of waterway closures so that mariners may plan accordingly. Such notifications will be made through various means, including, but not limited to, Local Notice to Mariners and at *http://homeport.uscg.mil/newyork.* For all of these reasons, the Coast Guard has determined that this rule would not be a significant regulatory action.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. For all of the reasons discussed in the Regulatory Planning and Review section, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves restricting vessel movement within a regulated navigation area. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard is amending 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREA

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0002 to read as follows:

§ 165.T01–0002 Regulated Navigation Area; Kill Van Kull and Newark Bay; Bayonne, NJ, NY Regulated Area.

(a) *Location.* The following area is a Regulated Navigation Area (RNA): All waters of Bergen Point East and West Reaches in the Kill Van Kull, and all waters of Newark Bay South Reach, bound by the following approximate positions: 40°38′51.93″ N., 074°06′47.90″ W.; thence to 40°38′41.53″ N., 074°07′18.54″ W.; thence to 40°38′38.20″ N., 074°07′41.30″ W.; thence to 40°38′40.47″ N., 074°08′01.61″ W.; thence to 40°38′34.20″ N., 074°08′41.71″ W.; thence to 40°38′39.67″ N., 074°08′51.86″ W.; thence to 40°38′50.20″ N., 074°08′55.19″ W.; thence to 40°39′17.54″ N., 074°08′38.20″ W.; thence to 40°39′19.00″ N., 074°08′53.09″ W.; thence to 40°39′07.94″ N., 074°08′59.04″ W.; thence to 40°38′46.87″ N., 074°09′23.03″ W.; thence to 40°38′33.40″ N., 074°09′19.87″ W.; thence to 40°38′24.86″ N., 074°09′02.71″ W.; thence to 40°38′23.93″ N., 074°08′52.56″ W.; thence to 40°38′31.40″ N., 074°08′07.56″ W.; thence to 40°38′31.80″ N., 074°07′55.66″ W.; thence to 40°38′30.06″ N., 074°07′41.13″ W.; thence to 40°38′33.80″ N., 074°07′14.86″ W.; thence to 40°38′43.93″ N., 074°06′45.45″ W.; thence to the point of origin (NAD 83).

(b) *Regulations.* (1) The general regulations contained in 33 CFR 165.10, 165.11, and 165.13 apply within the RNA.

(2) Any vessel transiting through the RNA must make a direct passage. No vessel may stop, moor, anchor or loiter within the RNA at any time unless they are working on the bridge construction. Movement within the RNA is subject to a ''Slow-No Wake'' speed limit. All vessels may not produce a wake and may not attain speeds greater than five (5) knots unless a higher minimum speed is necessary to maintain bare steerageway.

(3) There may be times that the First District Commander or the Captain of the Port (COTP) New York finds it necessary to close the RNA to vessel traffic. All closures will be limited to specific hours of the day. Mariners will be advised of all closure dates and times via Local Notice to Mariners and Broadcast Notice to Mariners in advance of closure times. During such closures, persons and vessels may request permission to enter the RNA by contacting the COTP or the COTP's on-scene representative on VHF–16 or via phone at 718–354–4353 (Sector New York Command Center).

(4) Vessels in the RNA must comply with directions given to them by the COTP or the COTP's on-scene representative. An ''on-scene representative'' of the COTP is any Coast Guard commissioned, warrant or petty officer who has been designated by the COTP to act on the COTP's behalf. An on-scene representative may be on a Coast Guard vessel; or other designated craft; or on shore and communicating with a Vessel Traffic Service New York Watchstander or vessels via VHF–FM radio or loudhailer. Members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(5) All other relevant regulations, including but not limited to the Rules of the Road, as codified in 33 CFR Subchapter E, Inland Navigational Rules, remain in effect within the RNA and must be strictly followed at all times.

(c) *Enforcement period.* This regulation will be enforced from 8:00 a.m. on February 1, 2016, until December 31, 2017. This RNA's speed restrictions are enforceable 24 hours a day as long as this RNA is in place. The Coast Guard will enforce waterway closures only when necessary to protect people and vessels from hazards associated with bridge construction.

(d) *Notification.* The Coast Guard will rely on the methods described in 33 CFR 165.7 to notify the public of the time and duration of any closure of the RNA. Violations of this RNA may be reported to the COTP at 718–354–4353 or on VHF-Channel 16.

Dated: August 31, 2015.

L.L. Fagan,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2015–23171 Filed 9–14–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

[NPS–LAMR–18708; PPWONRADE2, PMP00EI05.YP0000]

RIN 1024–AD86

Special Regulations; Areas of the National Park System, Lake Meredith National Recreation Area, Off-Road Motor Vehicles

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: The National Park Service is amending its special regulations for Lake Meredith National Recreation Area to require permits to operate motor vehicles off roads, designate areas and routes where motor vehicles may be used off roads, create management zones that will further manage this activity, and establish camping, operational, and vehicle requirements. These changes will allow off-road vehicle use for recreation while reducing associated impacts to resources. Unless authorized by special regulation, operating a motor vehicle off roads within areas of the National Park System is prohibited.

DATES: This rule is effective October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Robert Maguire, Superintendent, Lake Meredith National Recreation Area, P.O. Box 1460, Fritch, Texas 79036–1460, by phone at 806–857–3151, or by email at *Robert_Maguire@nps.gov.*

SUPPLEMENTARY INFORMATION:

Purpose and Significance of Lake Meredith National Recreation Area

Congress established Lake Meredith National Recreation Area (LAMR or recreation area) in 1990 ''to provide for public outdoor recreation use and enjoyment of the lands and waters associated with Lake Meredith in the State of Texas, and to protect the scenic, scientific, cultural, and other values contributing to the public enjoyment of such lands and waters. . . .'' 16 U.S.C. 460eee.

Situated approximately 35 miles north of Amarillo, Texas, within Potter, Moore, Hutchinson, and Carson counties, LAMR is approximately 45,000 acres in size and is the largest public landmass in the Texas Panhandle. LAMR includes a variety of habitats that are uncommon in the region, including aquatic, wetland, and riparian areas, and one of the few areas in the region with trees. The natural and

geologic resources of the area have enabled a continuum of human presence in the area for more than 13,000 years. The exposed geologic features on the walls of the Canadian River valley (*i.e.,* the ''breaks'') reveal active geologic processes that are easily visible to an extent not present elsewhere in the region. The recreation area is also home to the Arkansas River shiner (*Notropis girardi*), a fish species that is federally listed as threatened.

Authority To Promulgate Regulations

The National Park Service (NPS) manages LAMR under the statute commonly known as the NPS Organic Act of 1916 (Organic Act) (54 U.S.C. 100101 *et seq.*), which gives the NPS broad authority to regulate the use of the park areas under its jurisdiction. The Organic Act authorizes the Secretary of the Interior, acting through NPS, to ''prescribe such regulations as the Secretary considers necessary or proper for the use and management of [National Park] System units.'' 54 U.S.C. 100751(a).

Executive Order 11644, Use of Off-Road Vehicles on the Public Lands, issued in 1972 and amended by Executive Order 11989 in 1977, requires federal agencies to issue regulations designating specific areas and routes on public lands where the use of off-road vehicles may be used. The NPS implemented these Executive Orders in 36 CFR 4.10.

Under 36 CFR 4.10, the use of motor vehicles off established roads is not permitted unless routes and areas are designated for off-road motor vehicle use by special regulation. Under 36 CFR 4.10(b), such routes and areas ''may be designated only in national recreation areas, national seashores, national lakeshores and national preserves.'' The rule will designate routes and areas where motor vehicles may be used off roads in compliance with 36 CFR 4.10 and Executive Orders 11644 and 11989. The rule will replace regulations promulgated in 1975 that designate areas for off-road vehicle (ORV) use.

Off-Road Motor Vehicle Use at LAMR

Designated ORV Use Areas

LAMR provides a variety of visitor experiences, including the use of ORVs. In 1975, the NPS promulgated a special regulation (40 FR 762, January 3, 1975) at 36 CFR 7.57(a) designating two ORV use areas at LAMR: (i) Blue Creek, with 275 acres for ORV use in the creek bottom between the cutbanks; and (ii) Rosita, with approximately 1,740 acres for ORV use below the 3,000-foot elevation line. These two areas remain the only areas designated for ORV use in the recreational area.

The Blue Creek ORV area is in the Blue Creek riparian area at the northern end of the recreational area that empties into Lake Meredith. ORV use at Blue Creek is allowed only in the creek bottom along both sides from cutbank to cutbank. Cutbanks, also known as river-cut cliffs, are the outside banks of a water channel and are located at the base of the hills at the edges of the creek bed.

The Rosita ORV area is a riparian area of the Canadian River at the southern end of the recreation area. ORV use at Rosita is in the Canadian River bed as well as the surrounding hills, in some cases out to a mile or more. Although the authorized area is below the 3,000-foot elevation line, and ORV use outside the authorized area is prohibited, it is difficult for ORV users to determine the exact location of the 3,000-foot elevation line.

Changes in ORV Use at LAMR

ORV use at Blue Creek and Rosita has changed considerably since the areas were designated by special regulation in 1975, both in intensity and the types of vehicles used. ORV use has taken place at Blue Creek and Rosita since at least the 1950s. Throughout the 1960s, ORVs primarily consisted of a small number of ''river buggies'' crafted from old automobiles to operate in the Canadian River bottom. A few people used dirt bikes, motorcycles, or surplus military vehicles to access the area. Standard four-wheel-drive vehicles were rarely seen.

Today, visitors use a variety of vehicle types, including all-terrain vehicles (ATVs), utility task vehicles (UTVs), dune buggies, rock crawlers, and standard four-wheel-drive vehicles. Regardless of the vehicle type, the majority of ORV use at LAMR has been and continues to be for recreation, rather than transportation. ORV users are both local and from urban areas, especially at Rosita. ORV use is often, but not always, family focused. In February, an annual three-day event called Sand Drags is held just outside the recreation area north of Rosita. This locally sponsored racing event draws approximately 30,000 visitors to the area, including hundreds of motorcycles, four wheelers, sand rails, and river buggies. This event results in the highest annual visitation to the recreation area with a notable increase in recreational ORV use.

Changes in the intensity and type of ORV use at LAMR have impacted natural and cultural resources and raised concerns about visitor experience, health, and safety. Impacted resources include soils, vegetation, water, soundscapes, wildlife and wildlife habitat, threatened species, and archeological sites. These impacts are described in the January 2015 Final Off-Road Vehicle Management Plan/Environmental Impact Statement (FEIS) that is discussed below.

Off-Road Vehicle Management Plan/Environmental Impact Statement

The rule will implement the preferred alternative (Alternative D) for the recreation area described in the FEIS. On June 26, 2015, the Regional Director of the Intermountain Region signed a Record of Decision (ROD) identifying the preferred alternative as the selected action. The FEIS, which describes the purpose and need for taking action, the alternatives considered, the scoping process and public participation, the affected environment and environmental consequences, and consultation and coordination, and the ROD may be viewed on the recreation area's planning Web site at *http://parkplanning.nps.gov/lamr*, by clicking the link entitled ''ORV Management Plan and Regulation'' and then clicking ''Document List.''

Final Rule

Fee Permit System

The rule will require a special use permit to operate a motor vehicle off road in the recreation area. With each permit the NPS will issue a decal that must be affixed to each vehicle in a manner and location determined by the superintendent. Decals will be required for each ORV operating in the recreation area or transported into the recreation area on a trailer. Families may submit a single application for special use permits for multiple vehicles that are registered or titled to members of that family. Annual permits will be valid for the calendar year the permit is issued; three-day and one-day permits will also be available and valid from the date designated on the permit. There will be no limit to the number of annual or other permits issued.

Permits will be issued after the applicant reads educational materials and acknowledges in writing that he or she has read, understood, and agrees to abide by the terms in the permit governing ORV use in the recreation area. The permittee who signs the permit will be the responsible party for all vehicles listed on the permit, and must keep a hard copy of the permit with them on-site when the permittee or another person is operating the vehicle in the recreation area. The permittee is

responsible for the actions of all operators of a permitted vehicle, including compliance with the terms and conditions of the permit. Permit applications (NPS Form 10–933, ''Application for Special Use Permit—Vehicle/Watercraft Use'') will be available at headquarters (419 E. Broadway, Fitch, TX 79036) and on the recreation area's Web site. Completed permit applications may be submitted in person at headquarters or mailed to the recreation area at Lake Meredith National Recreation Area, P.O. Box 1460, Fritch, TX 79036. The NPS will process completed permit applications and provide a permit, or mail a permit, with instructions and educational materials to the applicant. After the applicant receives the permit, he or she will sign the permit and submit it to the park or mail it back to the park at the P.O. Box address. After the NPS receives the signed permit, it will provide or send a copy of the signed permit and a decal (to be affixed to the ORV) to the permit-holder. Violating the terms or conditions of any permit or failing to properly display the decal will be prohibited and may result in the suspension or revocation of the permit.

The NPS intends to recover the costs of administering the special use permit program under 54 U.S.C. 103104. In order to obtain a special use permit to operate a motor vehicle off roads in the recreational area, the rule will require applicants to pay a permit fee to allow the NPS to recover these costs. The NPS will post a fee schedule at the recreation area and on the recreation area's Web site. The initial fee will be $40.00 per application, no matter how many vehicles are included in the application.

Designated Routes and Areas

The rule will prohibit ORV use in the recreation area except for designated areas, routes, and access points. These locations will be identified on maps located at headquarters (419 E. Broadway, Fitch, TX 79036) and on the recreation area's Web site, and will be marked on the ground with signs, posts, or cables.

At Blue Creek, the rule will designate the following areas, routes, and access points for ORV use:

	Designated locations for ORV use	Part of a management zone?
Blue Creek	Approximately 133.5 acres on the river bottom Approximately one linear mile of routes and access points to the river bottom.	Low Speed Zone (partial overlap). No.

At Rosita, the rule will designate the following areas, routes, and access points for ORV use:

	Designated locations for ORV use	Part of a management zone?
Rosita	Approximately 170.2 acres south of the Canadian River (currently denuded of vegetation) at the western border of LAMR where HWY 287 nears the recreation area.	No.
	Approximately 65.2 acres south of the Canadian River and on the east side of Bull Taco Hill.	Hunting Zone (complete overlap).
	Approximately 119.3 acres on the river bottom	Resource Protection Zone (partial overlap).
	Approximately 15.1 linear miles of routes and access points to the river bottom.	Resource Protection Zone (partial overlap).
	Hunting Zone (complete overlap).	
	Approximately one linear mile of routes south of the Canadian River near HWY 287.	Beginner Zone (complete overlap).

Management Zones

As indicated in the tables above, the rule will also establish management zones at Blue Creek and Rosita. In some locations, the areas, routes, and access points designated for ORV use will enter into one or more of these management zones. When this occurs, special restrictions will apply to ORV use. These zones are designed to separate types of ORV use in the recreation area to avoid visitor conflict, protect the health and safety of visitors, and minimize impacts to natural and cultural resources. Zones will be identified on maps located at headquarters (419 E. Broadway, Fitch, TX 79036) and on the recreation area's Web site. The special restrictions for each management zone are described in the table below:

Management zone	Special restrictions	ORV use location
Beginner Zone	Speed limit: 20 mph (unless otherwise posted) Routes marked for beginner ORV operators only.	Rosita.
Camping Zone	Speed limit: 15 mph (unless otherwise posted). ORVs may only be used to access the campground; recreational use prohibited. ORVs may not be used from 10 p.m.–6 a.m. (unless otherwise posted), except that state-registered vehicles may be used during this time.	Blue Creek. Rosita.
Hunting Zone	ORVs may be used only for hunting during the Texas general white-tailed deer season.	Rosita.
Low-Speed Zone	Speed limit: 15 mph (unless otherwise posted)	Blue Creek.

Management zone	Special restrictions	ORV use location
Resource Protection Zone	ORVs with a wheel width greater than 65 inches are prohibited	Rosita.

Camping

In addition to conditions for camping established by the Superintendent in the recreation area's compendium, the rule will establish rules related to camping at Blue Creek and Rosita. Camping will be prohibited in designated ORV areas, routes, and access points and within 100 feet of these locations, except for marked camping zones where camping will be allowed in or next to a motor vehicle, including a tent trailer, RV, or van.

Operational and Vehicle Requirements

ORV use will be prohibited on vegetation anywhere in the recreation area. Driving through isolated pools of water will be prohibited at Rosita regardless of time or season for the protection of the Arkansas River shiner. Isolated pools of water means water that is not connected to or touching flowing water. ORVs will be allowed to cross flowing river water if they enter and exit the river bottom via designated access points. The decibel limit for all ORVs in the recreation area will be 96 dba. NPS personnel will enforce this rule by stopping and testing the decibel level of any ORV suspected of exceeding the noise limit. Noise level will be measured using the SAE J1287 standard. The rule will require ATVs to have a whip—a pole, rod, or antenna—securely mounted to the vehicle that extends at least eight feet from the surface of the ground with an orange colored safety flag at the top. The rule will define ATVs using the definition currently found in Texas Transportation Code 502.001. The rule will require that ORVs have a functioning muffler system and functioning headlights and taillights if the ORV is operating at night. Operators will be required to use headlights and taillights starting one half hour before sunset and ending one half hour after sunrise. Glass containers (*e.g.,* cups and bottles) will be prohibited in designated areas, routes, and access points, and in camping zones at Blue Creek and Rosita. Except for management zones with a slower speed limit, the speed limit will be 35 mph (unless otherwise posted) on ORV routes and 55 mph (unless otherwise posted) on the river bottom at Blue Creek and Rosita. Speed limits will be implemented for visitor safety and to reduce driving that may damage resources.

The provisions of 36 CFR part 4 (Vehicles and Traffic Safety), including state laws adopted by 36 CFR 4.2, will continue to apply within the recreation area. Currently, Texas law includes, but is not limited to, the following rules about ORVs:

- ORVs must have an off-highway vehicle (OHV) use decal issued by the State of Texas.
- ATV operators must wear eye protection and helmets approved by the Texas Department of Transportation.
- ATV operators must possess valid safety certificates issued by the State of Texas under Section 663.031 of the Texas Transportation Code.
- ATV operators under the age of 14 must be accompanied by a parent or guardian.
- ATV operators may not carry passengers unless the vehicle is designed by the manufacturer for carrying passengers.

Superintendent's Discretionary Authority

The rule will allow the superintendent to open or close designated areas, routes, or access points to motor vehicle use, or portions thereof, or impose conditions or restrictions for off-road motor vehicle use after taking into consideration public health and safety, natural and cultural resource protection, and other management activities and objectives. The superintendent will provide public notice of all such actions through one or more of the methods listed in 36 CFR 1.7.

Summary of Public Comments

The NPS published the proposed rule at 80 FR 11968 (March 5, 2015). The NPS accepted comments through the mail, hand delivery, and through the Federal eRulemaking Portal at *http://www.regulations.gov.* Comments were accepted through May 4, 2015. The NPS received one comment on the proposed rule. A summary of this comment and the NPS responses are provided below. After considering the public comments and after additional review, the NPS did not make any substantive changes to the proposed rule. The final rule contains the following clarifications:

- All designated ORV locations will be marked on the ground by signs, posts, or cables.
- Provides the linear mileage of designated routes in the beginner zone.
- Clarifies that the restrictions in the hunting zone apply during the Texas general white-tailed deer season, rather than the more general rifle hunting season.

Comment: The commenter suggested that, due to the proposed speed limits, the overnight camping zone in Rosita can be used by beginner riders and therefore the beginner zone is unnecessary.

NPS Response: For the safety of all campers including children, the NPS determined that recreational ORV use should occur outside of the camping zones. In the camping zones, ORVs will be allowed only to access the campground; recreational ORV use will be prohibited. The beginner zone was requested by the public during the scoping process for the EIS and will be established so that beginners have a safe environment to learn how to drive for recreation without potential collisions with campers who are likely to be outside of their vehicles, or ORVs traveling at fast speeds.

Comment: The commenter stated that education on signs and on the recreation area Web site, and the requirement to obtain a permit and decal is better than requiring ORVs to stay on designated trails. This comment also stated that ORVs should be allowed to cross or ride on the river bed at Rosita, especially when the water level is low.

NPS Response: There are designated ORV areas in Rosita where ORVs will not have to stay on designated routes or access points. The designated areas will be delineated on the ground by signs, posts or cables. Education through signs, Web sites, written materials, or the permit system is an important tool for informing visitors about the importance of staying on designated routes, access points, and within the designated ORV areas. ORVs will be permitted to enter and exit the river bottom in Rosita only at designated access points. Designated access points are necessary to protect the Arkansas river shiner and shoreline vegetation and to reduce erosion. ORV use within the river bottom, including through flowing water but excluding isolated pools of water, will be permitted because the river bottom is a designated ORV route.

Comment: The commenter suggested that, in Rosita, recreational ORVs be allowed in the hunting zone in the afternoon and at night during hunting season when there will no longer be an opportunity to harvest game.

NPS Response: Hunters may be using weapons within the hunting zone

throughout the general white-tailed deer season during daylight hours. For visitor protection and to avoid confusion about when ORVs may be used for recreational purposes in the hunting zone, the rule will prohibit recreational ORV use in the hunting zone only during the general white-tailed deer season, but at all times of day or night.

Compliance With Other Laws, Executive Orders, and Department Policy

Use of Off-Road Vehicles on the Public Lands (Executive Orders 11644 and 11989)

Executive Order 11644, as amended by Executive Order 11989, was adopted to address impacts on public lands from ORV use. The Executive Order applies to ORV use on federal public lands that is not authorized under a valid lease, permit, contract, or license. Section 3(a)(4) of Executive Order 11644 provides that ORV ''[a]reas and trails shall be located in areas of the National Park System, Natural Areas, or National Wildlife Refuges and Game Ranges only if the respective agency head determines that off-road vehicle use in such locations will not adversely affect their natural, aesthetic, or scenic values.'' Since the Executive Order clearly was not intended to prohibit all ORV use everywhere in these units, the term ''adversely affect'' does not have the same meaning as the somewhat similar terms ''adverse impact'' and ''adverse effect'' used in the National Environmental Policy Act of 1969 (NEPA). In analyses under NEPA, a procedural statute that provides for the study of environmental impacts, the term ''adverse effect'' includes minor or negligible effects.

Section 3(a)(4) of the Executive Order, by contrast, concerns substantive management decisions and must be read in the context of the authorities applicable to such decisions or applicable to the nature of the land management unit. LAMR is an area of the National Park System. NPS interprets the Executive Order term ''adversely affect'' consistent with its NPS Management Policies 2006. Those policies require that the NPS only allow ''appropriate use'' of parks and avoid ''unacceptable impacts.''

This rule is consistent with those requirements. It will not impede attainment of the recreation area's desired future conditions for natural and cultural resources as identified in the FEIS. NPS has determined that this rule will not unreasonably interfere with the atmosphere of peace and tranquility or the natural soundscape maintained in natural locations within the recreation area. Therefore, within the context of the resources and values of the recreation area, motor vehicle use on the routes and areas designated by this rule will not cause an unacceptable impact to the natural, aesthetic, or scenic values of the recreation area.

Section 8(a) of the Executive Order requires agency heads to monitor the effects of ORV use on lands under their jurisdictions. On the basis of information gathered, agency heads may from time to time amend or rescind designations of areas or other actions as necessary to further the policy of the Executive Order. The preferred alternative in the EIS includes monitoring and resource protection procedures and periodic review to provide for the ongoing evaluation of impacts of motor vehicle use on protected resources. The superintendent has authority to take appropriate action as needed to protect the resources of the recreation area.

Regulatory Planning and Review (Executive Orders 12866 and13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA)

This rule will not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This certification is based on the cost-benefit and regulatory flexibility analyses found in the report entitled ''Benefit-Cost Analysis of ORV Use Regulations in Lake Meredith National Recreation Area'' that can be viewed online at *http://parkplanning.nps.gov/lamr*, by clicking the link entitled ''ORV Management Plan and Regulation'' and then clicking ''Document List.'' According to that report, no small entities will be directly regulated by the rule, which will only regulate visitor use of ORVs.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the SBREFA. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (UMRA)

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on state, local or tribal governments or the private sector. The designated ORV routes and areas are located entirely within the recreation area, and will not result in direct expenditure by state, local, or tribal governments. This rule addresses public use of NPS lands, and imposes no requirements on other agencies or governments. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630. Access to private property adjacent to the recreation area will not be affected by this rule. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. The rule is limited in effect to federal lands managed by the NPS and will not have a substantial direct effect on state and local government. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the criteria in Executive Order 13175 and under the Department's tribal consultation policy and have determined that tribal consultation is not required because the rule will have no substantial direct effect on federally recognized Indian tribes.

During scoping for the EIS, recreational area staff sent letters to the Apache Tribe of Oklahoma, Caddo Nation of Oklahoma, Comanche Nation, Cheyenne-Arapaho Tribe of Oklahoma, Delaware Nation of Oklahoma, Fort Sill Apache Tribe of Oklahoma, Jicarilla Apache Nation, Kiowa Indian Tribe of Oklahoma, Mescalero Apache Tribe, Wichita & Affiliated Tribes requesting information on any historic properties of religious or cultural significance to the Tribes that will be affected by the FEIS. The same tribes were contacted when the recreation area released the Off-Road Vehicle Management Plan/Draft Environmental Impact Statement in January 2013. These tribes have not informed NPS staff of any concerns over historic properties of religious or cultural significance.

Paperwork Reduction Act (44 U.S.C. 3501 *et seq*.)

This rule does not contain any new collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. OMB has approved the information collection requirements associated with NPS Special Park Use Permits and has assigned OMB Control Number 1024–0026 (expires 08/31/16). An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act of 1969 (NEPA)

This rule constitutes a major Federal action significantly affecting the quality of the human environment. We have prepared the FEIS and the ROD under the NEPA. The FEIS and ROD are summarized above and available online at *http://www.parkplanning.nps.gov/lamr*, by clicking on the link entitled ''ORV Management Plan and Regulation'' and then clicking ''Document List.''

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

Drafting Information

The primary authors of this regulation are Lindsay Gillham, NPS Environmental Quality Division, and Jay Calhoun, NPS Regulations Program Specialist.

List of Subjects in 36 CFR Part 7

National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service amends 36 CFR part 7 as follows:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

■ 1. The authority citation for part 7 continues to read as follows:

Authority: 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under D.C. Code 10–137 and D.C. Code 50–2201.07.

■ 2. In § 7.57, revise paragraph (a) to read as follows:

§ 7.57 Lake Meredith National Recreation Area.

(a)(1) *What terms do I need to know?* In addition to the definitions found in § 1.4 of this chapter, the following definition applies to this § 7.57 only.

All-terrain vehicle or ATV means a motor vehicle that is:

(i) Equipped with a seat or seats for the use of the rider and a passenger, if the motor vehicle is designed by the manufacturer to transport a passenger;

(ii) Designed to propel itself with three or more tires in contact with the ground;

(iii) Designed by the manufacturer for off-highway use;

(iv) Not designed by the manufacturer primarily for farming or lawn care; and

(v) Not more than 50 inches wide.

(2) *Off-road motor vehicle use.* Operating a motor vehicle is allowed within the boundaries of Lake Meredith National Recreation Area off roads under the conditions in this paragraph (a).

(3) *Permit requirement.* (i) A special use permit issued and administered by the superintendent is required to operate a motor vehicle off roads at designated locations in the recreation area. There is no limit to the number of permits that the Superintendent may issue.

(ii) The NPS charges a fee to recover the costs of administering the special use permits. Permit applicants must pay the fee charged by the NPS in order to obtain a special use permit.

(iii) Annual permits are valid for the calendar year for which they are issued. Three-day permits are valid on the day designated on the permit and the following two days. One-day permits are valid on the day designated on the permit.

(iv) A permit applicant must acknowledge in writing that he or she understands the rules governing off-road vehicle use in the recreation area.

(v) Each motor vehicle permitted to operate off roads must display an NPS decal issued by the superintendent. The NPS decal must be affixed to the vehicle in a manner and location specified by the superintendent.

(vi) Permits may be requested from the recreation area headquarters in Fritch, Texas, or on the recreation area Web site.

(4) *Designated locations.* (i) The operation of a motor vehicle off roads within the recreation area is prohibited except at the locations designated by this paragraph (a). Designated locations are identified on maps available at the recreation area headquarters and on the recreation area Web site, and are marked on the ground with signs, posts, or cables.

(ii) Permitted motor vehicles may be used off roads at the following locations at Blue Creek, an area at the northern end of the recreational area that empties into Lake Meredith:

	Designated locations for off-road motor vehicle use	Part of a management zone?
Blue Creek	Approximately 133.5 acres on the river bottom Approximately one linear mile of routes and access points to the river bottom.	Low Speed Zone (partial overlap). No.

(iii) Permitted motor vehicles may be used off roads at the following locations at Rosita, an area of the Canadian River at the southern end of the recreation area:

	Designated locations for off-road motor vehicle use	Part of a management zone?
Rosita	Approximately 170.2 acres south of the Canadian River (currently denuded of vegetation) at the western border of LAMR where HWY 287 nears the recreation area.	No.
	Approximately 65.2 acres south of the Canadian River and on the east side of Bull Taco Hill.	Hunting Zone (complete overlap).
	Approximately 119.3 acres on the river bottom	Resource Protection Zone (partial overlap).
	Approximately 15.1 linear miles of routes and access points to the river bottom.	Resource Protection Zone (partial overlap). Hunting Zone (complete overlap).
	Approximately one linear mile of routes south of the Canadian River near HWY 287.	Beginner Zone (complete overlap).

(5) *Management zones.* Some of the designated locations for off-road motor vehicle use enter into or abut one or more management zones that further manage this activity. These zones are identified on maps available at headquarters and on the recreation area Web site. Each zone has special restrictions governing off-road motor vehicle use as set forth in the following table:

Zone	Special restrictions	Location
Beginner Zone	Speed limit: 20 mph (unless otherwise posted). Routes marked for beginner operators of off-road vehicles only	Rosita.
Camping Zone	Speed limit: 15 mph (unless otherwise posted). Off-road vehicles may only be used to access the campground; recreational use prohibited. Off-road vehicles that are not registered in a state may not be used from 10 p.m.–6 a.m. (unless otherwise posted).	Rosita. Blue Creek.
Hunting Zone	Off-road vehicles may be used only for hunting during the Texas general white-tailed deer season.	Rosita.
Low-Speed Zone	Speed limit: 15 mph (unless otherwise posted). Located approximately ½ mile on either side of the FM 1913 bridge	Blue Creek.
Resource Protection Zone	Off-road vehicles with a wheel width greater than 65 inches are prohibited.	Rosita.

(6) *Camping at Blue Creek and Rosita.* Camping is prohibited in designated ORV areas, routes, and access points and within 100 feet of these locations, except for marked camping zones where camping is allowed in or next to a motor vehicle, including a tent trailer, RV, or van.

(7) *Operational and vehicle requirements.* The following requirements apply to the use of motor vehicles off roads in the recreation area:

(i) At Rosita, operating a motor vehicle in an isolated pool of water that is not connected to or touching flowing water is prohibited.

(ii) Operating a motor vehicle on vegetation is prohibited.

(iii) Glass containers are prohibited in designated areas, routes, and access points, and in camping zones.

(iv) Operating a motor vehicle in excess of 35 mph (unless otherwise posted) on designated routes and access points at Blue Creek and Rosita is prohibited.

(v) Operating a motor vehicle in excess of the speed limits identified in paragraph (a)(5) (unless otherwise posted) in specific management zones is prohibited.

(vi) Operating a motor vehicle in excess of 55 mph (unless otherwise posted) in the designated areas that are not part of a Low-Speed Zone on the river bottoms at Blue Creek and Rosita is prohibited.

(vii) All ATVs must be equipped with a whip—a pole, rod, or antenna—that is securely mounted on the vehicle and stands upright at least eight feet from the surface of the ground when the vehicle is stopped. This whip must have a solid red or orange safety flag with a minimum size of six inches by twelve inches that is attached no more than ten inches from the top of the whip. Flags must have a pennant, triangle, square, or rectangular shape.

(viii) A motor vehicle must display lighted headlights and taillights during the period from one-half hour before sunset to one half hour after sunrise.

(ix) Motor vehicles must have a functioning muffler system. Motor vehicles that emit more than 96 decibels of sound (using the SAE J1287 test standard) are prohibited.

(x) Operating a motor vehicle with a wheel width greater than 65 inches in a Resource Protection Zone is prohibited.

(8) *Prohibited acts.* Violating any provision of this paragraph (a), including the special restrictions for

each management zone, or the terms, conditions, or requirements of an off-road vehicle permit is prohibited. A violation may also result in the suspension or revocation of the applicable permit by the superintendent.

(9) *Superintendent's authority.* The superintendent may open or close designated areas, routes, or access points to motor vehicle use, or portions thereof, or impose conditions or restrictions for off-road motor vehicle use after taking into consideration public health and safety, natural and cultural resource protection, and other management activities and objectives. The superintendent will provide public notice of all such actions through one or more of the methods listed in § 1.7 of this chapter. Violating any such closure, condition, or restriction is prohibited.

* * * * *

Dated: September 9, 2015.

Michael Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2015–23168 Filed 9–14–15; 8:45 am]

BILLING CODE 4310–EJ–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0270; FRL–9932–78–Region 7]

Partial Approval and Disapproval of Air Quality State Implementation Plans (SIP); State of Nebraska; Infrastructure SIP Requirements for the 2008 Ozone National Ambient Air Quality Standard (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to partially approve and disapprove elements of a State Implementation Plan (SIP) submission from the State of Nebraska addressing the applicable requirements of Clean Air Act (CAA) section 110 for the 2008 National Ambient Air Quality Standards (NAAQS) for Ozone (O_3), which requires that each state adopt and submit a SIP to support implementation, maintenance, and enforcement of each new or revised NAAQS promulgated by EPA. These SIPs are commonly referred to as ''infrastructure'' SIPs. The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA.

DATES: This final rule is effective September 15, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2015–0270. All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219 from 8:00 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory Crable, Air Planning and Development Branch, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, KS 66219; *telephone number:* (913) 551–7391; *fax number:* (913) 551–7065; *email address: crable.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. Background

On June 19, 2015, (80 FR 35284), EPA published a notice of proposed rulemaking (NPR) for the State of Nebraska. The NPR proposed partial approval and disapproval of Nebraska's submission that provides the basic elements specified in section 110(a)(2) of the CAA, or portions thereof, necessary to implement, maintain, and enforce the 2008 O_3 NAAQS.

II. Summary of SIP Revision

On February 11, 2013, EPA received a SIP submission from the state of Nebraska that addressed the infrastructure elements specified in section 110(a)(2) for the 2008 O_3 NAAQS. The submission addressed the following infrastructure elements of section 110(a)(2): (A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M). Specific requirements of section 110(a)(2) of the CAA and the rationale for EPA's proposed action to approve and disapprove the SIP submissions are explained in the NPR and will not be restated here.

During the public comment period for the NPR one comment was received. The commenter stated that EPA must disapprove 110(a)(2)(C) and (D)(i)(II) (prong 3), unless Nebraska has the $PM_{2.5}$ increments approved into its PSD SIP and its PSD program treats NO_X as a precursor for ozone. The $PM_{2.5}$ increments and the inclusion of NO_X as a precursor to ozone was approved by EPA into the Nebraska SIP on August 4, 2014. See 79 FR 45108, Approval and Promulgation of Implementation Plans; State of Nebraska; Fine Particulate Matter New Source Review Requirements.

III. Final Action

EPA is approving Nebraska's February 11, 2013 submission addressing the requirements of the CAA sections 110(a)(1) and (2) as applicable to the 2008 O_3 NAAQS. Specifically, EPA approves the following infrastructure elements, or portions thereof: 110(a)(2)(A), (B), (C), (D)(i)(II) (prong 3), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) which are necessary to implement, maintain, and enforce the 2008 O_3 NAAQS, as a revision to the Nebraska SIP. As discussed in each applicable section of the NPR, EPA is not taking action on section 110(a)(2)(D)(i)(I) (prongs 1 and 2) and section 110(a)(2)(I), Nonattainment Area Plan or Plan Revisions, under part D. And finally, EPA is disapproving section 110(a)(2)(D)(i)(II) (prong 4) as it relates to the protection of visibility.

IV. Statutory and Executive Order Review

Under the CAA the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 16, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

Dated: August 12, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart CC—Nebraska

■ 2. Amend § 52.1420 by adding and reserving an entry for ''(28)'', and by adding an entry for ''(29)'' in numerical order under paragraph (e), in the table entitled ''EPA-Approved Nebraska Nonregulatory Provisions''.

The addition reads as follows:

§ 52.1420 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NEBRASKA NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
*	* *	*	* *	* *
(28) [Reserved].				
(29) Section 110(a)(2) Infrastructure Requirements for the 2008 O_3 NAAQS.	Statewide	2/11/13	9/15/15, [Insert **Federal Register** citation].	[EPA–R07–OAR–2015–0270; Region 7] This action addresses the following CAA elements 110(a)(2)(A), (B), (C), (D)(i)(II), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[FR Doc. 2015–20619 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0565; FRL–9932–84–Region 7]

Approval and Promulgation of Air Quality Implementation Plans; State of Nebraska; Cross-State Air Pollution Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the State Implementation Plan (SIP) submitted by the State of Nebraska in a letter dated March 30, 2015. This SIP revision provides Nebraska's state-determined allowance allocations for existing electric generating units (EGUs) in the State for the 2016 control periods and replaces the allowance allocations for the 2016 control periods established by

EPA under the Cross-State Air Pollution Rule (CSAPR). The CSAPR addresses the ''good neighbor'' provision of the Clean Air Act (CAA or Act) that requires states to reduce the transport of pollution that significantly affects downwind air quality. In this final action EPA is approving Nebraska's SIP revision, incorporating the state-determined allocations for the 2016 control periods into the SIP, and amending the regulatory text of the CSAPR Federal Implementation Plan (FIP) to reflect this approval and inclusion of the state-determined allocations. EPA is taking direct final action to approve Nebraska's SIP revision because it meets the requirements of the CAA and the CSAPR requirements to replace EPA's allowance allocations for the 2016 control periods. This action is being taken pursuant to the CAA and its implementing regulations. EPA's allocations of CSAPR trading program allowances for Nebraska for control periods in 2017 and beyond remain in place until the State submits and EPA approves state-determined allocations for those control periods through another SIP. The CSAPR FIPs for Nebraska remain in place until such time as the State decides to replace the FIPs with a SIP revision.

DATES: This direct final rule will be effective October 26, 2015, without further notice, unless EPA receives adverse comment by October 15, 2015. If EPA receives adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0565, by one of the following methods:

1. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

2. *Email: Kemp.lachala@epa.gov*.

3. *Mail or Hand Delivery:* Lachala Kemp, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2015–0565. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or at the Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. The Regional Office's official hours of business are Monday through Friday, 8:00 to 4:30 excluding legal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Lachala Kemp, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7214 or by email at *Kemp.lachalasa@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following:

I. What is being addressed in this document?

EPA is taking direct final action to approve revisions to the SIP submitted by the State of Nebraska in a letter dated March 30, 2015, that modifies the allocations of allowances established by EPA under the CSAPR FIPs for existing EGUs for the 2016 control periods.[1] The CSAPR allows a subject state, instead of EPA, to allocate allowances under the SO_2 annual, NO_X annual, and NO_X ozone season trading programs to existing EGUs in the State for the 2016 control periods provided that the state meets certain regulatory requirements.[2] EPA issued the CSAPR on August 8, 2011, to address CAA section 110(a)(2)(D)(i)(I) requirements concerning the interstate transport of air pollution and to replace the Clean Air Interstate Rule[3] (CAIR), which the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) remanded to EPA for replacement.[4] EPA found that emissions of SO_2 and NO_X in 28 eastern, midwestern, and southern states[5] contribute significantly to nonattainment or interfere with maintenance in one or more downwind states with respect to one or more of three air quality standards—the annual $PM_{2.5}$ NAAQS promulgated in 1997[6] (15 micrograms per cubic meter ($\mu g/m^3$)), the 24-hour $PM_{2.5}$ NAAQS promulgated

[1] Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals; August 8, 2011 (76 FR 48208).

[2] The CSAPR is implemented in two Phases (I and II) with Phase I referring to 2015 and 2016 control periods, and Phase II consisting of 2017 and beyond control periods.

[3] Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; May 12, 2005 (70 FR 25162).

[4] *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), *modified on reh'g,* 550 F.3d 1176 (D.C. Cir. 2008).

[5] The CSAPR obligations related to ozone-season NO_X emissions for five states were established in a separate rule referred to here as the Supplemental Rule. Federal Implementation Plans for Iowa, Michigan, Missouri, Oklahoma, and Wisconsin and Determination for Kansas Regarding Interstate Transport of Ozone; December 27, 2011 (76 FR 80760).

[6] National Ambient Air Quality Standards for Particulate Matter; July 18, 1997 (62 FR 36852).

in 2006[7] (35 μg/m^3), and the 8-hour ozone NAAQS promulgated in 1997[8] (0.08 parts per million). The CSAPR identified emission reduction responsibilities of upwind states, and also promulgated enforceable FIPs to achieve the required emission reductions in each of these states through cost effective and flexible requirements for power plants.

Nebraska is subject to the FIPs that implement the CSAPR and require certain EGUs to participate in the EPA-administered federal SO_2 annual and NO_X annual cap-and trade programs.[9] Nebraska's March 30, 2015, SIP revision allocates allowances under the CSAPR to existing EGUs in the State for the 2016 control periods only. Nebraska's SIP revision includes state-determined allocations for the CSAPR NO_X annual and SO_2 Group 2 annual trading programs, and complies with the 2016 NO_X allocation and SO_2 allocation SIP requirements set forth at 40 CFR 52.38 and 52.39, respectively. Pursuant to these regulations, a state may replace EPA's CSAPR allowance allocations for existing EGUs for the 2016 control periods provided that the state submits a timely SIP revision containing those allocations to EPA that meets the requirements in 40 CFR 52.38 and 52.39.

Through this action, EPA is approving Nebraska's March 30, 2015, SIP revision, incorporating the allocations into the SIP, and amending the CSAPR FIP's regulatory text for Nebraska at 40 CFR 52.1428 and 52.1429 to reflect this approval and inclusion of the state-determined allowance allocations for the 2016 control periods. EPA's allocations of CSAPR trading program allowances for Nebraska for control periods in 2017 and beyond remain in place until the State submits and EPA approves state-determined allocations for those control periods through another SIP revision. EPA is not making any other changes to the CSAPR FIPs for Nebraska in this action. The CSAPR FIPs for Nebraska remain in place until such time the State decides to replace the FIPs with a SIP revision. EPA is taking direct final action to approve Nebraska's March 30, 2015, SIP submission because it complies with the CAA and the CSAPR regulations. Below is a summary of the provisions allowing a state to submit SIP revisions to EPA to modify the 2016 allowance allocations. For more detailed information on the CSAPR, refer to the August 8, 2011, preamble and other subsequent related rulemakings referenced throughout this rulemaking.

II. 2016 CSAPR SIPs

The CSAPR allows states to determine allowance allocations for the 2016 control periods through submittal of a complete SIP revision that is narrower in scope than an abbreviated or full SIP submission that states may use to replace the FIPs and/or to determine allocations for control periods in 2017 and beyond. Pursuant to the CSAPR, a state may adopt and include in a SIP revision for the 2016 control period a list of units and the amount of allowances allocated to each unit on the list, provided the list of units and the allocations meet specific requirements set forth in 40 CFR 52.38(a)(3) and (b)(3) for NO_X and 52.39(d) and (g) for SO_2. If these requirements are met, the Administrator will approve the allowance allocation provisions as replacing the comparable provisions in 40 CFR part 97 for the State. SIP revisions under this expedited process may only allocate the amount of each state budget minus the new unit set-aside and the Indian country new unit set-aside. For states subject to multiple trading programs, options are available to submit 2016 state-determined allocations for one or more of the applicable trading programs while leaving unchanged the EPA-determined allocations for 2016 in the remaining applicable trading programs.[10]

In developing this procedure, EPA set deadlines for submitting the SIP revisions for 2016 allocations and for recordation of the allocations that balanced the need to record allowances sufficiently ahead of the control periods with the desire to allow state flexibility for 2016 control periods. These deadlines allow sufficient time for EPA to review and approve these SIP revisions, taking into account that EPA approval must be final and effective before the 2016 allocations can be recorded and the allowances are available for trading. The CSAPR, as revised, set a deadline of October 17, 2011 or March 6, 2015 (in the case of allocations of ozone season NO_X allowances for states covered by the Supplemental Rule) for states to notify EPA of their intent to submit these SIP revisions.[11] *See* 40 CFR 52.38 and 52.39.

Twelve states, including Nebraska, notified EPA by the applicable deadlines of their intentions to submit SIP revisions affecting 2016 allocations.[12] Pursuant to EPA's December 3, 2014, Interim Final Rule,[13] the deadlines to submit these SIPs were delayed by three years, making the deadline for these twelve states to submit a 2016 allocation SIP revision April 1, 2015, or October 1, 2015, (in the case of allocations of ozone season NO_X allowances for states covered by the Supplemental Rule). Each state may submit a SIP to allocate allowances for the 2016 control periods provided it meets the following requirements pursuant to 40 CFR 52.38 and 52.39:

- Notify the EPA Administrator by October 17, 2011 or March 6, 2015 (in the case of allocations of ozone season NO_X allowances for states covered by the Supplemental Rule) of intent to submit state allocations for the 2016 control periods in a format specified by the Administrator. *See* 40 CFR 52.38(a)(3)(v)(A), 52.38(b)(3)(v)(A), 52.39(d)(5)(i), and 52.39(g)(5)(i).
- Submit to EPA the SIP revision modifying allowance allocations for the 2016 control periods no later than April 1, 2015, or October 1, 2015 (in the case of allocations of ozone season NO_X allowances for states covered by the Supplemental Rule). *See* 40 CFR 52.38(a)(3)(v)(B), 52.38(b)(3)(v)(B), 52.39(d)(5)(ii), and 52.39(g)(5)(ii).
- Provide 2016 state-determined allocations only for units within the State that commenced commercial operation before January 1, 2010. *See* 40 CFR 52.38(a)(3)(i), 52.38(b)(3)(i), 52.39(d)(1), and 52.39(g)(1).
- Ensure that the sum of the state-determined allocations is equal to or less than the amount of the total state budget for 2016 minus the sum of the

[7] National Ambient Air Quality Standards for Particulate Matter; October 17, 2006 (71 FR 61144).

[8] National Ambient Air Quality Standards for Ozone; July 18, 1997 (62 FR 38856).

[9] On July 28, 2015, the D.C. Circuit, issued an opinion upholding CSAPR, but remanding without vacatur certain state emissions budgets to EPA for reconsideration. *EME Homer City Generation, L.P.* v. *EPA,* No. 11–1302, slip op. CSAPR implementation at this time remains unaffected by the court decision, and EPA will address the remanded emissions budgets in a separate rulemaking. Moreover, Nebraska's emissions budgets were not among those remanded to EPA for reconsideration.

[10] States can also submit SIP revisions to replace EPA-determined, existing-unit allocations with state-determined allocations for control periods after 2016 via a separate process described at 40 CFR 52.38(a)(4), (a)(5), (b)(4), and (b)(5) and 52.39(e), (f), (h), and (i).

[11] For the five states (Iowa, Michigan, Missouri, Oklahoma, and Wisconsin) covered in the Supplemental Rule in the case of ozone season NO_X, March 6, 2012, was originally the date by which notifications of intentions to submit state allocations were due to the Administrator, but that date was later delayed to March 6, 2015. *See* 76 FR 80760 and 79 FR 71671.

[12] The docket for today's action contains Nebraska's October 17, 2011, letter notifying EPA of its intention to submit a SIP revision with respect to allocations of both annual NO_X allowances and annual SO_2 allowances.

[13] Rulemaking to Amend Dates in Federal Implementation Plans Addressing Interstate Transport of Ozone and Fine Particulate Matter; December 3, 2014 (79 FR 71663).

new unit set-aside and the Indian country new unit set-aside. *See* 40 CFR 52.38(a)(3)(ii), 52.38(b)(3)(ii), 52.39(d)(2), and 52.39(g)(2).

- Submit the list of units and the 2016 state-determined allowance allocations as a SIP revision electronically to EPA in the format specified by the Administrator. *See* 40 CFR 52.38(a)(3)(iii), 52.38(b)(3)(iii), 52.39(d)(3), and 52.39(g)(3).
- Confirm that the SIP revision does not provide for any changes to the listed units or allocations after approval of the SIP revision by EPA and does not provide for any change to any allocation determined and recorded by the Administrator under subpart AAAAA, BBBBB, CCCCC, or DDDDD of 40 CFR part 97. *See* 40 CFR 52.38(a)(3)(iv), 52.38(b)(3)(iv), 52.39(d)(4), and 52.39(g)(4).

Additionally, these limited SIP revisions for the 2016 state-determined allocations are required to comply with SIP completeness elements set forth in 40 CFR part 51, appendix V (*i.e.,* conduct adequate public notice of the submission, provide evidence of legal authority to adopt SIP revisions, and ensure that the SIP is submitted to EPA by the State's Governor or his/her designee). If a state submits to EPA a 2016 CSAPR SIP revision meeting all the above-described requirements, including compliance with the applicable notification and submission deadlines, and EPA approves the SIP submission by October 1, 2015 (or April 1, 2016, in the case of allocations of ozone season NO_X allowances for states covered by the Supplemental Rule), EPA will record state-determined allocations for 2016 by October 1, 2015 (or April 1, 2016) into the Allowance Management System (AMS). Nebraska's March 30, 2015 SIP submission addresses the aforementioned requirements allowing a state to allocate 2016 CSAPR allowances for the annual NO_X and Group 2 SO_2 trading programs. EPA's analysis of Nebraska's SIP submission is explained below in section III.

III. What is EPA's analysis of Nebraska's SIP submission?

On March 30, 2015, Nebraska submitted a SIP revision intended to replace the CSAPR FIP allocations of the CSAPR NO_X annual and SO_2 Group 2 allowances for the 2016 control periods. For approval, this SIP revision must meet the specific requirements found in 40 CFR 52.38(a)(3) and 52.39(g) described above. The following is a list of criteria under 40 CFR 52.38(a)(3) and (b)(3) and 52.39(d) and (g), described in section II in this document, and the results of EPA's analysis of Nebraska's SIP revision:

A. Notification from a State to EPA must be received by October 17, 2011, or March 6, 2015, in the case of ozone season NO_X SIP revisions for states covered by the December 27, 2011 Supplemental Rule (76 FR 80760), of its intent to submit a complete SIP revision for 2016 existing unit allocations (40 CFR 52.38(a)(3)(v)(A), 52.38(b)(3)(v)(A), 52.39(d)(5)(i), and 52.39(g)(5)(i)).

On October 17, 2011, Nebraska notified EPA via a letter of the State's intent to submit complete SIP revisions for allocating TR NO_X Annual and TR SO_2 Group 2 allowances [14] to existing units (*i.e.,* units that commenced commercial operation before January 1, 2010) for the second implementation year of the CSAPR trading programs.

B. A complete SIP revision must be submitted to EPA no later than April 1, 2015, or October 1, 2015, in the case of ozone season NO_X SIP revisions for states covered by the December 27, 2011 Supplemental Rule (76 FR 80760) (40 CFR 52.38(a)(3)(v)(B), 52.38(b)(3)(v)(B), 52.39(d)(5)(ii), and 52.39(g)(5)(ii)).

EPA has reviewed the March 30, 2015 submittal from Nebraska and found it to be complete. This submittal satisfies the applicable elements of SIP completeness set forth in appendix V to 40 CFR part 51.

C. The SIP revision should include a list of TR NO_X Annual, TR NO_X Ozone Season, TR SO_2 Group 1 or Group 2 units, whichever is applicable, that are in the State and commenced commercial operation before January 1, 2010 (40 CFR 52.38(a)(3)(i), 52.38(b)(3)(i), 52.39(d)(1), and 52.39(g)(1)).

As part of Nebraska's SIP revision, the State submitted a list of units to be allocated TR NO_X Annual and TR SO_2 Group allowances for the 2016 control periods. The list identifies the same units as were identified in the notice of data availability (NODA) published by EPA on December 3, 2014 (79 FR 71674). Hence, EPA has determined that each unit on the list submitted by Nebraska as part of the SIP revision is located in the State of Nebraska and had commenced commercial operation before January 1, 2010.

D. The total amount of TR NO_X Annual, TR NO_X Ozone Season, or TR SO_2 Group 1 or Group 2 allowance allocations, whichever is applicable, must not exceed the amount, under 40 CFR 97.410(a), 97.510(a), 97.610(a), or 97.710(a), whichever is applicable, for the State and the control periods in 2016, of the TR NO_X Annual, TR NO_X Ozone Season, TR SO_2 Group 1 or Group 2 trading budget minus the sum of the new unit set-aside and Indian country new unit set-aside (40 CFR 52.38(a)(3)(ii), 52.38(b)(3)(ii), 52.39(d)(2), and 52.39(g)(2)).

As amended, the CSAPR established the NO_X annual budget, new unit set-aside, and Indian country new unit set-aside for Nebraska for the 2016 control periods as 30,039 tons, 1,772 tons, and 30 tons, respectively, and established the SO_2 Group 2 budget, new unit set-aside, and Indian country new unit set-aside as 68,162 tons, 2,658 tons, and 68 tons, respectively. Nebraska's SIP revision, for approval in this action, does not affect these budgets, which are total amounts of allowances available for allocation for the 2016 control periods under the EPA-administered cap-and-trade programs under the CSAPR FIPs. In short, the abbreviated SIP revision only affects allocations of allowances under the established state budgets.

The Nebraska SIP revision allocating TR NO_X Annual allowances for the 2016 control period establishes allocations exceeding, by one (1) allowance due to rounding,[15] the amount of the budget under § 97.410(a) minus the sum of the new unit set-aside and the Indian county new unit set aside (30,039 tons − (1,772 tons + 30 tons)) = 28,237 tons). The Nebraska SIP revision allocates 28,238 TR NO_X annual allowances to existing units in the State. However, EPA notes that proportionately, one allowance is a tiny fraction of the overall new unit set-aside budget for new TR NO_X annual units in Nebraska (approximately 0.06%). In addition, for 2015, the number of TR NO_X annual allowances allocated from Nebraska's 2015 new unit set-aside to new units is well below the total number of allowances available in that set-aside,[16] and it appears highly likely this will be the case again in 2016. EPA therefore does not believe the extra allowance allocated to Nebraska's existing CSAPR units in 2016 should weigh negatively in EPA's evaluation of the State's 2016 CSAPR SIP submittal, and will enter 1,771 allowances from the Nebraska CSAPR 2016 budget

[14] The abbreviation ''TR'' in certain legal terms used in the CSAPR trading programs, including the legal terms for the trading program allowances, stands for ''Transport Rule,'' an earlier name for the CSAPR.

[15] The total of the state-determined TR NO_X Annual allowance allocations to existing units for 2016 under Nebraska's SIP revision (28,238 allowances) equals the total of the EPA-determined TR NO_X Annual allowance allocations to existing units for 2016 under the CSAPR as amended. This total differs by one allowance from the amount of the state's 2016 NO_X annual budget minus the sum of the new unit set-aside and the Indian country new unit set-aside due to rounding, as noted in the December 3, 2014, Notice of Data Availability regarding the EPA-determined allocations. *See* 79 FR 71674.

[16] *See* Allocations of Cross-State Air Pollution Rule Allowances From New Unit Set-Asides for the 2015 Compliance Year; July 28, 2015 (80 FR 44882).

(instead of 1,772 allowances) into the TR NO_X annual new unit set-aside for the 2016 control period.[17]

The Nebraska SIP revision allocating TR SO_2 Group 2 allowances for the 2016 control period does not establish allocations exceeding the amount of the budget under § 97.710(a) minus the sum of the new unit set-aside and Indian County new unit set-aside (68,162 tons − (2,658 tons + 68 tons)) = 65,436 tons). The Nebraska SIP revision allocates 65,432 TR SO_2 Group 2 allowances to existing units in the State. EPA will place the four unallocated allowances from the Nebraska CSAPR 2016 budget into the TR SO_2 Group 2 new unit set-aside for the 2016 control period.

E. The list should be submitted electronically in the format specified by the EPA (40 CFR 52.38(a)(3)(iii), 52.38(b)(3)(iii), 52.39(d)(3), and 52.39(g)(3)).

On March 30, 2015, EPA received an email submittal from Nebraska in the EPA-approved format.

F. The SIP revision should not provide for any changes to the listed units or allocations after approval of the SIP revision and should not provide for any change to any allocation determined and recorded by the Administrator under subpart AAAAA, BBBBB, CCCCC, or DDDDD of 40 CFR part 97 (40 CFR 52.38(a)(3)(iv), 52.38(b)(3)(iv), 52.39(d)(4), and 52.39(g)(4)).

The Nebraska SIP revision does not provide for any changes to the listed units or allocations after approval of the SIP revision and does not provide for any change to any allocation determined and recorded by the Administrator under subpart AAAAA, BBBBB, CCCCC, or DDDDD of 40 CFR part 97.

For the reasons discussed above, Nebraska's SIP revision complies with the 2016 allowance allocation SIP requirements established in the CSAPR FIPs as codified at 40 CFR 52.38 and 52.39. Through this action, EPA is approving Nebraska's March 30, 2015, SIP revision, incorporating the allocations into the SIP, and amending the CSAPR FIPs' regulatory text for Nebraska at 40 CFR 52.1428 and 52.1429 to reflect this approval and inclusion of the state-determined allowance allocations for the 2016 control periods. EPA is not making any other changes to the CSAPR FIPs for Nebraska in this action. EPA is taking final action to approve Nebraska's March 30, 2015, SIP revision because it is in accordance with the CAA and its implementing regulations.

[17] The quantities of allowances to be allocated through the new unit set-aside (NUSA) process may differ slightly from the NUSA amounts set forth in 40 CFR 97.410(a), 97.510(a), 97.610(a), and 97.710(a) because of rounding in the spreadsheet of CSAPR FIP allowance allocations to existing units.

IV. Final Action

EPA is taking final action to approve Nebraska's March 30, 2015, CSAPR SIP revisions that provide Nebraska's state-determined allowance allocations for existing EGUs in the State for the 2016 control periods to replace the allowance allocations for the 2016 control periods established by EPA under the CSAPR. Consistent with the flexibility given to states in the CSAPR FIPs at 40 CFR 52.38 and 52.39, Nebraska's SIP revision allocates allowances to existing EGUs in the State under the CSAPR's NO_X annual and SO_2 Group 2 trading programs. Nebraska's SIP revision meets the applicable requirements in 40 CFR 52.38 and 52.39 for allocations for the 2016 control periods of NO_X annual allowances and SO_2 Group 2 allowances, respectively. EPA is approving Nebraska's SIP revision because it is in accordance with the CAA and its implementing regulations.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective October 26, 2015 without further notice unless the Agency receives adverse comments by October 15, 2015. If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on October 26, 2015 and no further action will be taken on the proposed rule.

Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other

required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 16, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 12, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart CC—Nebraska

■ 2. In § 52.1420(e) the table is amended by adding a new entry (28) at the end of the table to read as follows:

§ 52.1420 Identification of Plan.

* * * * *

(e) * * *

EPA-APPROVED NEBRASKA NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic area or nonattainment area	State submittal date	EPA approval date	Explanation
*	* *		* *	* *
(28) Cross State Air Pollution Rule—State-Determined Allowance Allocations for the 2016 control periods.	Statewide	3/30/15	9/15/15 [Insert **Federal Register** citation].	

■ 3. Section 52.1428 is amended by adding paragraph (c) to read as follows:

§ 52.1428 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(c) Pursuant to § 52.38(a)(3), Nebraska's state-determined TR NO_X Annual allowance allocations established in the March 30, 2015, SIP revision replace the unit-level TR NO_X Annual allowance allocation provisions of the TR NO_X Annual Trading Program at 40 CFR 97.411(a) for the State for the 2016 control period with a list of TR NO_X Annual units that commenced operation prior to January 1, 2010, in the State and the state-determined amount of TR NO_X Annual allowances allocated to each unit on such list for the 2016 control period, as approved by EPA on September 15, 2015.

■ 4. Section 52.1429 is amended by adding paragraph (c) to read as follows:

§ 52.1429 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of sulfur dioxide?

* * * * *

(c) Pursuant to § 52.39(g), Nebraska's state-determined TR SO_2 Group 2 allowance allocations established in the March 30, 2015, SIP revision replace the unit-level TR SO_2 Group 2 allowance allocation provisions of the TR SO_2 Group 2 Trading Program at 40 CFR 97.711(a) for the State for the 2016 control period with a list of TR SO_2 Group 2 units that commenced operation prior to January 1, 2010, in the State and the state-determined amount of TR SO_2 Group 2 allowances allocated to each unit on such list for the 2016 control period, as approved by EPA on September 15, 2015.

[FR Doc. 2015–20631 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 80, No. 178
Tuesday, September 15, 2015

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3630; Directorate Identifier 2014–NM–253–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 747–400F series airplanes. This proposed AD was prompted by an analysis of the production methods used to increase fatigue resistance of the upper closure fittings at the nose cargo door portal's C–3 frame, which indicated that cracking could start too early to be caught in a timely manner by the inspection or maintenance program. This proposed AD would require inspections of the upper closure fitting and connected strap and doubler at the nose cargo door portal for cracking, and related investigative and corrective actions if necessary. We are proposing this AD to detect and correct such cracking, which could result in sudden decompression and loss of the airplane's structural integrity.

DATES: We must receive comments on this proposed AD by October 30, 2015.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal*: Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3630.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3630; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Bill Ashforth, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6432; fax: 425–917–6590; email: *bill.ashforth@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–3630; Directorate Identifier 2014–NM–253–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received a report indicating that an analysis of the production methods used to increase fatigue resistance of the upper closure fittings at the nose cargo door portal's C–3 frame showed that cracking could start too early to be caught in a timely manner by the inspection or maintenance program. The upper closure fittings used in the nose cargo door portal C–3 frame were shot peened to increase fatigue resistance. However, an analysis showed that the increase in fatigue resistance was still not enough to ensure that cracking would be caught by the inspection program specified in the Boeing 747–400 maintenance planning data (MPD) document. This condition, if not detected and corrected, could result in sudden decompression and loss of the airplane's structural integrity.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014. This service information describes procedures for a detailed inspection of the upper closure fitting and connected strap and doubler, a surface high frequency eddy current (HFEC) inspection of the upper closure fitting for cracking, and related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the Service Information.'' Refer to this service information for information on the procedures and compliance times. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3630.

The phrase ''related investigative actions'' is used in this proposed AD. ''Related investigative actions'' are follow-on actions that (1) are related to the primary actions, and (2) further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

The phrase ''corrective actions'' is used in this proposed AD. ''Corrective actions'' are actions that correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Differences Between This Proposed AD and the Service Information

Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 38 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	9 work-hours × $85 per hour = $765 per inspection cycle.	$0	$765 per inspection cycle.	$29,070 per inspection cycle.

We estimate the following costs to do any necessary repairs or replacements that would be required based on the results of the proposed inspection. Parts costs could be up to $42,930 per airplane. We have no way of determining the number of work hours (because the type of repair will vary depending on findings) or the number of aircraft that might need the repairs or replacements.

Explanation of ''RC'' Steps in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which steps in the service information are required for compliance with an AD. Differentiating these steps from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The steps identified as Required for Compliance (RC) in any service information identified previously have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

For service information that contains steps that are labeled as RC, the following provisions apply: (1) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD, and an AMOC is required for any deviations to RC steps, including substeps and identified figures; and (2) steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2015–3630; Directorate Identifier 2014–NM–253–AD.

(a) Comments Due Date

We must receive comments by October 30, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 747–400F series airplanes, certificated in any category, as identified in paragraph 1.A., ''Effectivity,'' of Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report that an analysis of the production methods used to increase fatigue resistance of the upper closure fittings at the nose cargo door portal's C–3 frame showed that cracking could still start too early to be caught in a timely manner by the inspection or maintenance program. We are issuing this AD to detect and correct such cracking, which could result in sudden decompression and loss of the airplane's structural integrity.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspections and Corrective Actions

Except as required by paragraph (h) of this AD, at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014: Do a detailed inspection of the upper closure fitting, strap, and doubler and a surface high frequency eddy current (HFEC) inspection of the upper closure fitting at the nose cargo door portal for cracking, and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014. Repeat the inspections at the time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014. Do the applicable investigative and corrective actions at the times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014.

(h) Exceptions to the Service Information

(1) Where paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014, refers to a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specific compliance time after the effective date of this AD.

(2) If any crack is found during any inspection required by this AD, and Boeing Alert Service Bulletin 747–53A2880, dated December 3, 2014, specifies to contact Boeing for appropriate action: Before further flight, repair the cracking using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (h)(2) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(4)(i) and (i)(4)(ii) apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

(1) For more information about this AD, contact Bill Ashforth, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6432; fax: 425–917–6590; email: *bill.ashforth@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on September 2, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–22926 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–1834; Airspace Docket No. 15–AGL–8]

Proposed Revocation and Establishment of Class E Airspace; Bowman, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Bowman, ND. Controlled airspace is necessary to accommodate new Standard Instrument Approach Procedures at Bowman Regional Airport, for the safety and management of Instrument Flight Rules (IFR) operations. Class E airspace would be removed at Bowman Municipal Airport, Bowman, ND, due to closure of the air traffic control tower.

DATES: Comments must be received on or before October 30, 2015.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, telephone (202) 366–9826. You must identify the docket number FAA–2015–1834; Airspace Docket No. 15–AGL–8, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_offederal-regulations/ibr_locations.html.*

FAA order 7400.9, Airspace Designations and Reporting Points is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone: 817–868–2914.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend controlled airspace for the Bowman, ND, area.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2015–1834/Airspace Docket No. 15–AGL–8.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), Part 71 by establishing Class E airspace extending upward from 700 feet above the surface within a 6.0-mile radius of Bowman Regional Airport, Bowman, ND, to accommodate new standard instrument approach procedures. Controlled airspace is needed for the safety and management of IFR operations at the airport. This action also would remove Class E airspace extending upward from 700 feet above the surface at Bowman Municipal Airport, Bowman, ND. The closing of the air traffic control tower at Bowman Municipal Airport has made this action necessary for continued safety within the NAS.

Class E airspace areas are published in Paragraph 6005 of FAA Order 7400.9Y, dated August 6, 2014, and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal.

Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

AGL ND E5 Bowman, ND [New]

Bowman Regional Airport, ND
(Lat. 46°09′56″ N., long. 103°18′03″ W.)

That airspace extending upward from 700 feet above the surface within a 6.0-mile radius of Bowman Regional Airport.

AGL ND E5 Bowman, ND [Removed]

Bowman Municipal Airport, ND

Issued in Fort Worth, TX, on August 27, 2015.

Robert W. Beck,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2015–22972 Filed 9–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2015–0671]

RIN 1625–AA08

Special Local Regulation, Tennessee River, Mile 255.0 to 256.5; Florence, AL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a special local regulation for all waters of the Tennessee River, beginning at mile marker 255.0 and ending at mile marker 256.5 on October 3, 2015 from 8:00 a.m. until 5:00 p.m. This proposed special regulation is necessary to provide safety for the participants in the ''Shoals Dragon Boat Festival,'' an event which will involve non-high speed boat races. Entry into this area will be prohibited unless specifically authorized by the Captain of the Port Ohio Valley or designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before September 22, 2015.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

(1) Federal eRulemaking Portal: *http://www.regulations.gov.*

(2) Fax: 202–493–2251.

(3) Mail or Delivery: Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Vera Max, MSD Nashville, Nashville, TN, at 615–736–5421 or at *vera.m.max@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number (USCG–2015–0671) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2015–0671) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not plan to hold a public meeting. But you may submit a request for one, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Basis and Purpose

The Kilby Laboratory School PTO is holding the ''Shoals Dragon Boat Festival'' on October 3, 2015. This event

is planned to take place at McFarland Park on the waters of the Tennessee River mile marker 255.0 through mile marker 256.5, at Florence, AL. The Captain of the Port Ohio Valley has determined that additional safety measures are necessary to protect participants, spectators, and waterway users during this event. Therefore, the Coast Guard proposes to establish a special local regulation on specified waters of the Tennessee River. This proposed regulation would be in effect on October 3, 2015 from 8:00 a.m. until 5:00 p.m.

The legal basis and authorities for this proposed rulemaking establishing a special local regulation are found in 33 U.S.C. 1233, which authorizes the Coast Guard to establish and define special local regulations for regattas under 33 CFR part 100.

C. Discussion of Proposed Rule

The Captain of the Port Ohio Valley is proposing to establish a special local regulated area for all waters of the Tennessee River beginning at mile marker 255.0 and ending at mile marker 256.5. Vessels or persons would not be able to enter into, depart from, or move within this area without permission from the Captain of the Port Ohio Valley or designated representative. Persons or vessels requiring entry into or passage through the proposed special local regulated area will be required to request permission from the Captain of the Port Ohio Valley, or designated representative. They could be contacted on VHF–FM Channel 13 or 16, or through Coast Guard Sector Ohio Valley at 1–800–253–7465. This proposed rule would be effective from 8:00 a.m. until 5:00 p.m. on October 3, 2015. The Captain of the Port Ohio Valley would inform the public through broadcast notices to mariners of the enforcement period for the special local regulated area as well if any changes in the planned schedule.

E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders.

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This proposed special local regulation restricts transit on the Tennessee River from mile marker 255.0 to mile marker 256.5, for a short duration of nine hours; Broadcast Notices to Mariners and Local Notices to Mariners will also inform the community of this special local regulation so that they may plan accordingly for this short restriction on transit. Vessel traffic may request permission from the COTP Ohio Valley or a designated representative to enter the restricted area.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit mile marker 255.0 to mile marker 256.5 on the Tennessee River, from 8:00 a.m. to 5:00 p.m. on October 3, 2015. This proposed special local regulated area will not have a significant economic impact on a substantial number of small entities as it will be enforced for a short period of time. Additionally, although the proposed special local regulated area will apply to the entire width of the river, traffic will be allowed to pass through the area with the permission of the Captain of the Port Ohio Valley or designated representative. Broadcast Notices to Mariners will also inform the community of this special local regulation so that they may plan accordingly for temporary restrictions on transit.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such expenditures, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the Captain of the Port Ohio Valley establishing a special local regulation for all waters of the Tennessee River beginning at mile marker 255.0 and ending at mile marker 256.5 to provide safety for the participants of the ''Shoals Dragon Boat Festival.'' This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the U.S. Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERWAYS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. A new special local regulation 100.801T01–0671 is added to read as follows:

§ 100.801T01–0671 Special Local Regulation; Tennessee River Mile 255.0 to River Mile 256.5, Florence, AL.

(a) *Location.* All waters of the Tennessee River beginning at mile marker 255.0 and ending at mile marker 256.5 at Florence, AL.

(b) *Periods of enforcement.* This proposed rule will be enforced from 8:00 a.m. to 5:00 p.m. on October 3, 2015. The Captain of the Port Ohio Valley or a designated representative will inform the public through broadcast notice to mariners of the enforcement period for the special local regulation.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.801 of this part, entry into this area is prohibited unless authorized by the Captain of the Port Ohio Valley or a designated representative.

(2) Persons or vessels requiring entry into or passage through the area must request permission from the Captain of the Port Ohio Valley or a designated representative. U.S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Ohio Valley and designated U.S. Coast Guard patrol personnel. On-scene U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

Dated: August 13, 2015.

R.V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2015–23169 Filed 9–14–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0565; FRL–9932–85–Region 7]

Approval and Promulgation of Air Quality Implementation Plans; State of Nebraska; Cross-State Air Pollution Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the State Implementation Plan (SIP) submitted by the State of Nebraska in a letter dated March 30, 2015. This SIP revision provides Nebraska's state-determined allowance allocations for existing electric generating units (EGUs) in the State for the 2016 control periods and replaces the allowance allocations for the 2016 control periods established by EPA under the Cross-State Air Pollution Rule (CSAPR). The CSAPR addresses the ''good neighbor'' provision of the Clean Air Act (CAA or Act) that requires states to reduce the transport of pollution that significantly affects downwind air quality. In this action EPA is proposing approval of Nebraska's SIP revision, incorporating the state-determined allocations for the 2016 control periods into the SIP, and amending the regulatory text of the CSAPR Federal

Implementation Plan (FIP) to reflect this approval and inclusion of the state-determined allocations. EPA is proposing to approve Nebraska's SIP revision because it meets the requirements of the CAA and the CSAPR requirements to replace EPA's allowance allocations for the 2016 control periods. This action is being proposed pursuant to the CAA and its implementing regulations. EPA's allocations of CSAPR trading program allowances for Nebraska for control periods in 2017 and beyond remain in place until the State submits and EPA approves state-determined allocations for those control periods through another SIP. The CSAPR FIPs for Nebraska remain in place until such time as the State decides to replace the FIPs with a SIP revision.

DATES: Comments on this proposed action must be received in writing by October 15, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0565, by mail to Lachala Kemp, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Lachala Kemp, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7214 or by email at *kemp.lachala@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxides.

Dated: August 12, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

[FR Doc. 2015–20630 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2015–0600: FRL–9934–07–Region 10]

Approval and Promulgation of Implementation Plans; Washington: Additional Regulations for the Benton Clean Air Agency Jurisdiction

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Washington State Implementation Plan (SIP) that were submitted by the Department of Ecology (Ecology) in coordination with Benton Clean Air Agency (BCAA) on August 25, 2015. In the fall of 2014 and spring of 2015, the EPA approved numerous revisions to Ecology's general air quality regulations. However, our approval of the updated Ecology regulations applied only to geographic areas where Ecology, and not a local air authority, has jurisdiction, and statewide to source categories over which Ecology has sole jurisdiction. Under the Washington Clean Air Act local clean air agencies, such as BCAA, have the option of adopting equally stringent or more stringent standards or requirements in lieu of Ecology's general air quality regulations, if they so choose. Therefore, the EPA stated that we would evaluate the general air quality regulations as they apply to local jurisdictions in separate, future actions. If finalized, this proposed action would allow BCAA to rely primarily on Ecology's general air quality regulations for sources within BCAA's jurisdiction, including implementation of the minor new source review and nonattainment new source review permitting programs. This action also proposes approval of a small set of BCAA regulatory provisions that replace or supplement parts of Ecology's general air quality regulations.

DATES: Comments must be received on or before October 15, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2015–0600, by any of the following methods:

A. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

B. *Mail:* Jeff Hunt, EPA Region 10, Office of Air, Waste and Toxics (AWT–150), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101.

C. *Email: R10-Public_Comments@epa.gov.*

D. *Hand Delivery:* EPA Region 10 Mailroom, 9th Floor, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. Attention: Jeff Hunt, Office of Air, Waste and Toxics, AWT–150. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R10–OAR–2015–0600. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider

your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Office of Air, Waste and Toxics, EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt at (206) 553–0256, *hunt.jeff@epa.gov,* or by using the above EPA, Region 10 address.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we'', ''us'' or ''our'' are used, it is intended to refer to the EPA.

Table of Contents

I. Background for Proposed Action

On January 27, 2014, Ecology submitted revisions to update the general air quality regulations contained in Chapter 173–400 of the Washington Administrative Code (WAC) that apply to sources under Ecology's direct jurisdiction. On October 3, 2014 (79 FR 59653), November 7, 2014 (79 FR 66291), and April 29, 2015 (80 FR 23721), the EPA approved updates to Chapter 173–400 WAC as they apply to geographic areas and source categories under Ecology's direct jurisdiction. Under the EPA-approved provisions of WAC 173–400–020, local clean air agencies have the authority to adopt equally stringent or more stringent standards or requirements in lieu of the provisions of Chapter 173–400 WAC. Local clean air agencies also have the option to rely on parts of Chapter 173–400 WAC, but substitute local standards or requirements for other corresponding provisions. For this reason, the EPA stated that we would address the applicability of Chapter 173–400 WAC in local clean air agency jurisdictions on a case-by-case basis in separate, future actions.

II. Washington SIP Revisions

On August 25, 2015, the Director of the Washington Department of Ecology, as the Governor's designee for SIP revisions, submitted a request to update the general air quality regulations as they apply to the jurisdiction of BCAA. See 40 CFR 52.2470(c)—Table 4. As shown in *Attachment 1* of the SIP revision, included in the docket for this action, BCAA relies primarily on the recently updated provisions of Chapter 173–400 WAC for sources within their jurisdiction in Benton County, including minor new source review permitting and major source nonattainment new source review (if necessary at some point in the future). *Attachment 2* of the SIP revision contains a small set of BCAA regulations that either supplement or substitute for provisions of Chapter 173–400 WAC that address regulatory authority, definitions of specific terms, and fugitive emissions. These provisions fall in two categories. The first category includes BCAA Regulation 1, sections: 1.01, *Name of Agency;* 2.01, *Powers and Duties of the Benton Clean Air Agency (BCAA);* 2.03, *Powers and Duties of the Board of Directors;* 2.05, *Severability;* and 2.06, *Confidentiality.* These provisions are generally administrative in nature, are adopted nearly verbatim from the Washington Clean Air Act (Revised Code of Washington 70.94), and have no direct corollaries in Chapter 173–400 WAC. The second category includes BCAA Regulation 1, sections: 1.02, *Policy and Purpose;* 1.03, *Applicability;* 2.02, *Requirements for Board of Directors Members;* 4.01(A), *Definitions—Fugitive Dust;* 4.02(B), *Particulate Matter Emissions—Fugitive Emissions;* 4.02(C)(1), *Particulate Matter Emissions—Fugitive Dust;* and 4.02(C)(3), *Particulate Matter Emissions—Fugitive Dust.* This second category of BCAA regulations adopt parts of Chapter 173–400 WAC nearly verbatim with minor changes for readability and clarity. The EPA is proposing to determine that these changes are consistent with our prior approvals of Chapter 173–400 WAC and meet Clean Air Act requirements.

III. The EPA's Proposed Action

A. Regulations To Approve and Incorporate by Reference Into the SIP

The EPA proposes to approve and incorporate by reference into the Washington SIP at 40 CFR 52.2470(c)—Table 4, Additional Regulations Approved for the Benton Clean Air Agency (BCAA) Jurisdiction, the BCAA and Ecology regulations listed in the tables below for sources within BCAA's jurisdiction.

BENTON CLEAN AIR AGENCY (BCAA) REGULATIONS FOR PROPOSED APPROVAL

State/local citation	Title/subject	State/local effective date	Explanation
	Regulation 1		
1.01	Name of Agency	12/11/14	
1.02	Policy and Purpose	12/11/14	Replaces WAC 173–400–010.
1.03	Applicability	12/11/14	Replaces WAC 173–400–020.
4.01(A)	Definitions—Fugitive Dust	12/11/14	Replaces WAC 173–400–030 (38).
4.01(B)	Definitions—Fugitive Emissions	12/11/14	Replaces WAC 173–400–030 (39).
4.02(B)	Particulate Matter Emissions—Fugitive Emissions	12/11/14	Replaces WAC 173–400–040(4).
4.02(C)(1)	Particulate Matter Emissions—Fugitive Dust	12/11/14	Replaces WAC 173–400–040(9)(a).
4.02(C)(3)	Particulate Matter Emissions—Fugitive Dust	12/11/14	Replaces WAC 173–400–040(9)(b).

WASHINGTON STATE DEPARTMENT OF ECOLOGY REGULATIONS FOR PROPOSED APPROVAL

State/local citation	Title/subject	State/local effective date	Explanation
Chapter 173–400 WAC, General Regulations for Air Pollution Sources			
173–400–030	Definitions	12/29/12	Except: 173–400–030(38); 173–400–030(39); 173–400–030(91).
173–400–036	Relocation of Portable Sources	12/29/12	
173–400–040	General Standards for Maximum Emissions.	4/1/11	Except: 173–400–040(2)(c); 173–400–040(2)(d); 173–400–040(3); 173–400–040(4); 173–400–040(5); 173–400–040(7), second paragraph; 173–400–040(9)(a); 173–400–040(9)(b).
173–400–050	Emission Standards for Combustion and Incineration Units.	12/29/12	Except: 173–400–050(2); 173–400–050(4); 173–400–050(5).
173–400–060	Emission Standards for General Process Units.	2/10/05	
173–400–070	Emission Standards for Certain Source Categories.	12/29/12	Except: 173–400–070(7); 173–400–070(8).
173–400–081	Startup and Shutdown	4/1/11	
173–400–091	Voluntary Limits on Emissions	4/1/11	
173–400–105	Records, Monitoring and Reporting.	12/29/12	
173–400–110	New Source Review (NSR) for Sources and Portable Sources.	12/29/12	Except: 173–400–110(1)(c)(ii)(C); 173–400–110(1)(e); 173–400–110(2)(d); —The part of WAC 173–400–110(4)(b)(vi) that says, ''not for use with materials containing toxic air pollutants, as listed in chapter 173–460 WAC,''; —The part of 400–110(4)(e)(iii) that says, ''where toxic air pollutants as defined in chapter 173–460 WAC are not emitted''; —The part of 400–110(4)(e)(f)(i) that says, ''that are not toxic air pollutants listed in chapter 173–460 WAC''; —The part of 400–110(4)(h)(xviii) that says, '', to the extent that toxic air pollutant gases as defined in chapter 173–460 WAC are not emitted''; —The part of 400–110(4)(h)(xxxiii) that says, ''where no toxic air pollutants as listed under chapter 173–460 WAC are emitted''; —The part of 400–110(4)(h)(xxxiv) that says, '', or ≤1% (by weight) toxic air pollutants as listed in chapter 173–460 WAC''; —The part of 400–110(4)(h)(xxxv) that says, ''or ≤1% (by weight) toxic air pollutants''; —The part of 400–110(4)(h)(xxxvi) that says, ''or ≤1% (by weight) toxic air pollutants as listed in chapter 173–460 WAC''; 400–110(4)(h)(xl), second sentence; —The last row of the table in 173–400–110(5)(b) regarding exemption levels for Toxic Air Pollutants.
173–400–111	Processing Notice of Construction Applications for Sources, Stationary Sources and Portable Sources.	12/29/12	Except: 173–400–111(3)(h); —The part of 173–400–111(8)(a)(v) that says, ''and 173–460–040,''; 173–400–111(9).
173–400–112	Requirements for New Sources in Nonattainment Areas—Review for Compliance with Regulations.	12/29/12	Except: 173–400–112(8).
173–400–113	New Sources in Attainment or Unclassifiable Areas—Review for Compliance with Regulations.	12/29/12	Except: 173–400–113(3), second sentence.
173–400–117	Special Protection Requirements for Federal Class I Areas.	12/29/12	Except facilities subject to the applicability provisions of WAC 173–400–700.
173–400–118	Designation of Class I, II, and III Areas.	12/29/12	
173–400–131	Issuance of Emission Reduction Credits.	4/1/11	
173–400–136	Use of Emission Reduction Credits (ERC).	12/29/12	
173–400–151	Retrofit Requirements for Visibility Protection.	2/10/05	
173–400–171	Public Notice and Opportunity for Public Comment.	12/29/12	Except: —The part of 173–400–171(3)(b) that says, ''or any increase in emissions of a toxic air pollutant above the acceptable source impact level for that toxic air pollutant as regulated under chapter 173–460 WAC''; 173–400–171(12).
173–400–175	Public Information	2/10/05	
173–400–200	Creditable Stack Height & Dispersion Techniques.	2/10/05	

WASHINGTON STATE DEPARTMENT OF ECOLOGY REGULATIONS FOR PROPOSED APPROVAL—Continued

State/local citation	Title/subject	State/local effective date	Explanation
173–400–560	General Order of Approval	12/29/12	Except: —The part of 173–400–560(1)(f) that says, ''173–460 WAC''.
173–400–800	Major Stationary Source and Major Modification in a Non-attainment Area.	4/1/11	
173–400–810	Major Stationary Source and Major Modification Definitions.	12/29/12	
173–400–820	Determining if a New Stationary Source or Modification to a Stationary Source is Subject to these Requirements.	12/29/12	
173–400–830	Permitting Requirements	12/29/12	
173–400–840	Emission Offset Requirements	12/29/12	
173–400–850	Actual Emissions Plantwide Applicability Limitation (PAL).	12/29/12	
173–400–860	Public Involvement Procedures	4/1/11	

B. Regulations To Approve But Not Incorporate by Reference

In addition to the regulations proposed for approval and incorporation by reference above, the EPA reviews and approves state and local clean air agency submissions to ensure they provide adequate enforcement authority and other general authority to implement and enforce the SIP. However, regulations describing such agency enforcement and other general authority are generally not incorporated by reference so as to avoid potential conflict with the EPA's independent authorities. The EPA has reviewed and is proposing to approve BCAA, Regulation 1, Article 2, *General Provisions,* as having adequate enforcement and other general authority for purposes of implementing and enforcing its SIP, but is not incorporating this section by reference into the SIP codified in 40 CFR 52.2470(c). Instead, the EPA is proposing to include sections 2.01, *Powers and Duties of the Benton Clean Air Agency (BCAA);* 2.02, *Requirements for Board of Directors Members* (replaces WAC 173–400–220); 2.03, *Powers and Duties of the Board of Directors;* 2.04, *Powers and Duties of the Control Officer;* 2.05, *Severability;* and 2.06, *Confidentiality of Records and Information,* in 40 CFR 52.2470(e), *EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures,* as approved but not incorporated by reference regulatory provisions. Finally, for the reasons discussed above, the EPA is proposing to move WAC 173–400–230, *Regulatory Actions;* WAC 173–400–240, *Criminal Penalties;* WAC 173–400–250, *Appeals;* and WAC 173–400–260, *Conflict of Interest,* currently incorporated by reference in 40 CFR 52.2470(c)—Table 4, to the list of provisions in 40 CFR 52.2470(e) that are approved but not incorporated by reference.

C. Regulations To Remove From the SIP

The regulations contained in Washington's SIP at 40 CFR 52.2470(c)—Table 4 were last approved by the EPA on June 2, 1995 (60 FR 28726). The EPA is proposing to remove from this table WAC 173–400–010 and 173–400–020 because these provisions will be replaced by the BCAA corollaries 1.02, *Policy and Purpose* and 1.03, *Applicability,* as shown in *Attachment 2* of the SIP revision. We are also proposing to remove WAC 173–400–100, because this outdated provision is no longer part of the EPA-approved SIP for Ecology's direct jurisdiction under CFR 52.2470(c)—Table 2 and BCAA has requested that it be removed from the BCAA's jurisdiction under CFR 52.2470(c)—Table 4. For more information please see the EPA's proposed (79 FR 39351, July 10, 2014) and final (79 FR 59653, October 3, 2014) actions on the general provisions of Chapter 173–400 WAC.

D. Scope of Proposed Action

This proposed revision to the SIP applies specifically to the BCAA jurisdiction incorporated into the SIP at 40 CFR 52.2470(c)—Table 4. As discussed in the EPA's proposed (79 FR 39351, July 10, 2014) and final (79 FR 59653, October 3, 2014) actions on the general provisions of Chapter 173–400 WAC, jurisdiction is generally defined on a geographic basis (Benton County); however there are exceptions. By statute, BCAA does not have authority for sources under the jurisdiction of the Energy Facilities Site Evaluation Council (EFSEC). See Revised Code of Washington Chapter 80.50. Under the applicability provisions of WAC 173–405–012, WAC 173–410–012, and WAC 173–415–012, BCAA also does not have jurisdiction for kraft pulp mills, sulfite pulping mills, and primary aluminum plants. For these sources, Ecology retains statewide, direct jurisdiction. Ecology also retains statewide, direct jurisdiction for the Prevention of Significant Deterioration (PSD) permitting program. Therefore, the EPA is not approving into 40 CFR 52.2470(c)—Table 4 those provisions of Chapter 173–400 WAC related to the PSD program. Specifically, these provisions are WAC 173–400–116 and WAC 173–400–700 through 750.

As described in the EPA's April 29, 2015 final action, jurisdiction to implement the visibility permitting program contained in WAC 173–400–117 varies depending on the situation. Ecology retains authority to implement WAC 173–400–117 as it relates to PSD permits (80 FR 23721). However for facilities subject to nonattainment new source review (NNSR) under the applicability provisions of WAC 173–400–800, we are proposing that BCAA would be responsible for implementing those parts of WAC 173–400–117 as they relate to NNSR permits. See 80 FR 23726.

Lastly, the SIP is not approved to apply in Indian reservations in the State, except for non-trust land within the exterior boundaries of the Puyallup Indian Reservation (also known as the 1873 Survey Area), or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

IV. Incorporation by Reference

In accordance with requirements of 1 CFR 51.5, the EPA is proposing to revise

our incorporation by reference of 40 CFR 52.2470(c)—Table 4 ''Additional Regulations Approved for the Benton Clean Air Agency (BCAA) Jurisdiction'' to reflect the regulations shown in the tables in section III.A. *Regulations to Approve and Incorporate by Reference into the SIP* and the rules proposed for removal from the SIP in section III.C. *Regulations to Remove from the SIP.* The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not impose substantial direct costs on tribal governments or preempt tribal law. As discussed above, the SIP is not approved to apply in Indian reservations in the state, except for non-trust land within the exterior boundaries of the Puyallup Indian Reservation (also known as the 1873 Survey Area), or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 2, 2015.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2015–23144 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 431, 447, 482, 483, 485, and 488

[CMS–3260–N]

RIN 0938–AR61

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Reopening of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: This document reopens the comment period for the July 16, 2015 proposed rule entitled ''Reform of Requirements for Long-Term Care Facilities''. The comment period for the proposed rule, which ends on September 14, 2015, is reopened for 30 days.

DATES: The comment period for the proposed rule published on July 16, 2015 (80 FR 42168), is reopened and ends on October 14, 2015.

ADDRESSES: In commenting, please refer to file code CMS–3260–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3260–P, P.O. Box 8010, Baltimore, MD 21244.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3260–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Ronisha Blackstone, (410) 786–6633.

SUPPLEMENTARY INFORMATION: On July 16, 2015, we published a proposed rule in the **Federal Register** (80 FR 42168) entitled, ''Reform of Requirements for Long-Term Care Facilities'' that would revise the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs. The proposed provisions include updating obsolete language, improving clarity, addressing ongoing healthcare priorities, and implementing certain Affordable Care Act provisions. These proposed changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These proposals are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

We have received inquiries from Hospital Associations and national industry organizations regarding the 60 day period to submit comments regarding this proposed rule. The organizations stated that they needed additional time to respond to the rule due to the scope and complexity of the proposal. Because of the scope of the proposed rule, and since we have specifically requested the public's comments on various aspect of the rule, we believe that it is important to allow ample time for the public to prepare comments on this proposed rule. Therefore, we have decided to reopen the comment period for an additional 30 days. This document announces the reopening of the public comment period to end on October 14, 2015.

Dated: September 9, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–23110 Filed 9–11–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2009–0038]

49 CFR Part 271

RIN 2130–AC11

Risk Reduction Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Proposed rule; notice of comment period reopening.

SUMMARY: On February 27, 2015, FRA published a Notice of Proposed Rulemaking (NPRM) that would require certain railroads to develop a Risk Reduction Program (RRP). On August 27, 2015, FRA held a public hearing to provide interested persons an opportunity to provide oral comments on the proposal. FRA is reopening the comment period for this proceeding to allow additional time for interested parties to submit written comments in response to views or information provided at the public hearing.

DATES: The comment period for this proceeding, consisting of the proposed rule published February 27, 2015, at 80 FR 10950, and the August 27, 2015, hearing, announced at 80 FR 45500, July 30, 2015, is reopened. Written comments must be received by September 18th, 2015. Comments received after that date will be considered to the extent possible without incurring additional expense or delay.

ADDRESSES: Written comments related to Docket No. FRA–2009–0038 may be submitted by any of the following methods:

- *Web site:* The Federal eRulemaking Portal, *http://www.regulations.gov.* Follow the Web site's online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590.
- *Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, Room W12–140 on the ground level of the West Building, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name, docket name, and docket number or Regulatory Identification Number (RIN) for this rulemaking. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: FRA has posted a transcript of the August 27, 2015, public hearing to the public docket in this proceeding. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, Room W–12–140 on the ground level of the West Building, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Miriam Kloeppel, Staff Director, Risk Reduction Program Division, Office of Safety Analysis, FRA, 1200 New Jersey Avenue SE., Mail Stop 25, Washington, DC 20590, (202) 493–6224, *Miriam.Kloeppel@dot.gov;* or Elizabeth Gross, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue SE., Mail Stop 10, Washington, DC 20590, (202) 493–1342, *Elizabeth.Gross@dot.gov.*

SUPPLEMENTARY INFORMATION: The Rail Safety Improvement Act of 2008 requires the development and implementation of railroad safety risk reduction programs. Risk reduction is a comprehensive, system-oriented approach to safety that (1) determines an operation's level of risk by identifying and analyzing applicable hazards and (2) involves the development of plans to mitigate that risk. Each RRP is statutorily required to be supported by a risk analysis and a Risk Reduction Program Plan, which must include a Technology Implementation Plan and a Fatigue Management Plan.

FRA held a public hearing on August 27, 2015, to receive oral comments in response to an NPRM requesting public comment on a proposed risk reduction rulemaking. *See* 80 FR 10950, Feb. 27, 2015 and 80 FR 45500, July 30, 2015. FRA also reopened the comment period to allow time for interested parties to submit written comments after the public hearing, and comments were due September 10, 2015. To afford interested parties additional time and opportunity to submit written comments in response to views or information provided at the public hearing, FRA is again reopening the comment period in this proceeding.

Written comments must be received by September 18th, 2015.

Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Issued in Washington, DC, on September 11th, 2015.

Patrick T. Warren,

Acting Associate Administrator for Railroad Safety and Chief Safety Officer.

[FR Doc. 2015–23233 Filed 9–11–15; 4:15 pm]

BILLING CODE 4910–06–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R5–ES–2015–0136; 4500030113]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the New England Cottontail as an Endangered or Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list the New England cottontail (*Sylvilagus transitionalis*) as an endangered or threatened species and to designate critical habitat under the Endangered Species Act of 1973, as amended (Act). After review of the best available scientific and commercial information, we find that listing the New England cottontail is not warranted at this time. However, we ask the public to submit to us any new information that becomes available concerning the threats to the New England cottontail or its habitat at any time.

DATES: The finding announced in this document was made on September 15, 2015.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R5–ES–2015–0136. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, New England Field Office, 70 Commercial Street, Suite 300, Concord, NH 03301. Please submit any new information, materials, comments, or questions concerning this finding to the above address.

FOR FURTHER INFORMATION CONTACT: Thomas R. Chapman, Field Supervisor, New England Field Office (see **ADDRESSES**); by telephone at 603–223–2541; or by facsimile at 603–223–0104. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), requires that, for any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information that listing the species may be warranted, we make a finding within 12 months of the date of receipt of the petition. In this finding, we will determine that the petitioned action is: (1) Not warranted, (2) Warranted, or (3) Warranted, but the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12-month findings in the **Federal Register**. Until now, making a 12-month finding that listing is warranted or not warranted for the New England cottontail was precluded by other higher priority national listing actions (71 FR 53756, September 12, 2006; 72 FR 69034, December 6, 2007; 73 FR 75176, December 10, 2008; 74 FR 57804, November 9, 2009; 75 FR 69222, November 10, 2010; 76 FR 66370, October 26, 2011; 77 FR 69993, November 21, 2012; 78 FR 70103, November 22, 2013; 79 FR 72449, December 5, 2014).

Previous Federal Actions

On December 30, 1982, we published our notice of review classifying the New England cottontail as a Category 2 species (47 FR 58454). Category 2 status included those taxa for which information in the Service's possession indicated that a proposed rule may be appropriate, but for which sufficient data on biological vulnerability and threats were not available to support a proposed rule at that time. This classification remained valid for the species in subsequent review publications for animals that occurred on September 18, 1985 (50 FR 37958), January 6, 1989 (54 FR 554), November 21, 1991 (56 FR 58804), and November 15, 1994 (59 FR 58982). In the February 28, 1996, candidate notice of review (CNOR) (61 FR 7596), we discontinued the designation of Category 2 species as candidates; therefore, the New England cottontail was no longer a candidate species.

On August 30, 2000, we received a petition dated August 29, 2000, from the Biodiversity Legal Foundation, Conservation Action Project, Endangered Small Animals Conservation Fund and Defenders of Wildlife, requesting that the New England cottontail be listed under the Act and critical habitat be designated. We acknowledged the receipt of the petition in a letter to The Biodiversity Legal Foundation, dated September 14, 2000, and stated that, due to funding constraints in fiscal year (FY) 2000, we would not be able to begin processing the petition in a timely manner. Those funding constraints persisted into FY 2001.

On December 19, 2000, Defenders of Wildlife sent a Notice of Intent (NOI) to sue the Service for violating the Act by failing to make a timely 90-day finding on the August 2000 petition. On February 8, 2002, Defenders of Wildlife sent another NOI to sue in response to the Service's failure to make a timely 12-month finding on the August 2000 petition. On May 14, 2002, we advised Defenders of Wildlife that we would begin action on the petition in FY 2002.

On June 30, 2004, the Service published in the **Federal Register** a 90-day finding that the petition presented substantial scientific and commercial information indicating that listing the New England cottontail as endangered may be warranted (69 FR 39395). We also announced the initiation of a status review to determine if listing the species was warranted and requested additional information and data regarding this species. On September 12, 2006, the Service published a finding that the petition presented substantial scientific and commercial information indicating that listing the New England cottontail as threatened or endangered was warranted, but precluded (71 FR 53756).

The Service has annually reviewed the status of the New England cottontail and reaffirmed the 2006 finding that listing of the species remained warranted but precluded with a Listing Priority Number of 2 in our CNORs published in 2007 (72 FR 69034; December 6, 2007), 2008 (73 FR 75176; December 10, 2008), 2009 (74 FR 57804; November 9, 2009), 2010 (75 FR 69222; November 10, 2010), 2011 (76 FR 66370; October 26, 2011), 2012 (77 FR 69993; November 21, 2012), 2013 (78 FR 70103; November 22, 2013), and 2014 (79 FR 72449; December 5, 2014).

Subsequent to the 2006 petition finding, the Service developed a national multi-year listing work plan associated with a multidistrict settlement agreement with the Center for Biological Diversity and WildEarth Guardians (*In re Endangered Species Act Section 4 Deadline Litigation, No. 1–377 (EGS), MDL Docket No. 2165 (D.D.C. May 20, 2011*)). The work plan represents a systematic process for the Service to make determinations as to whether the 250 identified candidate species still warrant listing as either threatened or endangered pursuant to the Act, and if so, proceed with appropriate rulemakings. Conversely, if the Service was to determine that listing of any candidate species is no longer warranted, candidate status would be withdrawn. Through the aforementioned work plan, we agreed to complete a final listing determination for the New England cottontail by September 30, 2015. This document constitutes the 12-month finding on the August 29, 2000, petition to list the New England cottontail as an endangered or threatened species and fulfills the aforementioned settlement agreement.

For additional previous Federal actions, see the New England cottontail's species' profile page at: *http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=A09B.*

Species Information

Species Description and Taxonomy

The New England cottontail (*Sylvilagus transitionalis*) is a medium-large-sized cottontail rabbit that may reach 1,000 grams (g) (2.2 pounds (lb)) in weight and is the only endemic cottontail in New England (Bangs 1894, p. 411; Allen 1904, entire; Nelson 1909, pp. 169, 170–171). Sometimes called the gray rabbit, brush rabbit, wood hare, or cooney, it can usually be distinguished from the sympatric (similar, but different, species that occur in the same area and are able to encounter each other) eastern cottontail (*S. floridanus*) and snowshoe hare (*Lepus americanus*) by several features. In general, the New England cottontail can be distinguished by its shorter ear length, slightly smaller body size, presence of a black spot between the ears, absence of a white spot on the forehead, and a black line on the anterior edge of the ears (Litvaitis *et al.* 1991, p. 11). Like the congeneric (separate species of the same genus) eastern cottontail, the New England cottontail can be distinguished from the snowshoe hare by its lack of seasonal variation in pelage (mammal's coat consisting of fur, hair, etc.) coloration.

New England and eastern cottontails can be difficult to distinguish in the field by external characteristics (Chapman and Ceballos 1990, p. 106). However, cranial (referring to the skull) differences, specifically the length of the supraorbital process (elongated bony structure located posterior (behind) to the eye) and the pattern of the nasal frontal suture (the junction between the nasal and frontal bones), are a reliable means of distinguishing the two cottontail species (Johnston 1972, pp. 6–11).

Prior to 1992, the New England cottontail was described as occurring in a mosaic pattern from southeastern New England, south along the Appalachian Mountains to Alabama (Bangs 1894, pp. 405 and 411; Nelson 1909, p. 196; Hall 1981, p. 305). However, Ruedas *et al.* (1989, p. 863) questioned the taxonomic status of *Sylvilagus transitionalis* based upon the presence of two distinct chromosomal races (genetically differentiated populations of the same species) within its geographic range. Individuals north and east of the Hudson River Valley in New York had diploid (a cell containing two sets of chromosomes (structure that contains genetic material) counts of 52, while individuals west and south of the Hudson River had counts of 46. Ruedas *et al.* (1989, p. 863) stated, ''To date, *Sylvilagus transitionalis* represents the only chromosomally polymorphic taxon within the genus *Sylvilagus,*'' and suggested that the two forms of *S. transitionalis* be described as distinct species.

Chapman *et al.* (1992, pp. 841–866) conducted a review of the systematics and biogeography of the species and proposed a new classification. Based upon morphological variation and earlier karyotypic (pertaining to the characteristics of a species' chromosomes) studies, Chapman *et al.* (1992, p. 848) reported clear evidence for two distinct taxa within what had been regarded as a single species. Accordingly, Chapman *et al.* (1992, p. 858) defined a new species, the Appalachian cottontail (*Sylvilagus obscurus*), with a range south and west of the Hudson River in New York. Thus, the New England cottontail (*S. transitionalis*) was defined as that species east of the Hudson River through New England. No subspecies of the New England cottontail are recognized (Chapman and Ceballos 1990, p. 106).

Litvaitis *et al.* (1997, entire) studied the variation of mtDNA (mitochondrial DNA, genetic material inherited from the mother) in the *Sylvilagus* complex occupying the northeastern United States. They found no evidence to suggest that hybridization is occurring between the New England cottontail and the eastern cottontail that was introduced into the New England cottontail's range, supporting the conclusions of others that the New England cottontail and the eastern cottontail have maintained genetic distinction (Wilson 1981, p. 99). Also, the limited variation observed in mtDNA led Litvaitis *et al.* (1997, p. 602) to conclude that the reclassification of *S. obscurus* as a distinct species was not supported. However, the more recent scientific view urges caution in interpreting the results of earlier mtDNA-based studies. Litvaitis *et al.* (1997, p. 597) sampled 25 individual *S. transitionalis/obscurus* across 15 locations in a geographic area that extended from southern Maine to Kentucky. The number of individuals sampled ranged from one to seven per site with a mean sample size of 1.7 individuals per location (Litvaitis *et al.* 1997, p. 598).

Allendorf and Luikart (2006, p. 391) warn that, ''many early studies that used mtDNA analysis included only a few individuals per geographic location, which could lead to erroneous phylogeny inferences'' regarding interpretations of descent and relationship among evolutionary species or groups. Furthermore, their analysis concentrated on the ''proline tRNA and the first 300 base pairs of the control region,'' which represents a relatively small fragment of mtDNA that can result in a failure to detect significant genetic differentiation when used to delineate taxonomic separation (Litvaitis *et al.* 1997, p. 599; King *et al.* 2006, p. entire). Strict adherence to the requirement of reciprocal monophyly (a genetic lineage where all members of the lineage share a more recent common ancestor with each other than with any other lineage on the evolutionary tree) in mtDNA as the sole delineating criterion for making taxonomic decisions often ignores important phenotypic, adaptive, and behavioral differences that are

important (Allendorf and Luikart 2006, p. 392; Knowles and Carstens 2007, pp. 887–895; Hickerson *et al.* 2006, pp. 729–739).

Notwithstanding the analyses discussed above, the results from Chapman *et al.* (1992) have been accepted by the scientific community (Wilson and Reeder 2005, pp. 210–211). The Service accepts the recognized taxonomic reclassification provided by Chapman *et al.* 1992 (p. 848) and concludes that *Sylvilagus transitionalis* and *S. obscurus* are valid taxa and are two separate species. Consequently, we find that the New England cottontail meets the definition of a species, as provided in section 3 of the Act, and is a listable entity.

Life History

The New England cottontail, like all cottontails, is primarily an herbivore and feeds on a wide variety of grasses and herbs during spring and summer and the bark, twigs, and buds of woody plants during winter (Dalke and Sime 1941, p. 216; Todd 1927, pp. 222–228). Cottontails are short-lived (usually less than 3 years), with predation being the cause of death of most individuals (Chapman and Litvaitis 2003, p. 118). Reproduction in cottontails begins at an early age with some juveniles breeding their first season (Chapman *et al.* 1982, p. 96). Litters probably contain three to five altricial (born in an underdeveloped state and requiring parental care) young, which are born in fairly elaborate nests where they receive maternal care (Chapman *et al.* 1982, p. 96). The number of litters produced by wild New England cottontails is unknown, but may attain a maximum of seven, based on the number of litters produced by other cottontail species (Chapman *et al.* 1982, p. 96). Young grow rapidly and are weaned by 26 days from birth (Perrotti, *in litt.* 2014). Female New England cottontails have a high incidence of post partum breeding (ability to mate soon after giving birth) (Chapman *et al.* 1982, p. 96). The reproductive capacity of cottontails remains relatively stable across population densities and is not believed to be a significant factor in regulating cottontail populations. Instead, survival, influenced mainly by predation, is believed to be the primary factor in regulating populations (Edwards *et al.* 1981, pp. 761–798; Chapman and Litvaitis 2003, p. 118). Consequently, habitat that provides abundant shelter is crucial to cottontail abundance (Chapman and Ceballos 1990, p. 96).

Metapopulation Dynamics

The relationship between habitat and survival of wild New England cottontails in New Hampshire was investigated by Barbour and Litvaitis (1993, entire). Their study revealed that the survival rate of cottontails occupying small patches was lower (0.35) than in larger patches (0.69) (Barbour and Litvaitis (1993, p. 325). Subsequent research found that by late winter rabbits in smaller patches were subsisting on a poorer diet, had lower body weights, were presumably less fit, and experienced greater predation rates, most likely as a result of the need to forage in areas of sparse cover (Villafuerte *et al.* 1997, p. 148). Based on the poor survival of cottontails on the smaller habitat patches, Barbour and Litvaitis (1993, p. 326) considered patches less than 2.5 hectares (ha) (less than 6.2 acres (ac)) in size to be ''sink habitats'' where mortality exceeds recruitment (reproduction and immigration). As a consequence of the variable quality of habitat patches and their ability to maintain occupancy, New England cottontail populations are believed to function as metapopulations; that is, a set of local populations comprising individuals moving between local patches (Hanski and Gilpin 1991, p. 7; Litvaitis and Villafuerte 1996, p. 686). Therefore, the spatial structure of a species' populations in addition to the species' life-history characteristics must be considered when formulating management systems for the species' viability (Hanski 1998, p. 41).

In metapopulations, population extinction and colonization at the patch-specific scale are recurrent rather than unique events (Hanksi 1998, p. 42). As with many metapopulations, local extinctions in New England cottontail populations are likely the result of demographic, environmental, and genetic stochasticities (Gaggiotti and Hanski 2004, pp. 337–366). For example, New England cottontails exhibit indicators of demographic stochasticity influencing local populations, because individuals on small patches are predominantly male (Barbour and Litvaitis 1993, entire). While there are no examples of genetic stochasticity that have led to inbreeding depression, recent analysis of gene flow among extant populations of New England cottontails in southeastern New Hampshire and Maine revealed evidence of genetic drift and population isolation due to geographic distance and fragmentation (Fenderson *et al.* 2014, entire), which may be a predictor of ongoing or future effects of genetic stochasticity (Gaggiotti and Hanski 2004, pp. 347–353).

Winter snow depth and persistence is an example of a stochastic environmental factor that could cause a local extinction. However, we recognize that winter severity operates at a regional scale that is not easily addressed. Therefore, the most effective means of addressing the effects of snow depth and persistence on New England cottontail is to ensure (1) representation of population diversity across the historical range; (2) resiliency of populations by ensuring enough individuals exist at local and patch scales to buffer environmental, demographic, and genetic stochasticity; and (3) redundancy of populations, because multiple populations will help guard against unexpected catastrophes such as disease outbreaks (Shaffer *et al.* 2002, p. 138). See Fuller and Tur (2012, pp. 32–41) for more information about the metapopulation dynamics of the New England cottontail.

Habitat Characteristics

New England cottontails occupy native shrublands associated with sandy soils or wetlands and regenerating forests associated with small-scale disturbances that set back forest succession. New England cottontails are considered habitat specialists, as they are dependent upon these early successional habitats, frequently described as thickets (Litvaitis 2001, p. 466). Suitable habitats for the New England cottontail contain dense (approximately greater than 9,000 woody stems per ha (greater than 3,600 stems per ac)), primarily deciduous understory cover (Litvaitis *et al.* 2003a, p. 879), with a particular affinity for microhabitats containing greater than 50,000 stem-cover units/hectare (ha) (20,234 stem-cover units/acre (ac)) (Barbour and Litvaitis 1993, p. 324; Gottfried 2013, p. 20). New England cottontails are also associated with areas containing average basal area (area occupied by trees) values of 53.6 square meters (m^2) per ha (233.6 square feet (ft^2) per ac), which indicates that tree cover is an important habitat component for the New England cottontail (Gottfried 2013, pp. 20–21). In addition to demonstrating a strong affinity for habitat patches of heavy cover, New England cottontails generally do not venture far from the patches (Smith and Litvaitis 2000, p. 2134). Smith and Litvaitis (2000, p. 2136) demonstrated via a winter experiment using animals in an enclosed pen that, when food was not available within the cover of thickets, New England cottontails were reluctant to forage in the open, lost a

greater proportion of body mass, and succumbed to higher rates of predation compared to eastern cottontails in the same enclosure. Consequently, New England cottontail populations decline rapidly as understory habitat thins during the processes of forest stand maturation (Litvaitis 2001, p. 467).

Today, New England cottontail habitats are typically associated with beaver (*Castor canadensis*) flowage wetlands, idle agricultural lands, power line corridors, coastal barrens, railroad rights-of-way, recently harvested forest, ericaceous thickets comprising *Kalmia* and *Rhododendron;* invasive-dominated shrublands comprising *Rosa multiflora, Lonicera spp.,* and others; forest understories dominated by *Smilax spp.;* and pine barrens (Litvaitis 1993b, p. 869; Tash and Litvaitis 2007, p. 594). In contrast, eastern cottontails appear to have relatively generalized habitat requirements, and although they sometimes co-occur with the New England cottontail, they can also be found in residential areas, where they utilize lawns and golf courses, and in active agriculture areas, where relatively small patches of thick cover are insufficient to support New England cottontails (Chapman and Ceballos 1990, p. 102).

Range and Distribution

Historical Distribution

In our previous assessments we described the historical distribution of the New England cottontail (71 FR 53756; 72 FR 69034; 73 FR 75176; 74 FR 57804; 75 FR 69222; 76 FR 66370; 77 FR 69993; 78 FR 70103; 79 FR 72449) as following the circa 1960 range delineation presented by Litvaitis *et al.* (2006, entire). This range description included the area east of the Hudson River in New York (excepting Long Island); all of Connecticut, Massachusetts, and Rhode Island; and much of Vermont, New Hampshire, and southwestern Maine (Litvaitis *et al.* 2006, p. 1191). We have reanalyzed existing information as well as previously unavailable information regarding land use and predator patterns (see Summary of Information Pertaining to the Five Factors—Factor A and Factor C, respectively, below). Based on this more thorough analysis, we conclude that the 1960 range of the New England cottontail was a product of extensive land use changes that led to a substantial increase in the availability of habitat and human pressure that altered ecological processes (Bernardos *et al.* 2004, p. 150; Ahn *et al.* 2002, p. 1). For the New England cottontail, these changes led to an artificially inflated abundance and distribution (Foster *et al.* 2002, p. 1345).

Lacking a description of the species' distribution prior to this range expansion, we relied on information pertaining to the distribution of habitat in the pre-European landscape and our understanding of the ecological factors (*e.g.,* competition with snowshoe hare and eastern cottontail (see Summary of Information Pertaining to the Five Factors—Factor C below) related to the species. Based on our review, we surmise that the historical distribution of the New England cottontail was confined to areas from the Hudson River in New York through southern New England to southeastern New Hampshire, with occurrences being confined to areas in close proximity to coastal areas, perhaps extending no farther inland than 100 kilometers (km) (60 miles (mi)), with occurrences also found on several offshore islands, including Nantucket Island and Martha's Vineyard, Massachusetts, and Long Island, New York (Cardoza, *pers. comm.*. 1999; Nelson 1909, pp. 196–199; A. Tur, *pers. comm.,* 2015).

Our full analysis of the historical distribution of the New England cottontail can be found at *http://www.regulations.gov.*

Current Distribution and Status

For the New England cottontail and other early-successional species, abundance and distribution increased with land clearing that peaked by the mid-19th century and persisted into the early 20th century, but then subsequently declined (Bernardos *et al.* 2004, pp. 142–158; Foster *et al.* 2002, pp. 1345–1346). By the mid-1900s, afforestation was progressing, and the abundant shrubby young growth that had fostered the expanded distribution of the New England cottontail's range was beginning to age. Decreases in the abundance of the New England cottontail were reported in the Champlain Valley, which may have been attributed to increases in red fox (*Vulpes vulpes*) or the increased mechanization that resulted in ''clean'' farming practices, such as drainage of wetlands and the removal of old rail fences that had favored shrubby field edges (Foote 1946, p. 37).

By the 1970s, contraction of the range of the New England cottontail was well underway. In Massachusetts, those declines were evident by the mid-1950s when Fay and Chandler (1955, entire) documented the distribution of cottontails within that State. Declines were also reported in Connecticut (Linkkila 1971, p. 15; Johnston 1972, p. 17). Jackson (1973, p. 21) conducted an extensive analysis of the distribution of cottontails in northern New England and stated that declines were ongoing in Vermont, Maine, and New Hampshire.

A systematic comprehensive survey consisting of standardized sampling units comprising U.S. Geological Survey 7.5-minute topographic quarter quadrangles and field collection protocols to determine the current distribution of the New England cottontail within its recent (1990 to 2004) historical range was conducted during the 2000–2001 through 2003–2004 winter seasons (Litvaitis *et al.* 2006, pp. 1190–1197). The results indicated that the range had declined substantially from the 1960 maximum historical distribution, estimated at 90,000 square kilometers (km^2) (34,750 square miles (mi^2)) to approximately 12,180 km^2 (4,700 mi^2), representing a reduction of approximately 86 percent (Litvaitis *et al.* 2006, p. 1192). Contraction of the New England cottontail's distribution occurred primarily toward the southern and eastern coastal regions, as well as interior landscapes associated with the Hudson, Housatonic, and Merrimack River valleys and associated uplands located respectively in New York, Connecticut, and New Hampshire (Litvaitis *et al.* 2006, p. 1193). This contraction was attributed primarily to habitat loss and fragmentation (Litvaitis *et al.* 2006, p. 1193). See Summary of Information Pertaining to the Five Factors—Factor A below for more information.

In addition to the observed range contraction, Litvaitis *et al.* (2006, p. 1193) stated that the range had been fragmented into five geographic areas, ranging in size from 1,260 to 4,760 km^2 (487 to 1,840 mi^2). These areas and their sizes are: (1) The seacoast region of southern Maine and New Hampshire, 3,080 km^2 (1,190 mi^2); (2) The Merrimack River Valley of New Hampshire, 1,260 km^2 (490 mi^2); (3) A portion of Cape Cod, Massachusetts, 980 km^2 (376 mi^2); (4) Eastern Connecticut and Rhode Island, 2,380 km^2 (920 mi^2); and (5) Portions of western Connecticut, eastern New York, and southwestern Massachusetts, 4,760 km^2 (1,840 mi^2). These acreage figures, however, substantially exceed the actual area occupied by the species because the calculations were based on the total area within each 7.5 minute USGS quadrangle map where one or more sites with an extant occurrence of the New England cottontail was recorded, rather than the total area of the actual habitat patches.

Since the 2000 to 2004 comprehensive rangewide survey,

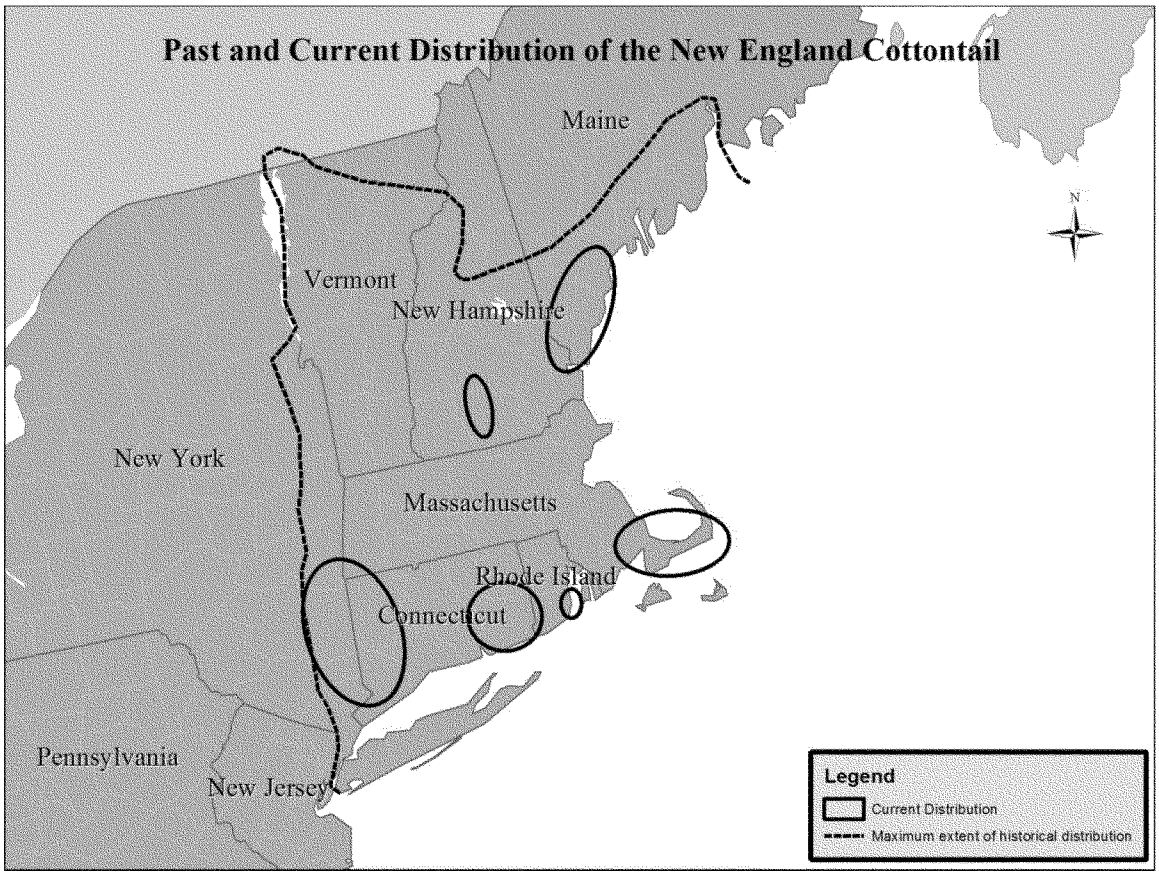
numerous efforts to determine the presence of New England cottontails have been expended throughout the species' range. Because those efforts involve wide variation in search intensity and methodology (*e.g.,* fecal pellet collection, hunter surveys, live trapping, and road mortality), direct comparison with the results of Litvaitis *et al.* (2006, pp. 1190–1197) is not appropriate for the purpose of determining trends in the species' status. Despite this shortcoming, the results of these various survey efforts provide useful information, including the detection of New England cottontails in a few notable areas previously considered vacant (*e.g.,* Cape Cod National Seashore and Nantucket Island, Massachusetts) (Beattie, *in litt.* 2013; Scarpitti, *in litt.* 2013). However, some biologists involved in these survey efforts conclude that the New England cottontail has declined since the early 2000s, particularly along the middle Merrimack River valley in New Hampshire, extending northward from the City of Manchester to Concord, and in the region of northern Rhode Island (Tur, *in litt.* 2005; Holman *et al., in litt.* 2014; Tefft *et al., in litt.* 2014).

Obtaining population estimates for species such as the New England cottontail, that are cryptic and subject to wide population fluctuations within relatively broad geographic areas occupied by similar species, is challenging. Nevertheless, wildlife biologists estimated New England cottontail population sizes for each State within the species' range by utilizing area-specific information that included factors such as the extent of potential habitat, the occurrence of sympatric eastern cottontail populations and local New England cottontail survey results. When totaled, these 2014 local estimates yield a rangewide population estimate of approximately 17,000 individual New England cottontails, consisting of: (1) Fewer than 100 rabbits in Rhode Island (Tefft *et al., in litt.* 2014); (2) Approximately 10,000 in Connecticut (Kilpatrick *et al., in litt.* 2014); (3) As many as 4,600 in Massachusetts (Scarpitti and Piche, *in litt.* 2014); (4) 700 in Maine (Boland *et al., in litt.* 2014); (5) 180 or fewer in New Hampshire (Holman *et al., in litt.* 2014); and (6) Approximately 1,600 in New York (Novak *et al., in litt.* 2014).

Rangewide, some of the occupied areas are quite small and support few New England cottontails. For example, two-thirds of the occupied habitat patches in Maine are less than 2.5 ha (6.2 ac) in size and are considered population sinks (Barbour and Litvaitis 1993, p. 326; Litvaitis and Jakubas 2004, p. 41) because these patches do not contain the necessary forage and shelter components for long-term occupancy. In New Hampshire, more than half of the 23 sites occupied by the New England cottontail are less than 3 ha (7.4 ac) (Litvaitis *et al.* 2006, p. 1194). Litvaitis *et al.* (2006, p. 1194) report that sampled patches in eastern Massachusetts, as well as the majority of those constituting the largest extant New England cottontail population (western Massachusetts, southeastern New York, and western Connecticut), are less than 3 ha (7.4 ac), probably supporting no more than three to four New England cottontails per site.

In 2014, State biologists estimated that there was: (1) More than 180 km^2 (46,000 ac) of potential habitat in Connecticut (Kilpatrick *et al., in litt.* 2014); (2) Approximately 6 km^2 (1,500 ac) in Maine (Boland *et al., in litt.* 2014); (3) 1.8 km^2 (450 ac) in New Hampshire (Holman *et al., in litt.* 2014); (4) 87 km^2 (21,000 ac) in New York (Novak *et al., in litt.* 2014); and (5) 30 km^2 (7,600 ac) in Rhode Island (Tefft *et al., in litt.* 2014). Estimates for Massachusetts are not available. However, there are several large habitat expanses in Massachusetts, such as at the 60 km^2 (15,000 ac) of unfragmented habitat found at the Massachusetts Military Reservation and a 2.4-km^2 (600-ac) or larger patch within Myles Standish State Forest in the southeastern part of the State (Scarpitti and Piche, *in litt.* 2014). While these population estimates are encouraging, it is not yet known whether they are sustainable due to their current distribution and quality of habitat. The population estimates in Connecticut, Massachusetts, and New York consist of areas where the species is likely secure because the populations are large enough to be self-sustaining and the habitat supporting those self-sustaining populations is being managed to maintain its suitability.

Figure 1. Past and current distribution of the New England cottontail



Summary of Range and Distribution—In summary, the distribution of the species at the time of European contact is unknown; however, the species was most likely found in greatest abundance in coastal areas where shrublands were concentrated and suitable habitat patches are presumed to have been relatively large. New England cottontail occurrence likely progressively diminished inland where suitable habitat patches tend to be smaller and relatively short lived. The presence of the snowshoe hare, a potential competitor, along with climatic conditions that favor the hare, likely naturally contributed to the foreshortened distribution of the New England cottontail. However, these natural control processes were disrupted when the land use patterns that accompanied European settlement changed. The land use patterns altered the abundance and distribution of shrublands, particularly in interior New England, and thus artificially inflated the amount of suitable habitat available to the New England cottontail. This artificial increase in suitable habitat offset the naturally controlling factors of climate and competition, thereby allowing the New England cottontail to disperse in more northerly and inland directions.

Despite the spatial and temporal gaps in the species' distribution records, analysis of the best available information documents the changes in the historical distribution of the New England cottontail over time. The evidence clearly indicates that the distribution greatly increased during the 19th and early 20th centuries, when regionwide conversion of mature forest to young forest habitat within the interior uplands was at its peak and shifts in snowshoe hare abundance provided ample expansion opportunities for the New England cottontail. In the case of the Hudson River and Lake Champlain valleys, the best available information indicates that over a 107-year period the species extended its range northward from Troy, New York, to the Canadian border, a distance of approximately 257 km (160 mi), at a rate of approximately 2.4 km (1.5 mi) per year (Bachman 1837, p. 328; Foote 1946, p. 39). In the latter half of the 20th century, harvesting of interior upland forests waned, and young forest habitat capable of maintaining New England cottontail populations and the distribution of the species contracted southward and eastward toward coastal areas. This contraction, however, is not representative of the species' pre-Columbian baseline distribution, because extensive amounts of the intervening landscape have been converted to other land uses that have degraded habitat for the species and contributed to its currently disjunct distribution.

Rangewide Conservation Efforts

Beginning in 2008, State and Service biologists began organizing a conservation effort for the New England cottontail. A governance structure was formalized in 2011 to enhance cooperation between the Maine Department of Inland Fisheries and Wildlife (MDIFW), the New Hampshire Fish and Game Department (NHFGD), the Massachusetts Division of Fisheries and Wildlife (MDFW), the Rhode Island Department of Environmental Management), the Connecticut Department of Energy and Environmental Protection, the New York Department of Environmental Conservation, the U.S. Department of

Agriculture's Natural Resources Conservation Service (NRCS), and the Service (hereafter referred to as the Parties). The Parties established an Executive Committee, facilitated by the Wildlife Management Institute (WMI), and adopted bylaws (Fuller and Tur 2012, p. 4) ''to promote recovery, restoration, and conservation of the New England cottontail and its associated habitats so that listing is not necessary'' (New England cottontail Executive Committee, *in litt.* 2011). This Executive Committee comprises high-level agency representatives, capable of making staffing and funding decisions.

The Executive Committee established a Technical Committee, comprising staff-level biologists with biological and conservation planning expertise, and delegated eight initial charges to advance the work of New England cottontail conservation, including preparation of a multifaceted conservation strategy with quantifiable objectives to measure conservation success (New England cottontail Executive Committee, *in litt.* 2011). The Technical Committee drafted, and the Executive Committee approved, the 2012 peer-reviewed *Conservation Strategy for the New England Cottontail* (Conservation Strategy) (Fuller and Tur 2012, available at *http://www.newenglandcottontail.org* (accessed March 18, 2015)). This Conservation Strategy describes: (1) An assessment of the conservation status of and threats facing the New England cottontail; (2) The process used to develop a conservation design that includes those landscapes, hereafter referred to as Focus Areas, where conservation actions will be taken to achieve a series of explicit conservation goals; (3) The objectives related to achieving those goals; (4) Important conservation actions needed to protect and manage habitat; (5) Communications needed to ensure implementation; (6) Research needed to improve understanding of the ecology of the New England cottontail; (7) Monitoring techniques to evaluate the effectiveness of the implemented actions and identify any changes needed to increase their effectiveness; (8) The commitment of the participating agencies to carry out the conservation effort; and (9) The process for modifying the Conservation Strategy in the future, if necessary, in light of any new and relevant information (Fuller and Tur 2012, p. 4). The Conservation Strategy focuses on securing New England cottontail within its current distribution (see figure 1). The Conservation Strategy includes an implementation plan through 2030.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be endangered or threatened based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms;

(E) Other natural or manmade factors affecting its continued existence.

In making this finding, information pertaining to the New England cottontail in relation to the five factors provided in section 4(a)(1) of the Act is discussed below. In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual effects to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species warrants listing as endangered or threatened as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely affected could suffice. The mere identification of factors that could affect a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species meets the definition of an endangered or threatened species under the Act. Although this language focuses on impacts negatively affecting a species, section 4(b)(1)(A) of the Act requires us to consider efforts by any State, foreign nation, or political subdivision of a State or foreign nation to protect the species. Such efforts would include measures by Federal agencies, Native American Tribes, businesses, organizations, and individuals that positively affect the species' status. Also, Federal, Tribal, State, and foreign recovery actions (16 U.S.C. 1533(f)), and Federal consultation requirements (16 U.S.C. 1536) constitute conservation measures.

Read together, sections 4(a)(1) and 4(b)(1)(A), as reflected in our regulations at 50 CFR 424.119(f), require us to take into account those factors that either positively or negatively affect a species status so that we can determine whether a species meets the definition of threatened or endangered. In so doing, we analyze a species' risk of extinction by assessing its status (*i.e.,* is it in decline or at risk of decline and at what rate) and consider the likelihood that current and future conditions and actions will promote or threaten a species' persistence by increasing, eliminating, or adequately reducing one or more threats to the species. This determination requires us to make a prediction about the future persistence of a species.

In making our 12-month finding on the petition, we considered and evaluated the best available scientific and commercial information.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The New England cottontail requires thicket habitat and is frequently associated with shrublands and other ephemeral stages of forest regeneration after a disturbance such as fire, forest insect outbreak, timber harvesting, or beaver activity (Litvaitis 2001, p. 466). Because early successional species require habitats that generally persist only for a short time, continual turnover of mature forest somewhere on the landscape is necessary for the species to maintain its distribution and abundance.

The amount of early successional forest cover is limited in the States where the New England cottontail occurs. Data from the U.S. Department of Agriculture indicate that the area of early successional forest cover in the southern New England States (Massachusetts, Connecticut, and Rhode Island) declined from 36 percent of the total timber land area in the early 1950s to 5 percent in the late 1990s (Brooks 2003, p. 68). Jackson (1973, p. 21) reported a decline in New England cottontails in Vermont, New Hampshire, and Maine, and attributed the decline to changes in habitat, primarily to the reduction of cover on a landscape scale.

Inventories from the U.S. Forest Service reveal that the extent of forest in the seedling-sapling stage (thickets favorable to the New England cottontail) declined by more than 80 percent in New Hampshire from 845,425 ha (2,089,091 ac) to 131,335 ha (324,536 ac) during the period 1960 to 1983 (R. Brooks, personal communication, in Litvaitis and Villafuerte 1996, p. 689) and by 14 percent in New York from 1980 to 1993 (Askins 1998, p. 167). While the forest inventory results reported by Brooks (2003, p. 68) found an increase in the early successional forest component of northern New England States, most of the increase occurred in the industrial forest land of northern Maine, well north of the historical and current range of the New England cottontail. Maine's southernmost counties (York and Cumberland) that still support populations of New England cottontails, have experienced declines in young forest stands, from about 38 percent in 1971 to 11 percent in 1995 (Litvaitis *et al.* 2003b, p. 881). Litvaitis *et al.* (1999, p. 106) reported that remaining shrub-dominated and early successional habitats in the northeast continue to decline in both coverage and suitability to the wildlife species dependent upon them.

The decline of early successional forest in the Northeast is primarily due to forest maturation (Litvaitis 1993b, p. 870), which is a natural process. However, other influences are compounding the situation. Habitat destruction and modification are occurring as a result of human population growth and development (Brooks 2003, p. 65). The three southern New England States, Connecticut (greater than 270 inhabitants per km^2 (700 inhabitants per mi^2)), Rhode Island (greater than 380 inhabitants per km^2 (1,000 inhabitants per mi^2)), and Massachusetts (greater than 300 inhabitants per km^2 (800 inhabitants per mi^2)), which constitute the center of the New England cottontail's range, are among the most densely populated areas in the United States, with only New Jersey and the District of Columbia being more densely populated (U.S. Census Bureau, 2012). Similarly, New York, at greater than 150 inhabitants per km^2 (400 inhabitants per mi^2), ranks eighth among the 50 States in population density, though much of this density is centered around a few urban areas, especially New York City. Rhode Island is most developed to the east of Narragansett Bay; the largest forest patches remain along the less developed western edge of the State. Connecticut is most developed in the southwestern corner and up the Connecticut River Valley. Notably, the most densely human-populated areas of Connecticut and Rhode Island are relatively devoid of New England cottontails. In association with human populations, early successional habitats that once supported New England cottontails have been converted to a variety of uses that make them unsuitable for the cottontail, thereby contributing to habitat loss and fragmentation (Litvaitis *et al.* 2006, p. 1194). In the Seacoast Region of New Hampshire and Maine, the effects of habitat fragmentation are having a deleterious effect on remnant populations of the New England cottontail, such that enhancing gene flow by improving habitat or conducting translocations may be required to maintain populations in those landscapes (Fenderson *et al.* 2014, pp. 1–23). Among shrub-dominated plant communities, scrub oak and pitch pine barrens that provide cottontail habitat have been heavily modified or destroyed by development (Patterson 2002, unpublished presentation abstract).

Litvaitis *et al.* (1999, p. 106) concluded that shrub-dominated and early successional habitat may be the most altered and among the most rapidly declining communities in the Northeast. Based on changes in human populations and associated development, without intervention, this trend will likely continue. For example, U.S. Census Bureau data for the New England States indicate a 3.8-percent population growth, equating to an increase of 522,348 people, during the period 2000 to 2010 (U.S. Census Bureau 2011). Analyses of U.S. Census data demonstrates that, in 1982, the number of acres developed for every new person was 0.68 in New England (*http://wrc.iewatershed.com* (accessed May 2006)), but in 1997, the number of acres developed for every new person was 2.33, an almost four-fold increase. Given the 1997 rate of development for each additional resident (0.94 ha (2.33 ac) per person) and the measured population growth for New England, 491,007 additional ha (1.2 million additional ac) of wildlife habitat would have been converted and fragmented during the period 2000 to 2010 (adapted from U.S. Census Bureau 2011, (*http://wrc.iewatershed.com* (accessed May 2006)), and it is highly likely that this included habitat that was suitable and supported New England cottontails.

As an example, The Society for the Protection of New Hampshire's Forests (Sundquist and Stevens 1999, p. entire) estimated that New Hampshire will lose approximately 80 percent of its forest land to various types of development by the year 2020. Further, this analysis predicted that the greatest loss of forest lands, approaching 24,281 ha (60,000 ac), would occur in the southeastern portion of the State, principally in Rockingham, Hillsborough, and Strafford Counties. These counties account for all known New England cottontail occurrences in the State. In fact, observations by Service biologists in 2005 confirmed that 2 of the 23 New Hampshire cottontail sites known to be occupied at some time from 2001 to 2003 had been lost to development, and 5 other sites were posted ''for sale.''

Noss and Peters (1995, p. 10) consider eastern barrens to be among the 21 most endangered ecosystems in the United States. Some eastern barrens, such as the pitch pine and scrub oak barrens of Cape Cod, Massachusetts, are suitable habitat for the New England cottontail. It is unclear to what extent barrens in other States also supported occurrences of New England cottontails; however, as of 2014 the barrens of southeastern Massachusetts are known to be occupied by the New England cottontail (Scarpitti and Piche, *in litt.* 2014).

Within the historical range of the New England cottontail, the abundance of early successional habitats continues to decline (Litvaitis *et al.* 1999, p. 106; Brooks 2003, p. 65), and for the most part, remaining patches are small and located in substantially modified landscapes (Litvaitis and Villafuerte 1996, p. 687; Litvaitis 2003, p. 115; Litvaitis *et al.* 2008, p. 179). The fragmentation of remaining suitable habitats into smaller patches separated by roads and residential and other types of development can have profound effects on the occupancy and persistence of New England cottontail populations. Barbour and Litvaitis (1993, p. 321) found that New England cottontails occupying small patches of habitat less than or equal to 2.5 ha (approximately 6 ac) were predominantly males, had lower body mass, consumed lower quality forage, and had to feed farther from protective cover than rabbits in larger patches (5 ha or greater than 12 ac). This study also demonstrated that New England cottontails in the smaller patches had only half the survival rate of those in the larger patches due to increased mortality from predation. Barbour and Litvaitis (1993, p. 321) state that the skewed sex ratios (or single occupant) and low survival among rabbits on small patches may effectively prevent reproduction from occurring on small patches. Due to skewed sex ratios and low survival rates, the presence of New

England cottontails in these small patches is dependent on the dispersal of individuals from source populations (Barbour and Litvaitis 1993, p. 326). Litvaitis *et al.* (2008, p. 179) and Barbour and Litvaitis (1993, p. 321) view these small patches as sink habitats. The relationship between winter survival and food resources is supported by a 2010 study on eastern cottontail, the results of which could be extrapolated to New England cottontail, which concluded supplemental feeding of animals in small habitat patches enhanced winter survival (Weidman 2010, p. 20).

Natural or anthropogenic disturbances that create small, scattered openings may no longer provide habitats capable of sustaining New England cottontail populations because, in contemporary landscapes, generalist predators effectively exploit prey restricted to such patches (Brown and Litvaitis 1995, p. 1005; Villafuerte *et al.* 1997, p. 148). Barbour and Litvaitis (1993, p. 321) concluded that local populations of New England cottontails may be vulnerable to extinction if large patches of habitat are not maintained. The Service concludes this likely explains why 93 percent of the apparently suitable habitat patches that were searched by Litvaitis *et al.* (2006, pp. 1190–1197) were found to be unoccupied.

Human population growth has had another effect, in addition to habitat loss and fragmentation, on forests within the New England cottontail range. Between 1950 and 2000, the human population increased 44 percent in southern New England and 71 percent in northern New England (Brooks 2003, p. 70). With the increase in human population, an increase in the parcelization (*i.e.,* the fragmentation of ownership) of northeastern forests into smaller and smaller parcels followed. The majority of private northeastern forest owners, excluding industrial forest owners, own less than 4 ha (10 ac) each; about 12 percent of timberland in the Northeast is publicly owned (Brooks 2003, p. 69). An increasingly urbanized landscape, with many small, partially forested residential parcels, imposes societal and logistical restrictions on forest management options (Brooks 2003, p. 65). Shrublands, clear cuts, and thickets are ''unpopular habitats'' among the public (Askins 2001, p. 407), and private forest owners are resistant to managing for this type of habitat (Trani *et al.* 2001, p. 418; Kilpatrick *et al., in litt.* 2014). Timber harvesting and fire or other disturbance regimes that would maintain or regenerate early successional habitat for thicket-dependent species like the New England cottontail are less likely to occur in a landscape with many small landowners.

Based on computer simulations demonstrating that populations dominated by small patches were likely to go extinct (Livaitis and Villafuerte 1996, entire), Litvaitis *et al.* (2006, p. 1194) conclude that the five remaining disjunct populations of the New England cottontail, as currently configured, do not represent a stable condition for long-term persistence. More recently, genetic analysis of New England cottontail populations in Maine and Seacoast New Hampshire corroborated the negative effects of fragmentation (Fenderson *et al.* 2014, pp. 13 and 17). Fenderson *et al.*'s (2014, p. 17) findings of isolated populations with low effective population sizes and low genetic diversity suggest that populations in the study area were vulnerable to extirpation.

In summary, the best available information indicates that in parts of the species' range, New England cottontails occur on small parcels, where food quality is low and winter mortality to predators (see Factor C below) is unsustainably high (Barbour and Litvaitis 1993, p. 321; Brown and Litvaitis 1995, p. 1005). In contrast, several large habitat tracts occur in the Cape Cod area of Massachusetts, western Connecticut, and eastern New York, and those populations are likely secure (Scarpitti and Piche, *in litt.* 2014; Kilpatrick *et al., in litt.* 2014; Novak *et al., in litt.* 2014). Further, the current distribution of the species is discontinuous, being divided by expanses of unsuitable habitat that separate the range into five population clusters.

Among the factors contributing to the long-term and rangewide reduction in habitat, habitat succession was considered by Litvaitis (1993b, p. 866) to be the most important. However, at a local or individual patch scale, loss or modification of habitat due to development is also significant. In general, the range of the New England cottontail has contracted by 86 percent since 1960 (Litvaitis *et al.* 2006, p. 1190), and current land use trends in the region indicate that the rate of change, about 2 percent range loss per year, is likely to continue if conservation actions to address the decline are not implemented (Litvaitis and Johnson 2002, p. 4; Litvaitis *et al.* 2006, p. 1195; Fenderson *et al.* 2014, p. 17). This is supported by results from various State surveys conducted since 2004 (Tefft *et al., in litt.* 2014; Holman *et al., in litt.* 2014; Boland *et al., in litt.* 2014; Kilpatrick *et al., in litt.* 2014).

Conservation Efforts To Reduce Habitat Destruction, Modification, or Curtailment of Its Range

As described above, the Conservation Strategy (Fuller and Tur 2012, entire) guides the New England cottontail's rangewide conservation and was specifically developed to consider the species' life-history traits or resource needs. These traits commonly include morphological, developmental, and behavioral characteristics such as body size; growth patterns; size and age at maturity; reproductive effort; mating success; the number, size, and sex of offspring; and rate of senescence (Ronce and Olivieri 2004, p. 227). Factors addressing habitat quality and quantity were also considered. Given the species' life history characteristics, the key to its viability is ensuring that ample resources are available to support population increases, as opposed to maximizing the survival of individuals. In addition, we also recognize that the landscape-level alterations occurring throughout the species' range have fragmented New England cottontail populations and substantially increased the risk of extinction (Litvaitis *et al.* 2006, p. 1195; Fenderson *et al.* 2014, p. 17).

The Conservation Strategy (Fuller and Tur 2012, p. 19) contains a summary of the information contained in the Service's 2013 Species Assessment and Listing Priority Assignment Form (Service 2013, entire) and concluded that the primary threat to the species was habitat modification resulting, in part, from: (1) Forest maturation; (2) Disruption of disturbance regimes that set back succession; and (3) Habitat modification, fragmentation, and destruction resulting from development (Fuller and Tur 2015, pp. 19, 21–23). The Conservation Strategy prescribes forest management practices on public and private lands to reverse forest maturation and increase habitat capable of supporting the New England cottontail (Fuller and Tur 2012, pp. 20–21) and identifies potential landscapes (*e.g.,* Focus Areas) where conservation actions would be implemented. The Conservation Strategy identified 41 separate Focus Areas distributed across all 6 States within the species' current range and containing a total habitat area in excess of 20,000 ha (50,000 ac). Each individual Focus Area will contain populations ranging from 100 to 2,500 animals, as appropriate (Fuller and Tur 2012, p. 30).

The Conservation Strategy specifies that conservation of the species will be achieved by implementing rangewide conservation actions that establish:

○ 1 New England cottontail landscape capable of supporting 2,500 or more individuals;

○ 5 landscapes each capable of supporting 1,000 or more individuals; and

○ 12 landscapes each capable of supporting 500 or more individuals.

Each New England cottontail landscape/Focus Area should comprise a network of 15 or more habitat patches, each 10 ha (25 ac) or greater in size, and situated within dispersal distance (less than 1 km (0.6 miles)) to other patches of suitable habitat (Fuller and Tur 2012, p. 43). This dispersal distance was based on Litvaitis and Villafuerte's (1996, p. 689) conclusion that dispersal of New England cottontail fits a geometric distribution, with a maximum distance of 3 km (1.9 mi). Recent analysis of gene flow confirms the accuracy of this distance, as evidenced by Fenderson *et al.'*s (2014, p. 15) conclusion that New England cottontails have difficulty traversing distances greater than 5 km (3 mi).

The Conservation Strategy Landscape planning further specifies that actions should take into account the habitat matrix (condition of the landscape surrounding habitat patches), because areas with numerous anthropogenic features or substantial natural barriers are likely to be highly fragmented and form barriers to dispersal that may otherwise encumber conservation efforts (Fuller and Tur 2012, p. 43). The Technical Committee addressed the habitat matrix conditions by building in redundancy as expressed in the creation of the 41 Focus Areas—not all 41 Focus Areas will be needed to achieve the landscape goals specified above. The Conservation Strategy identifies a suite of implementation objectives, many of which are intended to reduce the threat of habitat destruction, modification, and curtailment of the New England cottontail's range (Fuller and Tur 2012, pp. 44–87).

The Conservation Strategy's 2014 Annual Performance Report documents previous and ongoing implementation actions that have and are addressing loss of habitat for the New England cottontail (Fuller and Tur 2015, entire). For example, by the autumn of 2013, approximately 14,000 ac (5,666 ha) of habitat were under evaluation or contract for appropriate management actions, and by the end of 2014, specific habitat treatments were estimated to be complete on more than 6,700 ac (2,711 ha) of State, other public, or private land (Fuller and Tur 2015, p. 55). In addition, more than 10,000 ac (4,047 ha) of self-sustaining New England cottontail habitat has been identified (Fuller and Tur 2015, p. 55). However, although we have evidence of demonstrated implementation success, not all of the actions implemented have yet to show full effectiveness for the species (see Policy for the Evaluation of Conservation Efforts Analysis section below). The 2014 Annual Performance Report acknowledges that suitable habitat is not equally distributed across the Focus Areas and that due to the ephemeral nature of most of the species' habitat, additional management and maintenance actions are necessary to keep the habitat in suitable condition (Fuller and Tur 2015, p. 55).

Summary of Factor A—We identified a number of threats to New England cottontail habitat that have resulted in the destruction and modification of habitat and a concomitant curtailment in the species' range. Although implementation of the Conservation Strategy is underway, the population and habitat levels specified have not yet been attained (Fuller and Tur 2015, p. 18). Consequently, despite previous and ongoing conservation actions, we conclude that the destruction, modification, or curtailment of the New England cottontail's range continues to be a threat. In the Policy for the Evaluation of Conservation Efforts Analysis section below we further evaluate the Conservation Strategy to determine if the threat is expected to persist into the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Recreational Hunting

The New England cottontail is considered a small game animal by the northeastern States' wildlife agencies. It is legally hunted within season and with bag limitations in four of the six States known to have extant populations: New York, Connecticut, Massachusetts, and Rhode Island. Maine closed its cottontail season in 2004, and it remains closed (MEDIFW 2004, MEDIFW 2015). New Hampshire has modified its hunting regulations to prohibit the take of cottontails in those portions of the State where the New England cottontail is known to occur (NHFG 2004, NHFG 2015).

One turn-of-the-century account relative to hunting New England cottontails (Fisher 1898, p. 198) states that ''although hundreds are killed every winter nevertheless they appear to be just as common at the present time as 20 years ago.'' Tracy (1995, p. 12) reported extensive hunting as a possible cause for the lack of cottontails at one Connecticut site, but provided no supporting data.

Carlton *et al.* (2000, p. 46) suggest that overhunting of New England cottontails led to their decline in the mid-20th century, and that this decline indirectly contributed to the deleterious introduction of eastern cottontails by hunters seeking to compensate for the lost opportunity to hunt rabbits. The Service concurs that the introduction of eastern cottontails, a nonnative competitor, has been a factor in the decline of New England cottontail populations (see Factor C below) because eastern cottontails are now the predominant rabbit throughout all of the former range of the New England cottontail, except southern Maine. The prevailing view indicates the primary determinant of cottontail abundance is habitat (Chapman *et al.* 1982, p. 114). Available evidence suggests that habitat loss through forest maturation and other causes (Jackson 1973, p. 21; Brooks and Birch 1988, p. 85; Litvaitis *et al.* 1999, p. 101), rather than hunting pressure, was the primary reason for the decline of New England cottontail populations in the mid-20th century.

Although hunting of New England cottontails occurs, hunting pressure is low relative to the overall abundance of eastern and New England cottontails and not a significant source of mortality compared to other factors. State wildlife biologists postulate that hunting has a minimal effect on the New England cottontail population in those States where hunting is legal (Parker, *in litt.* 2004; Stolgitis, *in litt.* 2000; Scarpitti and Piche, *in litt.* 2014; Tefft *et al., in. litt.* 2014; Kilpatrick *et al., in litt.* 2014, Novak *et al., in litt.* 2014). Most States now have fewer rabbit and other small game hunters than in earlier decades (S. Cabrera, *in litt.* 2003; J. Organ, *in litt.* 2002; U.S. Department of the Interior and U.S. Department of Commerce 2002), and the New England cottontail is not the rabbit species harvested by most small game hunters. For example, in a 54-month study of eastern and New England cottontails in Connecticut, approximately 87 percent of the 375 rabbits killed by hunters and examined by the State were identified as eastern cottontails, and approximately 13 percent were New England cottontails (adapted from Goodie *et al.* 2005, p. 4 and Table 2). Similarly, in Rhode Island, most rabbit hunting occurs on farm lands, where the eastern cottontail is most often the targeted species and New England cottontails are absent (Stolgitis, *in litt.* 2000; Tefft *et al., in litt.* 2014). In a New Hampshire study prior to the closing of cottontail hunting, of 50 collared New England cottontails

monitored, only 1 was taken by a hunter (J. Litvaitis, *pers. comm.,* 2000).

In addition to level of hunter effort, the New England cottontail's behavior also influences its risk of exposure to hunting mortality. For example, New England cottontails forage within or close to dense cover (Smith and Litvaitis 2000, p. 2134), and typically hold in safe areas when disturbed. They also tend to remain in dense habitat and are, therefore, not as easily run by hounds and taken by hunters as eastern cottontails or snowshoe hares (Kilpatrick *et al., in litt.* 2014). Research shows that New England cottontails are more vulnerable to mortality from predation in smaller patches of habitat than in larger ones (Barbour and Litvaitis 1993, p. 321). This pattern may hold true for hunting mortality as well because rabbits on small patches eventually exploit food available in the best cover, and venture farther from shelter to feed where there is less escape cover in which to hide.

Pest Management

Rabbits may be regarded as pests and killed by gardeners and farmers. However, because of differences in habitat preference of the two cottontail species, most farmers and homeowners are more likely to encounter eastern cottontails, which occur in the more open habitats of farms and residential lawns, than New England cottontails. Therefore, targeted pest management of rabbits is unlikely to be a significant source of mortality of New England cottontails.

In summary, based on the best available information, we concur with Litvaitis' (1993a, p. 11) previous assessment that hunting restrictions or other nonhabitat-based management will likely have no influence on current or future populations of the species, and we conclude that current hunting pressure is a stressor for only a very limited number of individual New England cottontails and does not appear to be a significant mortality factor or threat for the species as a whole. While the best available information indicates the hunting is not a threat now or likely to be in the future, should the New England cottontail's population decline to substantially low levels in the future such that the viability of individual animals become substantially important to the species as a whole, the current stressor of hunting mortality may rise to the level of a threat. In addition, we have no information to indicate that pest management actions are affecting New England cottontails.

Conservation Efforts To Reduce Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

As discussed above, New Hampshire does not allow cottontail hunting in areas where the New England cottontail is known to occur, and Maine does not allow cottontail hunting at all. We are unaware of any other conservation efforts to eliminate the very limited hunting mortality occurring in the species' range. However, as discussed above, increasing habitat patch size (Factor A) may further reduce the limited exposure that individual New England cottontails have to hunting mortality.

Summary of Factor B—We conclude based on the best scientific and commercial information available that overutilization for commercial, recreational, scientific, or educational purposes does not currently pose a threat to the New England cottontail, nor is it likely to become a threat in the future.

Factor C. Disease or Predation

Disease

Cottontails are known to contract a number of different diseases, such as tularemia, and are naturally afflicted with both ectoparasites such as ticks, mites, and fleas and endoparasites such as tapeworms and nematodes (Eabry 1968, pp. 14–15). Disease has been attributed to population declines in rabbits over numerous areas (Nelson 1909, p. 35); however, there is little evidence to suggest disease is currently a limiting factor for the New England cottontail. DeVos *et al.* (1956) *in* Eabry (1983, p. 15) stated that the introduced eastern cottontail on the Massachusetts islands of Nantucket and Martha's Vineyard probably competed with the native New England cottontail and introduced tularemia to the islands. However, it is not known whether tularemia played a role in the disappearance of New England cottontail from the islands. Chapman and Ceballos (1990, p. 96) do not identify disease as an important factor in the dynamics of contemporary cottontail populations. Rather, they indicate that habitat is key to cottontail abundance and that populations are regulated through mortality and dispersal (see the Life History and Factor A sections above for further discussion regarding the importance of habitat).

Three efforts are currently underway involving research and monitoring of disease and parasites in the New England cottontail. First, wild New England cottontails obtained as breeding stock for the captive-breeding effort at the Roger Williams Park Zoo in Providence, Rhode Island, receive a complete veterinary exam (Fuller and Tur 2015, p. 50). Additionally, researchers at Brown University are studying the disease ecology of New England and eastern cottontails (Smith, *in litt.* 2014). And lastly, in New York, researchers are studying parasites (Fuller and Tur 2015, p. 54). To date, no incidences of disease or parasites have been reported from these three monitoring efforts or from other sources. The best available information indicates that disease is not a threat to the New England cottontail.

Predation

Brown and Litvaitis (1995, p. 1007) found that mammalian predators accounted for the loss of 17 of 40 New England cottontails in their study. Barbour and Litvaitis (1993, p. 325) determined that coyotes (*Canis latrans*) and red foxes were the primary predators of New England cottontails in New Hampshire. Coyotes first appeared in New Hampshire and Maine in the 1930s, in Vermont in the 1940s, and in southern New England in the 1950s (Foster *et al.* 2002, p. 1348; DeGraaf and Yamasaki 2001, p. 341). Since then, coyote populations have increased throughout the Northeast (Foster *et al.* 2002, p. 1348; Litvaitis and Harrison 1989, p. 1180), and they even occur on many offshore islands. Further, coyotes have become especially abundant in human-dominated habitats (Oehler and Litvaitis 1996, p. 2070). Litvaitis *et al.* (1984, p. 632) noted that cottontails were a major prey of bobcats (*Felis rufus*) in New Hampshire during the 1950s, and were recorded in the stomachs of 43 percent of the bobcats examined; later, it was determined that the cottontails found in the bobcat study were most likely all New England cottontails (Litvaitis, *in litt.* 2005). In addition to coyotes and bobcats, other mammalian predators of cottontail rabbits in New England include weasels (*Mustela sp.*) and fishers (*Martes pennanti*). Avian predation is also considered a source of mortality for New England cottontails (Smith and Litvaitis 1999, p. 2136), and both barred owls (*Strix varia*) and great horned owls (*Bubo virginianus*) took cottontails in a New Hampshire study, where an enclosure prevented losses to mammalian predators. Litvaitis *et al.* (2008, p. 180) conclude that the abundance of hunting perches for red-tailed hawks (*Buteo jamaicensis*) and other raptors reduces the quality of

habitat afforded cottontails along power lines.

Winter severity, measured by persistence of snow cover, is believed to affect New England cottontail survival because it increases the rabbits' vulnerability to predation, particularly in low-quality habitat patches (Brown and Litvaitis 1995, pp. 1005–1011). Compared to snowshoe hares, New England cottontails have proportionately heavier foot loading (*i.e.,* feet sink farther into the snow) and do not turn white in winter (pelage color contrasts with snow making the species more visible to predators). Villafuerte *et al.* (1997, p. 151) found that snow cover reduces the availability of high-quality foods, and likely results in rabbits becoming weakened nutritionally. In a weakened state, rabbits are more vulnerable to predation. Brown and Litvaitis (1995, pp. 1005–1011) found that, during winters with prolonged snow cover, a greater proportion of the cottontails in their study were killed by predators. Eighty-five percent of the current occurrences of the New England cottontail are within 50 miles of the coast, and 100 percent are within 75 miles of the coast. Litvaitis and Johnson (2002, p. 21) hypothesize that snow cover may explain this largely coastal distribution of this species in the Northeast (generally less snow falls and fewer snow cover days occur in coastal versus interior areas) and may be an important factor defining the northern limit of its range. The preceding studies suggest that a stochastic event, such as a winter or consecutive winters with unusually persistent snowfall (see Factor E—Climate Change), will reduce the number and distribution of New England cottontails due to predation. This effect would not have been a concern under historical conditions. However, with the current level of habitat fragmentation and the number of small patches of habitat (Factor A), coupled with vulnerability to predation in these small patches, winter severity could affect the persistence of local populations and could contribute to further reductions in the range of the species.

New England cottontails are known or expected to be killed by domestic dogs (*Canis familiaris*) and cats (*Felis catus*) (Walter *et al.* 2001, p. 17; Litvaitis and Jakubas 2004, p. 15; Kays and DeWan 2004, p. 4). The significance of the domestic cat as a predator on numerous species is well known (Coleman *et al.* 1997, pp. 1–8). The domestic cat has been identified as a significant predator of the endangered Lower Keys marsh rabbit (*Sylvilagus palustris hefneri*), and is considered the single biggest threat to the recovery of that species (Forys and Humphrey 1999, p. 251). According to the American Veterinary Medical Association (2002), cats occur in 31.6 percent of homes in the United States, and the average number of cats per household is 2.1. We do not have direct evidence regarding the role of domestic cats in influencing New England cottontail populations; however, Rhode Island biologists hypothesize that cats may be a threat to New England cottontails in that State (Tefft *et. al., in litt.* 2014). Given the high human population and housing densities found throughout the range of the New England cottontail, the domestic cat may be a predator of the species, though the lack of specific information makes it impossible to determine the extent of the possible predation.

Predation is a natural source of mortality for all rabbits. Under historical circumstances predation would not have been a factor that posed a risk to the New England cottontail's survival. However, the majority of present-day thicket habitats supporting New England cottontails are of an insufficient size to provide adequate cover and food to sustain the species' populations amid high predation rates from today's more diverse set of natural and human-induced mid-sized carnivores (Brown and Litvaitis 1995, pp. 1005–1011; Villafuerte *et al.* 1997, pp. 148–149).

The best available information suggests that land use patterns influence predation rates and New England cottontail survival in several ways. Brown and Litvaitis (1995, pp. 1005–1011) compared the survival of transmitter-equipped New England cottontails with habitat features in surrounding habitat patches. They found that the extent of developed lands, coniferous cover, and lack of surface water features were associated with an increase in predation rates. In addition, Oehler and Litvaitis (1996, pp. 2070–2079) examined the effects of contemporary land uses on the abundance of coyotes and foxes and concluded that the abundance of these generalist predators doubled as forest cover decreased and agricultural land use increased. Thus, the populations of predators on the New England cottontail increased substantially at the times prior to the regeneration of agricultural and other lands to more mature forests, which further depressed New England cottontail populations.

The abundance of food and risk of predation are highly influential in determining the persistence of small- and medium-sized vertebrates such as the New England cottontail. Barbour and Litvaitis (1993, pp. 321–327) found that, as food in the most secure areas was depleted, New England cottontails were forced to utilize lower quality forage or feed farther from cover where the risk of predation was greater and that, as a result, New England cottontails on small patches of habitat were killed at twice the rates and earlier in winter than cottontails on larger habitat patches. Furthermore, Villafuerte *et al.*'s (1997, pp. 149–150) study of New England cottontail urea nitrogen:creatinine ratios demonstrated that New England cottontails on small patches exhibited reduced ratios that were indicative of nutrient deprivation and that may have led individuals to forage in suboptimal cover where they experienced higher predation rates than individuals occupying larger patches (Villafuerte *et al.* 1997, pp. 149–150). Villafuerte *et al.* (1997, p. 151) concluded that forage limitations imposed by habitat fragmentation determine the viability of local populations of New England cottontails by influencing their vulnerability to predation.

Thus, as landscapes become more fragmented, vulnerability of New England cottontails to predation increases not only because there are more predators, but also because cottontail habitat quantity and quality (forage and escape cover) are reduced (Smith and Litvaitis 2000, pp. 2134–2140). Individuals on larger patches were less vulnerable to predation; therefore, large patches of habitat may be essential for sustaining populations of this species in a human-altered landscape.

Conservation Efforts To Reduce Disease or Predation

As discussed above, disease is not known to be a threat to the New England cottontail. Therefore, no conservation measures to manage disease have been planned or implemented (Fuller and Tur 2012, p. 55). Nevertheless, as described above, three conservation efforts are underway to monitor and investigate new instances of disease should they occur within the species.

Predation is considered to be a stressor, in that small New England cottontail populations occupying landscapes containing insufficient amounts of high-quality habitat are particularly vulnerable. Currently, there are no efforts in place to suppress predator numbers to increase New England cottontail survival (Fuller and Tur 2012, p. 65; Boland *et al., in litt.* 2014; Holman *et al., in litt.* 2014; Scarpitti and Piche, *in litt.* 2014; Tefft *et*

al., in litt. 2014; Kilpatrick *et al., in litt.* 2014; Novak *et al., in litt.* 2014). Instead, conservation efforts to increase habitat availability, as described in the Conservation Actions to Reduce Habitat Destruction, Modification, or Curtailment of Its Range section above, are being implemented that indirectly reduce New England cottontail vulnerability to predation.

Summary of Factor C—Disease does not appear to be an important factor affecting New England cottontail populations and is not considered a threat to the species, nor is it expected to become a threat in the future. Predation is a routine aspect of the life history of most species, and under natural conditions (*i.e.,* prior to settlement by Europeans in the Northeast and the substantial habitat alteration that has followed) predation was likely not a threat to the persistence of the New England cottontail. Today, however, the diversity of predators has increased, the amount of suitable cottontail habitat has decreased, and the remaining habitat is highly fragmented with remnant habitat patches often small in size. The best available information strongly suggests that most cottontails occupying small habitat patches will be killed by predators, as few rabbits that disperse into or are born in those areas live long enough to breed; thus, most small thicket habitat patches are unoccupied by cottontails. Since predation is strongly influenced by habitat quantity and quality, we conclude that the primary threat to the species is the present destruction, modification, and curtailment of its habitat and range (Factor A), and that predation is a contributing threat to the New England cottontail's viability. In the Policy for the Evaluation of Conservation Efforts Analysis section below we further evaluate the Conservation Strategy to determine if the threat of predation is expected to persist into the future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

There are only limited regulatory mechanisms available to address the destruction or modification of New England cottontail habitat, especially on private lands. Local governments regulate development through zoning ordinances; we are unaware of any locally developed regulatory mechanisms that specifically address threats to New England cottontail habitat. Some New England cottontail occurrences are associated with sites that contain or are adjacent to riparian vegetation, such as borders of lakes, beaver wetlands, and rivers. However, the New England cottontail is primarily an upland, terrestrial species that sometimes occurs along the margins of these wetland types. Federal and State laws, such as section 404 of the Clean Water Act of 1972 (86 Stat. 816) and Maine's Natural Resources Protection Act (Title 38, section 435–449), that provide protection to wetlands and upland buffers offer protection to only a small number of New England cottontail occurrences.

State wildlife agencies in the Northeast have the authority to regulate hunting of the New England cottontail by setting hunting seasons and bag limits. However, most northeastern States cannot restrict the take of New England cottontails without also reducing hunting opportunities for the eastern cottontail, a common species, because the two species are similar in appearance and cannot be easily distinguished at a distance, and sometimes occur within the same habitat patches (Walter *et al.* 2001, p. 21). In Maine, where the only cottontail species is the New England cottontail, cottontail hunting has been prohibited since 2004 (MEDIFW 2004; MEDIFW 2014). In recognition of the declining status of the New England cottontail, New Hampshire similarly closed the eastern cottontail hunting season in 2004/2005 in those portions of the State where New England cottontails are known to occur, and it has remained closed (NHFG 2004; NHFG 2014). Harvest of New England cottontail is legal in Massachusetts, Rhode Island, Connecticut, and New York (see discussion under Factor B). Under Factor B, above, we concluded that hunting, by itself, is not a threat to the New England cottontail at the species level, but may be a concern for small localized populations where hunting mortality may contribute to further declines in those areas.

The New England cottontail is currently listed under State endangered species laws in Maine and New Hampshire (Boland *et al., in litt.* 2014; Holman *et al., in litt.* 2014). No other State currently lists the New England cottontail as a threatened or endangered species. The Endangered Species Conservation Act (ESCA) of New Hampshire prohibits the export, take, and possession of State species that have been identified as endangered or threatened (Revised Statutes Annotated [RSA] 212–A:7). However, the executive director of NHFGD may permit certain activities, including those that enhance the survival of the species. Penalties for violations of RSA 212–A:7 of the ESCA are identified (RSA 212–A:10, II). The Maine Endangered Species Act (MESA) prohibits the export, take, and possession of State species that have been identified as endangered or threatened (12 MRS sections 12801–12810). Under MESA's endangered designation, the State agencies have the ability to review projects that are carried out or funded by State and Federal agencies and assess those projects for effects to the New England cottontail. In some cases, projects may be modified or mitigated to ensure that deleterious effects to the New England cottontail are minimized. However, the existing statutes cannot require the creation and maintenance of suitable habitat at the spatial scales described under Factor A; consequently, the loss of habitat due to natural forest succession is likely to proceed.

Since the State listing of the species, the distribution of the New England cottontail has continued to decline in Maine (Fenderson 2010, p. 104), while in New Hampshire the distribution declined, but is now improving at some locations where active management is occurring (Fenderson 2014, p. 12; H. Holman, *pers. comm.,* 2015). This slight improvement, however, is likely attributed to implementation of voluntary conservation measures to improve habitat and population augmentation efforts described under Factor A (H. Holman, *pers. comm.,* 2015), and not to regulatory processes. The New England cottontail has been identified as a ''Species of Greatest Conservation Concern'' (SGCN) in all seven State Comprehensive Conservation Strategies throughout the species' historical and current range. Species of Greatest Conservation Concern are defined as species that are rare or imperiled or whose status is unknown. As a result, the New England cottontail is receiving additional attention by State managers. For example, New Hampshire suggests development of early successional habitat networks in landscapes currently occupied by the species (*http://www.wildlife.state.nh.us/Wildlife/wildlife_plan.htm* (accessed March 2015)). However, the identification of the New England cottontail as an SGCN is intended to convey concern so as to draw conservation attention to the species and provides no regulatory function.

Conservation Efforts To Increase Adequacy of Existing Regulations

While there are conservation efforts to raise awareness of the species' habitat needs, these are not regulatory in nature. We are unaware of any ongoing conservation efforts to increase the

adequacy of existing regulatory mechanisms.

Summary of Factor D—We conclude that the best available information indicates hunting is not a limiting factor for the species and the existing regulatory mechanism to control the legal take of New England cottontails through hunting is adequate. Conversely, we are unaware of any locally developed regulatory mechanisms, such as local zoning ordinances, specifically designed to address the threat of habitat destruction, modification, or curtailment for this species. While we cannot consider non-regulatory mechanisms here under Factor D, we acknowledge in Factor A above and the Policy for the Evaluation of Conservation Efforts section below that the threat of habitat destruction, modification, or curtailment is being managed now and is likely to continue to be managed into the future.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Competition

The eastern cottontail was released into much of the range of the New England cottontail, and the introduction and spread of eastern cottontails have been a factor in reducing the range and distribution of the New England cottontail. Prior to their introduction, the eastern cottontail extended northeast only as far as the lower Hudson Valley (Bangs 1894, p. 412). By 1899, tens of thousands of individuals of four or five different subspecies of the eastern cottontail were introduced to the New England cottontail's range, beginning on Nantucket Island, Massachusetts (Johnston 1972, p. 3). By the 1930s, eastern cottontails were known to occur in western Connecticut (Goodwin 1932, p. 38), most likely as a result of introductions (Hosley 1942, p 18). Large-scale introductions of eastern cottontails to New Hampshire (Silver 1957, p. 320), Rhode Island (Johnston 1972, p. 6), Massachusetts (Johnston 1972, pp. 4–5), and possibly Vermont (Kilpatrick, *in litt.* 2002) have firmly established the eastern cottontail throughout most of New England where it remains common. The exception is Maine, where the New England cottontail remains the only *Sylvilagus* species (Litvaitis et al. 2006, p. 1193; Boland *et al., in litt.* 2014; Kilpatrick *et al., in litt.* 2014; Tefft *et al., in litt.* 2014; Novak *et al., in litt.* 2014).

The eastern cottontail is larger (1,300 gm (2.9 lb)) than the New England cottontail (Chapman and Ceballos 1990, p. 96). Probert and Litvaitis (1996, p. 289) found that eastern cottontails, though larger, were not physically dominant over New England cottontails and concluded that interference competition did not explain the change in the distribution and abundance of the latter. In a follow-up investigation, Smith and Litvaitis (2000, entire) assessed winter foraging strategies used by the two species by monitoring the response of eastern and New England cottontails to variations in food and cover within large enclosures. Smith and Litvaitis (2000, p. 239) found that the eastern cottontail was able to maintain physical condition when food resources in cover were low by venturing into open areas to feed from feeders supplied with commercially available rabbit forage. In contrast, New England cottontails were reluctant to venture into open areas to exploit these resources, and their physical condition declined (Smith and Litvaitis 2000, p. 2138). Smith and Litvaitis (2000, pp. 2138–2139) also found that when New England cottontails did venture into open areas for forage, they experienced higher rates of predation by owls than did eastern cottontails.

Smith and Litvaitis (2000, p. 2139) suggest that the increased survival of eastern cottontails foraging in low cover areas is made possible by their enhanced predator detection ability. In a companion study, Smith and Litvaitis (1999, p. 57) reported that the eastern cottontail had a larger exposed surface area of the eye and consequently had a greater reaction distance to a simulated owl than did New England cottontails. Consequently, eastern cottontails have the ability to use a wider range of habitats, including relatively open areas such as meadows and residential back yards, compared to the New England cottontail, and may be able to exploit newly created habitats sooner than New England cottontails (Litvaitis *et al.* 2008).

In addition to the morphological and behavioral differences between the two species, there are important physiological differences that may influence competition between the two species. Tracy (1995, pp. 65–67) compared the metabolic physiology of the two species and found that the eastern cottontail had a significantly higher basal metabolism (the amount of energy expended while at rest). Based on the findings, Tracy (1995, pp. 68–75) suggested that the difference in metabolic rate may confer a competitive advantage on eastern cottontails, by affording eastern cottontails an increased reproductive capacity and predator avoidance capability, and to displace the New England cottontail from areas containing high quality food resources. Conversely, eastern cottontails may be unable to meet their metabolic demands in habitats characterized by relatively nutrient poor food resources such as ericaceous (related to the heath family) forests, whereas the New England cottontail may be able to persist. The ability to maintain winter body condition while occupying small habitat patches may be the reason the eastern cottontail is more fecund (capable of producing offspring) than the New England cottontail (Chapman and Ceballos 1990, p. 96) and the reason eastern cottontails, once established, are not readily displaced by New England cottontails (Probert and Litvaitis 1996, p. 292).

The competitive advantage of eastern cottontails, however, may be lost in nutrient-deficient sites, such as in pine barrens and ericaceous shrublands, where resources to meet the higher energy demands of this species are lacking but may be adequate to support the resource needs of the New England cottontail (Tracy 1995, p. 69). These nutrient-deficient sites are relatively stable and persistent through time in comparison to other disturbance-generated habitats, such as young forests. Litvaitis et al. (2008, p 176) suggested that relatively stable shrublands may allow New England cottontails to coexist with eastern cottontails. This ability to persist in stable habitats may explain why habitats occupied by the New England cottontail in Connecticut are characterized by greater canopy cover and basal area than sites occupied by eastern cottontails (Gottfried 2013, p. 18).

Throughout most of the New England cottontail's range, conservationists consider the presence of eastern cottontails among the most substantial conservation issues to be addressed if efforts to restore the New England cottontail are to be successful (Probert and Litvaitis 1996, p. 294; Fuller and Tur 2012, p. 20; Scarpitti and Piche, *in litt.* 2014; Tefft *et al., in litt.* 2014; Kilpatrick *et al., in litt.* 2014; Novak *et al., in litt.* 2014). Uncertainty remains, however, regarding the best approaches to managing New England and eastern cottontail populations to ensure that the former persists (Fuller and Tur 2012, pp. 20–21). The best available information strongly suggests that competition with eastern cottontails has been a factor in the decline of the New England cottontail and that the effect is greatest in landscapes comprising small habitat patches. Therefore, we conclude that the primary threat to the species is the present destruction, modification, and curtailment of its habitat and range

(Factor A), and that competition with eastern cottontails is a contributing threat to the New England cottontail's viability.

White-Tailed Deer Herbivory

In our previous CNORs (71 FR 53756; 72 FR 69034), we concluded that competition with, and habitat degradation by, white-tailed deer (*Odocoileus virginianus*) may be a risk factor to the New England cottontail as a result of the deer's effect on forest regeneration. This earlier conclusion was based on the white-tailed deer's high population densities (J. McDonald, *in litt.* 2005), their similar food habits to cottontails (Martin *et al.* 1951, pp. 241–242, 268–270), and their documented negative direct and indirect effects on forest vegetation in many areas of the eastern United States (Latham *et al.* 2005, pp. 66–69, 104; deCalesta 1994, pp. 711–718). While it was reasonable to conclude at the time that white-tailed deer may be competing with New England cottontail for food because the two species overlapped in areas of occurrence and it was the best available information, we had no direct evidence that deer herbivory was having an actual effect on New England cottontail. Since then, we requested specific information from State wildlife agencies indicating that the presence of deer is affecting the status of the New England cottontail. The State wildlife agencies responded that they had no information indicating deer herbivory was affecting New England cottontail (Boland *et al., in litt.* 2014; Holman *et al., in litt.* 2014; Scarpitti and Piche, *in litt.* 2014; Tefft *et al., in litt.* 2014; Kilpatrick *et al., in litt.* 2014; Novak *et al., in litt.* 2014). Furthermore, we have no such information from any other source that this one-time potential risk factor is presently having negative effects on New England cottontail. Consequently, lacking direct evidence that herbivory by white-tailed deer is currently compromising habitat quality and quantity for the New England cottontail, we conclude that excessive herbivory by white-tailed deer is currently not a threat to the species.

Road Mortality

State wildlife agencies report that road kills are an important source for obtaining specimens of rabbits, including the New England cottontail. Road-killed rabbits were second only to hunting mortality as a source for cottontail specimens for a distributional study in Connecticut: Of 108 cottontail specimens obtained, 3 were identified as New England cottontails (Walter *et al.* 2001, pp. 13–19). Although road mortality does result in the death of a few individuals, New England cottontail populations are not considered to be significantly affected by vehicular mortality (Boland *et al., in litt.* 2014; Holman *et al., in litt.* 2014; Scarpitti and Piche, *in litt.* 2014; Tefft *et al., in. litt.* 2014; Kilpatrick *et al., in litt.* 2014; Novak *et al., in litt.* 2014).

Small Population Size

As provided in the Life History section, extant populations of New England cottontails are believed to function as metapopulations with local extinction events likely the result of demographic, environmental, and genetic stochasticity. Existing populations in Maine likely contain fewer than 700 individuals scattered across four separate areas (Boland *et al., in litt.* 2014). Similarly, in New Hampshire the current population is thought to contain fewer than 200 individuals located within two distinct areas (Holman *et al., in litt.* 2014). As a consequence of habitat fragmentation and loss, these populations exhibit the effects of small population size, as evidenced by the presence of genetic drift (change in the frequency of alleles (gene variants) in a population due to random sampling of individuals) and critically low effective population sizes (number of individuals who contribute offspring to the next generation) (Fenderson *et al.* 2014, entire). For these populations, Fenderson *et al.* (2014, p. 17) suggested that habitat creation alone may be insufficient to improve their status and that translocations may be necessary to augment existing populations. The effect of small population size is likely exhibited in Rhode Island's remaining population, since current estimates indicate that there are fewer than 100 individuals within the State (Tefft *et al., in litt.* 2014). In the remainder of the New England cottontail's range, populations are generally larger and presumed to be less affected by fragmentation (Scarpitti and Piche, *in litt.* 2014; Kilpatrick *et al., in litt.* 2014; Novak *et al., in litt.* 2014); consequently, the effects of small population size are not anticipated to be a significant biological consequence throughout the species' range. However, if the total number of New England cottontail populations continues to decline, the remaining populations may experience the deleterious effects of small population size.

Climate Change

Our analyses under the Act include consideration of observed or likely environmental effects related to ongoing and projected changes in climate. As defined by the Intergovernmental Panel on Climate Change (IPCC), ''climate'' refers to average weather, typically measured in terms of the mean and variability of temperature, precipitation, or other relevant properties over time, and ''climate change'' thus refers to a change in such a measure that persists for an extended period, typically decades or longer, due to natural conditions (*e.g.,* solar cycles) or human-caused changes in the composition of the atmosphere or in land use (IPCC 2013, p. 1450). Detailed explanations of global climate change and examples of various observed and projected changes and associated effects and risks at the global level are provided in reports issued by the IPCC (2014 and citations therein); information for the United States at national and regional levels is summarized in the National Climate Assessment (Melillo *et al.* 2014 entire and citations therein; see Melillo *et al.* 2014, pp. 28–45 for an overview). Because observed and projected changes in climate at regional and local levels vary from global average conditions, rather than using global-scale projections we use ''downscaled'' projections when they are available and have been developed through appropriate scientific procedures, because such projections provide higher resolution information that is more relevant to spatial scales used for analyses of a given species and the conditions influencing it (see Melillo *et al.* 2014, Appendix 3, pp. 760–763 for a discussion of climate modeling, including downscaling). In our analysis, we use our expert judgment to weigh the best scientific and commercial information available in our consideration of relevant aspects of climate change and related effects.

Downscaled climate change models for the Northeastern United States (Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, and Pennsylvania) indicate that temperatures will increase in the future, more so in summer than in winter (Hayhoe *et al.* 2008, p. 433). Overall, the region is expected to become drier overall, but average seasonal precipitation is expected to shift toward winter increases of 20 to 30 percent with slightly drier summers (Hayhoe *et al.* 2008, p. 433). Variations across the region are also expected, with northern portions of the region drying out more than southern areas, with a ''hot spot'' developing over coastal southern Maine (Hayhoe *et al.* 2008, p. 433). Although the New England cottontail is a habitat specialist that is reliant upon dense

shrublands (see Life History section), sites occupied by the species are variable and range from droughty (*e.g.,* pitch pine-scrub oak) to wet (*e.g.,* shrub wetlands). Given the range of habitats occupied by the species, predicting the effects of climate change is complicated.

Climate change is anticipated to alter the frequency, intensity, duration, and timing of forest disturbance (Dale *et al.* 2001, entire), which is likely to positively influence habitat for the species. Climate change is also expected to affect invasive species disproportionately to native species (Hellmann *et al.* 2008, entire), which is likely to influence the distribution and abundance of the eastern cottontail, as well as those habitats comprising exotic invasive shrubs (*e.g., Rosa multiflora* and *Lonicera spp.*), and, therefore, may affect the New England cottontail. Consequently, accurately predicting climate change effects to the New England cottontail is not easily disentangled. That said, the bioclimatic envelope (species distribution as predicted by climate) for the New England cottontail is predicted to increase by 110 percent by the end of the century and shift approximately 1 degree poleward (Leach *et al.* 2014, p. 126), which suggests that the species' distribution may increase with climate change.

Conservation Efforts To Reduce Other Natural or Manmade Factors Affecting Its Continued Existence

Competition

As previously described under Conservation Actions to Reduce Habitat Destruction, Modification, or Curtailment of Its Range, there are many previous and ongoing conservation efforts to increase and maintain suitable habitat. Increased habitat patch size and connectivity will reduce the effects of eastern cottontail competition. However, there remain uncertainties regarding the best approaches to managing sympatric populations; therefore, research and monitoring has been identified as a top-priority need to address the conservation needs of the New England cottontail (Fuller and Tur 2012, pp. 20, 53, 77–80, 114–120). For example, a study to determine the efficacy and benefits of managing eastern cottontails for the benefit of the New England cottontail is underway, and the results will be integrated into the Conservation Strategy's adaptive management process so that it may inform future management actions (Tur and Eaton, *in litt.* 2013; Fuller and Tur 2012, p. 114) (see the Policy for the Evaluation of Conservation Efforts Analysis section below for additional information).

Small Population Size

To address the threat of small population size, the Conservation Strategy identifies the need for specific population management objectives, including captive breeding and relocation of New England cottontails (Fuller and Tur 2012, p. 61–67), which is further corroborated by Fenderson *et al.* (2014, entire) for populations in New Hampshire and Maine. A captive-breeding pilot program has been initiated at the Roger Williams Park Zoo (RWPZ) to evaluate and refine husbandry, captive propagation, and reintroduction protocols for the New England cottontail. A Technical Committee Captive-breeding Working Group facilitates and monitors implementation of this conservation tool. Since 2011, approximately 131 young have been produced at the RWPZ, and individually marked New England cottontails are released at sites in Rhode Island and New Hampshire (Fuller and Tur 2015, pp. 49–53). Success of these efforts is indicated by the presence of unmarked animals, which suggests that released animals are successfully breeding (Fuller and Tur 2015, pp. 51–52).

Through these efforts, populations of New England cottontails may be increasing and less susceptible to demographic and environmental stochastic events. Since these introductions involve the descendants from numerous geographic areas (Perrotti, *in litt.* 2014), we anticipate that genetic drift has been ameliorated and the possibility of genetic stochasticity affecting remnant populations in Rhode Island and New Hampshire has been reduced or eliminated. Nevertheless, genetic monitoring to determine the genetic health of these populations will be conducted (Fuller and Tur 2012, p. 54) (see the Policy for the Evaluation of Conservation Efforts Analysis section below). In contrast, plans to implement population augmentation in Maine may not occur until 2030 (Boland *et al., in litt.* 2014). Given the critically low effective population sizes in Maine, however, habitat creation alone may be insufficient (Fenderson *et al.* 2014, p. 17).

Summary of Factor E—In summary, habitat modification resulting from high densities of white-tailed deer was once thought to be a threat to the New England cottontail, but is no longer a concern. The best available information indicates that climate change and road mortality are not threats: In fact, climate change may benefit the species. Eastern cottontails compete with New England cottontails for food and space and may be suppressing New England cottontail populations. Since the effects of small population size and competition with eastern cottontails are inextricably linked to habitat quality, quantity, and connectivity, we conclude that the primary threat to the species throughout most of its range is the present destruction, modification, and curtailment of its habitat and range (Factor A), and that small population size is a contributing threat to the New England cottontail's viability. In the Policy for the Evaluation of Conservation Efforts Analysis section below we further evaluate the Conservation Strategy to determine if the threat of small population size and eastern cottontails is expected to persist into the future, as required by section 4(b)(1)(A) of the Act.

Cumulative Effects From Factors A Through E

As discussed above, habitat loss (Factor A) is the most significant threat to the New England cottontail. This directly affects the species through insufficient resources to feed, breed, and shelter and indirectly affects the species by amplifying the effects of predation (Factor C), competition with eastern cottontails (Factor E), and small population size (Factor E). In our analysis of these threats, we discussed previous and ongoing conservation efforts addressing these rangewide threats, which will be further analyzed in the Policy for the Evaluation of Conservation Efforts Analysis section below.

Policy for Evaluation of Conservation Efforts Analysis

As presented in the Summary of Information Pertaining to the Five Factors above, section 4(b)(1)(A) of the Act and our regulations at 50 CFR 424.119(f) require us to consider efforts by any State, foreign nation, or political subdivision of a State or foreign nation to protect the species. Such efforts would include measures by Native American Tribes and organizations. Also, Federal, Tribal, State, and foreign recovery actions (16 U.S.C. 1533(f)) and Federal consultation requirements (16 U.S.C. 1536) constitute conservation measures.

In addition to identifying such efforts under the Act and our policy implementing this provision, known as the Policy for Evaluation of Conservation Efforts (PECE) (68 FR 15100; March 28, 2003), we must, at the time of the listing determination,

evaluate whether formalized conservation efforts provide sufficient certainty of effectiveness on the basis of whether the effort or plan establishes specific conservation objectives; identifies the necessary steps to reduce threats or factors for decline; includes quantifiable performance measures for the monitoring of compliance and effectiveness; incorporates the principles of adaptive management; and is likely to improve the species' viability by eliminating or adequately reducing one or more of the threats identified in our section 4(a)(1) analysis. We must also evaluate the conservation efforts to determine the certainty that they will be implemented on the basis of the availability of resources necessary to carry out the effort; the authority of the parties to carry out the identified actions; the regulatory and procedural requirements necessary to carry out the action are in place; the schedule for completing and evaluating the efforts; and the extent of voluntary participation necessary to achieve the conservation goals has been identified and will be secured. The criteria for PECE are not considered comprehensive evaluation criteria for evaluating certainty of the formalized conservation effort, and consideration of species, habitat, location, and effort is provided when it is appropriate. To satisfy the requirements of PECE, conservation plans should, at a minimum, report data on existing populations, describe activities taken toward conservation of the species, demonstrate either through data collection or best available science how these measures will alleviate threats, provide a mechanism to integrate new information (adaptive management), and provide information regarding certainty of implementation.

An integral part of determining whether a species meets the definition of threatened or endangered requires us to analyze a species' risk of extinction. Central to this risk analysis is an assessment of the status of the species (*i.e.,* is it in decline or at risk of decline, and what is the rate of decline or risk of decline) and consideration of the likelihood that current or future conditions or actions will promote or threaten a species' persistence. This determination requires us to make a prediction about the future persistence of a species, including consideration of both future negative and positive effects of anticipated human actions. For formalized conservation efforts that are not fully implemented, or where the results have not been demonstrated, we will consider PECE criteria in our evaluation of whether, and to what extent, the formalized conservation efforts affect the species' status under the Act. The results of our analysis may allow us to conclude that the threats identified in the section 4(a)(1) analysis have been sufficiently reduced or eliminated to such an extent that the species does not meet the definition of threatened or endangered, or is threatened rather than endangered.

An agreement or plan intended to improve a species' status may contain numerous conservation objectives, not all of which are sufficiently certain to be implemented and effective. Those conservation efforts that are not sufficiently certain to be implemented and effective cannot contribute to a determination that listing is unnecessary, or a determination to list as threatened rather than endangered. Further, it is important to note that a conservation plan is not required to have absolute certainty of implementation and effectiveness to contribute to a listing determination. Rather, we need to be certain that the conservation objectives identified within the plan will be implemented and effective, such that the threats to the species are expected to be sufficiently reduced or eliminated. Regardless of the adoption of a conservation agreement or plan, if the best scientific and commercial information indicates that the species meets the definition of endangered or threatened on the day of the listing decision, then we must proceed with appropriate rulemaking under section 4 of the Act.

Because the certainty of implementation and effectiveness of formalized conservation efforts may vary, PECE specifies that each effort will be evaluated individually (68 FR 15114). In the Rangewide Conservation Efforts section above, we introduced the development of a conservation planning effort beginning in 2008, which was later formalized in 2011 and resulted in the development of the Conservation Strategy (Fuller and Tur 2012, entire). This Conservation Strategy represents the Parties' planning process and guides actions intended to improve and maintain populations of New England cottontails throughout the species' current range. There are a number of other formalized actions interrelated to the Conservation Strategy, some of which precede its completion but were integral to its development and implementation. Since these interrelated formalized actions contribute to the overall Conservation Strategy and its goal of addressing the New England cottontail's primary threat—loss of habitat—we conclude that they can be batched as a single conservation effort, and that we are not required to analyze each agreement separately; rather, we briefly describe in our full PECE analysis (available at *http://www.regulations.gov*) those actions, such as the two Candidate Conservation Agreements with Assurances for Maine and New Hampshire, as contributing to the collective effort.

Using the criteria in PECE, we evaluated the degree of certainty to which the Conservation Strategy would be effective at minimizing or eliminating threats to the New England cottontail. Our evaluation was facilitated by a recent report, entitled *New England Cottontail Conservation Progress, 2014 Annual Performance Report* (Fuller and Tur 2015, entire, available at *www.newenglandcottontail.org*), hereafter referred to as the Performance Report. In addition to our review of performance, we assessed the status of the New England cottontail, the specific threats to New England cottontail populations, and conservation actions planned and implemented to address those threats, at the local or Focus Area-specific scale. This information was provided in individual Focus Area Status Screening Templates (FASSTs) that were prepared for most of the Focus Areas identified in the Conservation Strategy (Fuller and Tur 2012, pp. 90–113). We used this information to determine if the conservation actions planned within the Focus Areas would maintain or increase populations to the extent that they might contribute to the goals of the Conservation Strategy. Further, in October 2014, we convened a meeting of the Parties, with facilitation support provided by WMI, to assess the Parties' commitment to implementing the Conservation Strategy and its individual components.

PECE Analysis Summary

Using the criteria in PECE, we evaluated the certainty of implementation and effectiveness of the Conservation Strategy. We have determined that the conservation objectives described therein have a high certainty of being implemented, based on the Parties' previous actions and commitments (Fuller and Tur 2015, entire) and the recent reaffirmation to its continuation (Sparks *et al., in litt.* 2014; Riexinger *et al., in litt.* 2014; Hyatt *et al., in litt.* 2014; Connolly, *in litt.* 2014; MacCallum, *in litt.* 2014; Ellingwood and Kanter, *in litt.* 2014; Weber, *pers. comm.* 2014; Weller, *pers. comm.* 2014). We have determined that the Conservation Strategy provides a high degree of certainty that it will be

effective. This is supported, in part, by the identification of all known threats, the development of actions to ameliorate them, monitoring, and application of the principles of adaptive management. Specifically, we find that the Conservation Strategy presents an effective approach that establishes a network of habitats of sufficient quality and quantity that is likely to compensate for the destruction, modification, and curtailment of the New England cottontail's habitat and range, the primary threat to the species. For example, the Conservation Strategy identifies 3,310 ha (8,179 ac) for land management activities to create, restore, or maintain suitable habitat; these management activities have been planned, initiated or completed and the initiated or completed projects have demonstrated examples of populations that have increased within specific patches (Fuller and Tur 2015, entire). Based on our evaluation of the conservation effort described in the Conservation Strategy and associated documents, we find that the conservation effort provides a high degree of certainty of implementation and effectiveness.

Our full analysis of the New England cottontail conservation effort pursuant to PECE can be found at *http://www.regulations.gov.*

Finding

As required by the Act, we considered the five factors in assessing whether the New England cottontail is endangered or threatened throughout all of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by the New England cottontail. We reviewed the petition, information available in our files, and other available published and unpublished information, and we consulted with recognized species and habitat experts and other Federal, State, and Tribal agencies. Based on our evaluation of the threats to the New England cottontail, we find that the present or threatened destruction, modification, or curtailment of its habitat or range (Factor A) is the most significant threat to the species. This directly affects the species through insufficient resources to feed, breed, and shelter and indirectly affects the species by amplifying the effects of predation (Factor C), competition with eastern cottontails (Factor E), and small population size (Factor E). Without the ongoing and planned implementation of the conservation measures described in the Conservation Strategy, these identified threats would remain at a level that would warrant listing of the New England cottontail.

Thus, we next considered conservation efforts pursuant to section 4(b)(1)(A) of the Act and our regulations at 50 CFR 424.119(f). This consideration includes an evaluation under the PECE policy of those conservation efforts within the Conservation Strategy, including commitments of funding and other resources, that have been implemented and not yet shown to be effective and those actions proposed for the future (see the Policy for the Evaluation of Conservation Efforts Analysis section above). Based on our evaluation of the conservation effort, as described in the Conservation Strategy and associated documents, we find that sufficient certainty of implementation and effectiveness is provided and the conservation effort forms part of the basis for our final listing decision for the New England cottontail. We find those actions taken under the auspices of the Conservation Strategy have yet to completely remove the threats specified above, but have been successful, and are anticipated to be fully successful in the future, in ameliorating the threats. For example, as of January 2015, the NRCS created or maintained approximately 3,700 ac (1,497 ha) of New England cottontail habitat under the Working Lands for Wildlife program (Fuller and Tur 2015, p. 59), and the agency anticipates implementing management actions on additional habitat as part of NRCS' 5-year plan. In addition, the 2,107 ac (852 ha) of scrub oak shrublands found on the Camp Edwards Training Site owned by the MDFW and leased to the Massachusetts Army National Guard are considered a stronghold for the New England cottontail, and conservation efforts to maintain and expand habitats are ongoing primarily through the use of prescribed fire (McCumber, *in litt.* 2015). Therefore, we conclude that the conservation efforts have reduced or eliminated current and future threats to the New England cottontail to the point that the species no longer is in danger of extinction now or in the foreseeable future.

Additionally, although the current rangewide estimate suggests there are approximately 17,000 New England cottontails, we estimate that only 10,500 individuals currently occupy landscapes where persistence of the species is anticipated. This estimate falls short of the population goal of 13,500 individuals. Nevertheless, the conservation actions implemented have demonstrably improved the population status of the New England cottontail at some locations, and that improvement is expected to continue through the Conservation Strategy's 2030 planning period, based on a high degree of certainty that the conservation effort will continue to be implemented and effective.

On the basis of the best scientific and commercial information available, we find that the current and future threats are not of sufficient imminence, intensity, or magnitude to indicate that the New England cottontail is in danger of extinction (endangered), or likely to become endangered within the foreseeable future (threatened). Therefore, the New England cottontail does not meet the definition of a threatened or endangered species, and we are withdrawing our previous ''warranted, but precluded findings'' and removing the species from the list of ''candidate'' species.

Significant Portion of the Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so throughout all or a significant portion of its range. The Act defines ''endangered species'' as any species which is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species which is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The term ''species'' includes ''any subspecies of fish or wildlife or plants, and any distinct population segment [DPS] of any species of vertebrate fish or wildlife which interbreeds when mature.'' We published a final policy interpreting the phrase ''Significant Portion of its Range'' (SPR) (79 FR 37578). The final policy states that (1) if a species is found to be endangered or threatened throughout a significant portion of its range, the entire species is listed as an endangered or a threatened species, respectively, and the Act's protections apply to all individuals of the species wherever found; (2) a portion of the range of a species is ''significant'' if the species is not currently endangered or threatened throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range; (3) the range of a species is considered to be the general geographical area within which that species can be found at the time FWS or NMFS makes any particular status determination; and (4) if a vertebrate species is endangered or

threatened throughout an SPR, and the population in that significant portion is a valid DPS, we will list the DPS rather than the entire taxonomic species or subspecies. As stated above, we find the New England cottontail does not warrant listing throughout its range. Therefore, we must consider whether there are any significant portions of the range of the New England cottontail.

The SPR policy is applied to all status determinations, including analyses for the purposes of making listing, delisting, and reclassification determinations. The procedure for analyzing whether any portion is an SPR is similar, regardless of the type of status determination we are making. The first step in our analysis of the status of a species is to determine its status throughout all of its range. If we determine that the species is in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range, we list the species as an endangered (or threatened) species and no SPR analysis will be required. If the species is neither in danger of extinction nor likely to become so throughout all of its range, we determine whether the species is in danger of extinction or likely to become so throughout a significant portion of its range. If it is, we list the species as an endangered or a threatened species, respectively; if it is not, we conclude that listing the species is not warranted.

When we conduct an SPR analysis, we first identify any portions of the species' range that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be significant and endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that (1) the portions may be significant and (2) the species may be in danger of extinction in those portions or likely to become so within the foreseeable future. We emphasize that answering these questions in the affirmative is not a determination that the species is endangered or threatened throughout a significant portion of its range—rather it is a step in determining whether a more detailed analysis of the issue is required. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are affecting it uniformly throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats apply only to portions of the range that clearly do not meet the biologically based definition of ''significant'' (*i.e.,* the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species), those portions will not warrant further consideration.

If we identify any portions that may be both (1) significant and (2) endangered or threatened, we engage in a more detailed analysis to determine whether these standards are indeed met. The identification of an SPR does not create a presumption, prejudgment, or other determination as to whether the species in that identified SPR is endangered or threatened. We must go through a separate analysis to determine whether the species is endangered or threatened in the SPR. To determine whether a species is endangered or threatened throughout an SPR, we will use the same standards and methodology that we use to determine if a species is endangered or threatened throughout its range.

Depending on the biology of the species, its range, and the threats it faces, it may be more efficient to address the ''significant'' question first, or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there; if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.''

The threats currently affecting the New England cottontail, without consideration for the planned or implemented conservation efforts, are occurring throughout the species' range. Habitat loss, predation, and the effects of small population size are affecting the species relatively uniformly across its range. In addition, the Conservation Strategy and its specific actions will continue to be implemented throughout the species' range, and we have a high level of certainty that those efforts will be effective in addressing the species' rangewide threats. Therefore, we find that factors affecting the species are essentially uniform throughout its range, indicating no portion of the range warrants further consideration of possible endangered or threatened status under the Act.

Our review of the best available scientific and commercial information indicates that the New England cottontail is not in danger of extinction (endangered) nor likely to become endangered within the foreseeable future (threatened), throughout all or a significant portion of its range. Therefore, we find that listing the New England cottontail as an endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, the New England cottontail to our New England Field Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor the New England cottontail and encourage its conservation. If an emergency situation develops for the New England cottontail, we will act to provide immediate protection.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* at Docket Number FWS–R5–ES–2015–0136 and upon request from the New England Field Office (see **ADDRESSES** section).

Author(s)

The primary author(s) of this document are the staff members of the New England Field Office.

Authority

The authority for this section is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: August 26, 2015.

Daniel M. Ashe,

Director, U.S. Fish and Wildlife Service.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R4–ES–2015–0129; 4500030113]

RIN 1018–BA93

Endangered and Threatened Wildlife and Plants; Threatened Species Status for Platanthera integrilabia (White Fringeless Orchid)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list *Platanthera integrilabia* (white fringeless orchid), a plant species from Alabama, Georgia, Kentucky, Mississippi, South Carolina, and Tennessee, as a threatened species under the Endangered Species Act (Act). If we finalize this rule as proposed, it

would extend the Act's protections to this species.

DATES: We will accept comments received or postmarked on or before November 16, 2015. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by October 30, 2015.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov*. In the Search box, enter FWS–R4–ES–2015–0129, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R4–ES–2015–0129; U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see *Public Comments,* below, for more information).

FOR FURTHER INFORMATION CONTACT: Mary Jennings, Field Supervisor, U.S. Fish and Wildlife Service, Tennessee Ecological Services Field Office, 446 Neal Street, Cookeville, TN 38501; by telephone 931–528–6481; or by facsimile 931–528–7075. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species is an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Listing a species as an endangered or threatened species and designations and revisions of critical habitat can only be completed by issuing a rule.

This rule proposes the listing of *Platanthera integrilabia* (white fringeless orchid) as a threatened species. The white fringeless orchid is a candidate species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation has been precluded by other higher priority listing activities. This rule reassesses all available information regarding status of and threats to the white fringeless orchid.

This rule does not propose critical habitat for white fringeless orchid. We have determined that designation of critical habitat would not be prudent for this species because:

- Designation would increase the likelihood and severity of illegal collection of white fringeless orchid and thereby make enforcement of take prohibitions more difficult.
- This threat outweighs the benefits of designation.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the threats to white fringeless orchid consist primarily of destruction and modification of habitat (Factor A) resulting in excessive shading, soil disturbance, altered hydrology, and proliferation of invasive plant species; collecting for recreational or commercial purposes (Factor B); herbivory (Factor C); and small population sizes and dependence on specific pollinators and fungi to complete its life cycle (Factor E). Existing regulatory mechanisms have not led to a reduction or removal of threats posed to the species from these factors (see Factor D discussion).

We will seek peer review. We will seek comments from independent specialists to ensure that our designation is based on scientifically sound data, assumptions, and analyses. We will invite these peer reviewers to comment on our listing proposal.

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The white fringeless orchid's biology, range, and population trends, including:

(a) Biological or ecological requirements of the species, including habitat requirements for germination, growth, and reproduction;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation such that the designation of critical habitat is not prudent.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We request that you

send comments only by the methods described in the **ADDRESSES** section.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov*.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Tennessee Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Because we will consider all comments and information received during the public comment period, our final determinations may differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise with the white fringeless orchid's biology, habitat, physical or biological factors, distribution, and status, or have general botanical and conservation biology expertise.

Previous Federal Action

The Act requires the Service to identify species of wildlife and plants that are endangered or threatened, based on the best available scientific and commercial data. Section 12 of the Act directed the Secretary of the Smithsonian Institution to prepare a report on endangered and threatened plant species, which was published as House Document No. 94–51. The Service published a notice in the **Federal Register** on July 1, 1975 (40 FR 27824), in which we announced that more than 3,000 native plant taxa named in the Smithsonian's report and other taxa added by the 1975 notice would be reviewed for possible inclusion in the List of Endangered and Threatened Plants. The 1975 notice was superseded on December 15, 1980 (45 FR 82480), by a new comprehensive notice of review for native plants that took into account the earlier Smithsonian report and other accumulated information. On November 28, 1983 (48 FR 53640), a supplemental plant notice of review noted the status of various taxa. Complete updates of the plant notice were published on September 27, 1985 (50 FR 39526), February 21, 1990 (55 FR 6184), and September 30, 1993 (58 FR 51144).

White fringeless orchid was first listed as a Category 1 candidate in the December 15, 1980, review. Category 1 candidates included taxa for which the Service had sufficient information on hand to support the biological appropriateness of listing as endangered or threatened species. The species was reclassified as a Category 2 candidate in the November 28, 1983, review. Category 2 candidates included taxa for which the Service had information indicating that proposing to list the species as endangered or threatened was possibly appropriate, but for which sufficient data on biological vulnerability and threat were not available. Further biological research and field study usually was necessary to ascertain the status of taxa in this category.

In 1996, the Service eliminated candidate categories (February 28, 1996; 61 FR 7596), and white fringeless orchid was no longer a candidate until it was again elevated to candidate status on October 25, 1999 (64 FR 57534). The species was also included in subsequent candidate notices of review on October 30, 2001 (66 FR 54808), June 13, 2002 (67 FR 40657), May 4, 2004 (69 FR 24876), May 11, 2005 (70 FR 24870), September 12, 2006 (71 FR 53756), December 6, 2007 (72 FR 69034), December 10, 2008 (73 FR 75176), November 9, 2009 (74 FR 57804), November 10, 2010 (75 FR 69222), October 26, 2011 (76 FR 66370), November 21, 2012 (77 FR 69994), November 22, 2013 (78 FR 70104), and December 5, 2014 (79 FR 72450).

The 2011 Multi-District Litigation (MDL) settlement agreement specified that the Service will systematically, over a period of 6 years, review and address the needs of 251 candidate species to determine if they should be added to the Federal Lists of Endangered and Threatened Wildlife and Plants. The white fringeless orchid was on that list of candidate species. Therefore, the Service is making this proposed listing determination in order to comply with the conditions outlined in the MDL agreement.

Background

Species Information

Taxonomy and Species Description

White fringeless orchid was first recognized as a distinct taxon when D.S. Correll (1941, pp. 153–157) described it as a variety of *Habenaria* (*Platanthera*) *blephariglottis.* C.A. Luer (1975, p. 186) elevated the taxon to full species status. The currently accepted binomial for the species is *Platanthera integrilabia* (Correll) Luer. The description of this taxon at the full species level used the common name of ''monkey-face'' (Luer 1975, p. 186), as have some other publications (Zettler and Fairey 1990, p. 212; Zettler 1994, p. 686; Birchenko 2001, p. 9). A status survey report for the species recognized both ''white fringeless orchid'' and ''monkeyface'' as common names (Shea 1992, p. 1). The Service used the common name ''white fringeless orchid'' when the species was first recognized as a candidate for listing, and we retain usage of this common name here.

White fringeless orchid is a perennial herb with a light green, 60-centimeters (cm) (23-inches (in)) long stem that arises from a tuber (modified underground stem of a plant that is enlarged for nutrient storage). The leaves are alternate with entire margins and are narrowly elliptic to lanceolate (broadest below the middle and tapering toward the apex) in shape. The lower leaves are 20 cm (8 in) long and 3 cm (1 in) wide. The upper stem leaves are much smaller. The white flowers are borne in a loose cluster at the end of the stem. The upper two flower petals are about 7 millimeters (mm) (0.3 in) long, and the lower petal (the lip) is about 13 mm (0.5 in) long. The epithet ''integrilabia'' refers to the lack of any prominent fringe on the margin of the lip petal (Luer 1975, p. 186). The plants flower from late July through September, and the small narrow fruiting capsule matures in October (Shea 1992, p. 23).

Distribution

To determine the current distribution of white fringeless orchid, we used data provided by Natural Heritage Programs (NHP), housed in State agencies or universities in each of the States in the species' geographic range: Alabama Natural Heritage Program at Auburn University (ANHP 2014); Georgia Department of Natural Resources (GDNR 2014); Kentucky State Nature Preserves Commission (KSNPC 2014); Mississippi Department of Wildlife, Fisheries, and Parks (MDWFP 2014); North Carolina Department of Environment and Natural Resources (NCDENR 2014); South Carolina Department of Natural Resources (SCDNR 2012); and Tennessee Department of Environment and Conservation (TDEC 2014). In addition to NHP data, we used Shea's (1992, entire) *Status Survey Report on Platanthera integrilabia* to determine the species' historical distribution.

In most cases, a mapped occurrence in the databases maintained by the NHPs represented a single group of plants growing together in a patch of suitable habitat. However, the Kentucky NHP combined multiple groups of plants (*i.e.,* sub-occurrences), growing in distinct habitat patches in close proximity to one another, into single occurrences. In two instances, the Tennessee NHP also grouped several sub-occurrences into a single occurrence, where they were all located in separate stream heads draining into a single headwater stream. In describing the current range and distribution of white fringeless orchid, we have adopted these groupings in those instances where all of the sub-occurrences were located within the drainage of a single headwater stream. In two instances, where Kentucky NHP grouped sub-occurrences from drainages of separate headwater streams into a single occurrence, we split the sub-occurrences into two separate occurrences by grouping together only those that were located within a single headwater drainage.

Historical Distribution—As of 1991, there were 30 extant occurrences and 13 with uncertain status, distributed among 20 counties in 5 southeastern States (see Table 1, below). Shea (1992, pp. 14–17) also reported on six locations with historical occurrences and six from which the species had been extirpated.

As of 2015, there are records for 13 historical and 12 extirpated occurrences in NHP databases. Accounting for two locations that Shea (1992, pp. 11–14) reported as extirpated and a third reported as uncertain but now considered to be historical, none of which is included in NHP databases, there are 28 occurrences that currently are considered historical or extirpated. In 1991, five of these were extant and the status of five was uncertain (Shea 1992, pp. 7–14). Based on these data, the species' historical range included Cobb County, Georgia; Henderson County, North Carolina; and Roane County, Tennessee, in addition to the 35 counties listed below in Table 1 for the species' range as of 2014. The species has been extirpated completely from North Carolina.

Shea (1992, pp. 17–18) lists additional records from Butler County, Alabama; Cherokee County, North Carolina; Hamilton County, Tennessee; and Lee County, Virginia, whose validity she could neither verify nor refute based on available data. Lacking sufficient data to document the collection of white fringeless orchid from Lee County, the authors of the Flora of Virginia did not include the species (Townsend 2012, pers. comm.). Lacking any substantive data for white fringeless orchid's historical presence in the other three counties above, we also consider them to not be part of the species' historical range.

Current Distribution—Using available data, we categorized the current status of each occurrence as extant, extirpated, historical, or uncertain. Extant occurrences are those for which recent (*i.e.,* since ca. 2000) observations of flowering plants are available to confirm the species' persistence at a given site, or from which material was collected and cultivated in a greenhouse to produce flowering specimens confirming the identification of vegetative plants that were observed in the field. Because white fringeless orchid commonly occurs with three congeners (species belonging to the same genus) that share similar leaf characteristics, conclusive identification in the absence of flowering specimens is not possible. Extirpated occurrences are those where the species' absence is considered to be certain due to lack of recent observations of flowering white fringeless orchids, or vegetative plants of any species of *Platanthera,* associated with modification of the habitat to an unsuitable condition for white fringeless orchid. White fringeless orchid was last seen flowering at one extirpated occurrence as recently as 2004, but habitat in this former transmission line right-of-way is no longer maintained and has become unsuitable due to woody vegetation encroachment. Similarly, recent observation of flowering white fringeless orchids or vegetative plants of any species of *Platanthera* is lacking for historical occurrences, but the habitat has not been visibly altered at these locations. We have assigned uncertain status to occurrences where recent observation of flowering white fringeless orchids is lacking, but where basal leaves of non-flowering *Platanthera* spp. orchids typically have been observed during one or more recent visits. In addition, we have assigned uncertain status to one Mississippi occurrence, where a single white fringeless orchid was seen flowering in 2011, because the hydrology at this site was subsequently altered by a drainage ditch and the species' persistence at this site is now questionable.

The white fringeless orchid's distribution is concentrated in the Cumberland Plateau section of the Appalachian Plateaus physiographic province, with isolated populations scattered across the Blue Ridge, Piedmont, and Coastal Plain provinces (Fenneman 1938, pp. 68, 134–137, 172, 333–334). The species is currently extant at 58 occurrences distributed among 32 counties, spanning 5 southeastern States (Table 1). There are an additional 22 occurrences (Table 1) whose current status is uncertain, which include one additional State and three additional counties. We consider the species' current distribution to include the 6 States and 35 counties where NHP database records for these extant and uncertain occurrences exist (Table 1). We included records of uncertain status in defining the species' current distribution to ensure that all relevant State and local governments and private stakeholders are aware of white fringeless orchid's potential presence and opportunities for conserving the species and its habitat.

TABLE 1—COUNTY-LEVEL DISTRIBUTION OF EXTANT AND UNCERTAIN STATUS WHITE FRINGELESS ORCHID OCCURRENCES, CIRCA 1991 (SHEA 1992) AND 2014 (ANHP 2014, GDNR 2014, KSNPC 2014, MDWFP 2014, NCDENR 2014, SCDNR 2012, TDEC 2014)

State	County	1991		2014	
		Extant	Uncertain	Extant	Uncertain
Alabama	Calhoun	.....	.....	2	.....
	Clay	.....	1	1	.....
	Cleburne	.....	.....	1	.....
	DeKalb	.....	.....	1	.....
	Jackson	.....	.....	.....	1
	Marion	1	.....	1	2
	Tuscaloosa	1	.....	1	.....
	Winston	1	.....	1	.....
Georgia	Bartow	.....	.....	1	.....
	Carroll	2	.....	2	.....
	Chatooga	.....	.....	1	.....
	Cobb	1	.....	.....	.....
	Coweta	1	.....	1	.....
	Forsyth	.....	1	1	.....
	Pickens	.....	.....	1	.....
	Rabun	1	.....	1	.....
	Stephens	1	.....	1	.....
Kentucky	Laurel	.....	.....	2	2
	McCreary	4	.....	2	1
	Pulaski	1	1	2	.....
	Whitley	.....	.....	1	.....
Mississippi	Alcorn	.....	.....	.....	1
	Itawamba	.....	.....	2	1
	Tishomingo	.....	.....	1	1
South Carolina	Greenville	1	.....	.....	1
Tennessee	Bledsoe	.....	2	2	1
	Cumberland	.....	.....	1	.....
	Fentress	.....	.....	2	.....
	Franklin	3	2	5	5
	Grundy	5	5	4	4
	Marion	2	.....	8	.....
	McMinn	1	.....	1	.....
	Polk	.....	.....	1	.....
	Scott	.....	.....	1	.....
	Sequatchie	2	1	1	1
	Van Buren	2	.....	5	1
Total	.....	30	13	58	22

More occurrences are included in the species' current distribution than were historically known to exist, likely as a result of increased survey effort having been devoted to white fringeless orchid due to its status as a candidate for Federal listing. However, low numbers of flowering plants have been observed at most sites (Figure 1). For example, fewer than 50 flowering plants have ever been observed at one time at 45 (64 percent) of the 70 extant and uncertain occurrences for which data are available. At 26 (37 percent) of these occurrences, fewer than 10 flowering plants have ever been recorded.

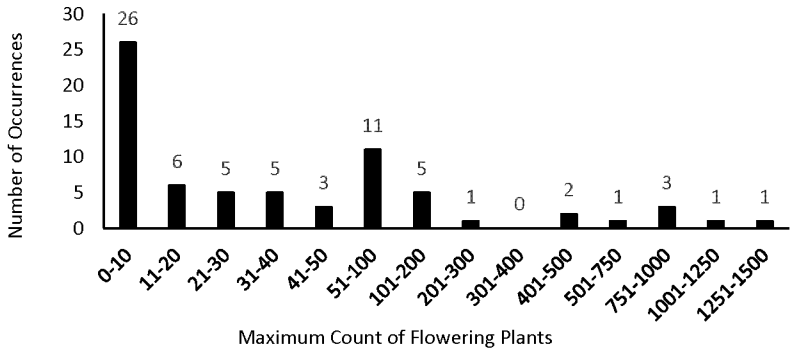

FIGURE 1.--Histogram of maximum number of flowering white fringeless orchids ever recorded at 70 extant and uncertain occurrences. Specific counts of flowering plants were not available for 10 extant and uncertain occurrences.

There are 32 extant occurrences that are located entirely, or in part, on lands owned or managed by local, State, or Federal government entities (Table 2). In addition, there are seven uncertain, five extirpated, and two historical occurrences that are similarly situated. Two additional occurrences, one extant and one uncertain, are located on private lands that are protected by conservation easements.

TABLE 2—STATUS AND NUMBER OF WHITE FRINGELESS ORCHID OCCURRENCES ON PUBLICLY OWNED OR MANAGED LANDS

[Note: One site is on privately owned lands that GDNR leases for use as a wildlife management area]

Ownership	Extant	Uncertain	Extirpated	Historical
National Park Service	3			
U.S. Forest Service	9	3	3	
U.S. Fish and Wildlife Service	2			
Alabama Department of Conservation and Natural Resources		1		
Georgia Department of Natural Resources	2			
Kentucky State Nature Preserves Commission	1			1
Mississippi Department of Fish, Wildlife, and Parks	1			
North Carolina Plant Conservation Program			1	
South Carolina State Parks		1		
Tennessee Department of Transportation	1			
Tennessee Division of Forestry	7			
Tennessee State Parks	5	1		1
Tennessee Wildlife Resources Agency	1		1	
Forsyth County, Georgia		1		
Total	31	8	5	2

Habitat

In Correll's (1941, pp. 156–157) description of white fringeless orchid as a distinct variety, he included notes from herbarium specimens that describe the species' habitat variously as ''bog,'' ''boggy sphagnum ravine,'' ''sphagnum bog,'' ''grassy swamps,'' and ''marshy ground.'' Luer (1975, p. 186) described the habitat as ''. . . the deep shade of damp deciduous forests . . . in the thick leaf litter and sphagnum moss along shallow wet ravines and depressions.'' Zettler and Fairey (1990, p. 212) observed the species growing in ''shaded and level bogs, swamps or seepage slopes usually containing *Sphagnum.''* Shea (1992, p. 19) described the habitat as ''wet, flat, boggy areas at the head of streams or on seepage slopes . . . with *Sphagnum* . . . usually grows in partial shade.''

Hoy (2012, p. 53) demonstrated that precipitation was the primary hydrologic source for three wetlands at a white fringeless orchid site on the Cumberland Plateau in Kentucky, which was commonly referred to as a seep. Thus, describing many of the sites where white fringeless orchid occurs as ''seeps'' or ''seepage slopes'' may contradict the typical characterization of seeps as wetlands where water from subsurface sources emerges at the surface (Soulsby *et al.* 2007, p. 200). The term ''bogs'' refers to a specific wetland type that accumulates peat, lacks significant inflow or outflow, and harbors mosses adapted to acidic environments, particularly *Sphagnum* (Mitsch and Gosselink 2000, p. 41). Peat is fibric organic soil material, meaning that some plant forms incorporated into the soil are identifiable (U.S. Department of Agriculture, Natural Resources Conservation Service 2006, p. 32). However, despite the common usage of the terms ''bog'' or ''boggy'' to describe them and the nearly ubiquitous presence of *Sphagnum* spp. (sphagnum moss) in them, the wetlands that white fringeless orchid inhabits occur on mineral soils and do not accumulate peat. Further, they often are located at stream heads and connected to ephemeral streams via dispersed sheet flow or concentrated surface flow in incipient channels.

Weakley and Schafale (1994, pp. 164–165) commented on the discrepancy between regional use of the terms ''bogs'' and ''fens'' to describe non-

alluvial wetlands of the Southern Blue Ridge in which sphagnum moss is prominently featured and their more traditional usage in peatland classifications. Noting that most of the region's non-alluvial wetlands lacked organic soils, these authors nonetheless chose to maintain the regional usage of these terms in their classification, to emphasize differences in sources of hydrology and their effects on water chemistry (nutrient-poor precipitation in ''bogs'' versus mineral-rich groundwater seepage in ''fens''). Similar to the non-alluvial wetlands of the Southern Blue Ridge, further study is needed to characterize the range of variation in soils, hydrology, physicochemistry, and origin of wetlands throughout the range of white fringeless orchid.

Most sites where white fringeless populations exist are on soils formed over sandstone bedrock, which usually are low in fertility and organic matter content and are acidic (Shea 1992, p. 20). The species often occurs in swamps dominated by *Acer rubrum* (red maple) and *Nyssa sylvatica* (blackgum), where common shrubs and woody vines include *Alnus serrulata* (smooth alder), *Decumaria barbara* (climbing hydrangea), *Smilax* spp. (greenbrier), and *Viburnum nudum* (possumhaw). Common herbaceous associates of white fringeless orchid include *Doellingeria umbellata* (parasol flat-top white aster), *Gymnadeniopsis clavellata* (green woodland orchid), *Lobelia cardinalis* (cardinal flower), *Lycopus virginicus* (Virginia bugleweed), *Osmunda cinnamomea* (cinnamon fern), *O. regalis* (royal fern), *Oxypolis rigidior* (stiff cowbane), *Parnassia asarifolia* (kidneyleaf grass of parnassus), *Platanthera ciliaris* (yellow fringed orchid), *P. cristata* (crested yellow orchid), *Sphagnum* spp. (sphagnum moss), *Thelypteris noveboracensis* (New York fern), *Viola primulifolia* (primrose-leaf stemless white violet), and *Woodwardia areolata* (chainfern) (Zettler and Fairey 1990, p. 213; Shea 1992, p. 22; Patrick 2012, pers. comm.). Sites located in powerline rights-of-way share many of the herbaceous taxa listed above, but lack a canopy or well-developed shrub stratum due to vegetation management. Nomenclature follows the Integrated Taxonomic Information System (retrieved on January 16, 2015, from the Integrated Taxonomic Information System online database, *http://www.itis.gov*).

Biology

Orchid seeds are dust-like and lack an endosperm (the tissue produced inside seeds of most flowering plants that provides nutrient reserves) making them dependent upon acquiring carbon from an external source (Yoder *et al.* 2010, p. 7). Like most terrestrial orchids, white fringeless orchid depends on a symbiotic (interdependent) relationship with mycorrhizal fungi (an association of a fungus and a plant in which the fungus lives within or on the outside of the plant's roots) to enhance seed germination and promote seedling development and establishment (Zettler and McInnis 1992, pp. 157–160; Rasmussen and Whigham 1993, p. 1374). In addition to providing a carbon source for seedling development, mycorrhizal fungi enhance germination by promoting increased water uptake by orchid seeds (Yoder *et al.* 2000, 149). Their small size permits dispersal of orchid seeds to new environments via wind currents; however, very few of the seeds likely encounter suitable habitats where host fungi are present (Yoder *et al.* 2010, pp. 14–16). This likelihood is further reduced in the case of species such as white fringeless orchid, which may rely on a single fungal host species, *Epulorhiza inquilina,* to complete its life cycle (Currah *et al.* 1997, p. 340).

White fringeless orchid has a self-compatible breeding system, allowing individuals to produce seed using their own pollen; however, the proportions of fruits produced through self-pollination versus cross-pollination are not known (Zettler and Fairey 1990, p. 214). Rates of fruit set, measured as the proportion of individual flowers that produced capsules, varied in studies of populations in Georgia (6.9 percent), South Carolina (20.3 percent) (Zettler and Fairey 1990, p. 214), and Tennessee (56.9 percent) (Zettler *et al.* 1996, p. 20). While these observations were made at these populations in different years, the Tennessee population, where pollination was observed, is considerably larger than the Georgia or South Carolina populations, where no pollination was observed. Zettler *et al.* (1996, p. 22) reasoned that inbreeding depression was a likely cause for the lower fruit set in the smaller populations, noting that in a separate study both germination rates and propagation success were greater in white fringeless orchid seeds collected from the largest of these populations (Zettler and McInnis 1992, p. 160). They speculated that higher rates of fruit set were probably more typical historically, when larger populations provided greater opportunities for cross-pollination to occur.

White fringeless orchid is capable of prodigious seed production, which might help to compensate for the likely dispersal of many seeds into unsuitable habitats. In the Tennessee population studied by Zettler *et al.* (1996, p. 20), more than half of the flowers on inflorescences (the complete flower head of a plant including stems, stalks, bracts, and flowers) set fruit, resulting in a mean of 4.7 capsules per plant. The capsules produced an average of 3,433 seeds each, indicating that each inflorescence averaged over 16,000 seeds. With 577 inflorescences counted in the study area, Zettler *et al.* (1996, p. 20) estimated that over 9,000,000 seeds were produced. However, in separate studies of *in vitro* and *in situ* seedling development, even with fungal inoculation less than 3 percent of seeds developed into protocorms (young seedlings) that could be established on soil (Zettler and McInnis 1992, pp. 157–160; Zettler 1994, pp. 65).

Known pollinators for white fringeless orchid include three diurnal species from two families of butterflies (Lepidoptera): Silver spotted skipper (Hesperiidae: *Epargyreus clarus*), spicebush swallowtail (Papilionidae: *Papilio troilus*), and eastern tiger swallowtail (Papilionidae: *P. glaucus*) (Zettler *et al.* 1996, p. 16). Based on floral characteristics, including white flowers and a long nectiferous (nectar bearing) spur, as well as pollinaria morphology in relation to potential pollinator morphology, it is likely that more effective pollinators for white fringeless orchid exist in the nocturnal sphingid moth family (Lepidoptera: Sphingidae) (Zettler *et al.* 1996, pp. 17–18); however, this has not been confirmed. Pollinaria are the pollen-bearing structure on orchids, consisting of pollen masses (pollinia) attached to a stalk that has a sticky pad (viscidium), which attaches the pollinaria to pollinators (Argue 2012, p. 5). Despite the fact that nectar concentrations in white fringeless orchid flowers did not fluctuate significantly over a 24-hour observation period, Zettler *et al.* (1996, p. 20) noticed the floral fragrance produced by a large Tennessee population intensified between the hours of 7:00 p.m. and 11:00 p.m., suggesting the species possesses adaptions for attracting nocturnal pollinators.

Genetics

Birchenko (2001, pp. 18–23, 47–48) analyzed genetic structure among 25 white fringeless orchid populations, distributed across Alabama, Georgia, Tennessee, and Kentucky. Her ''populations'' corresponded to specific NHP occurrences. The majority (79 percent) of the genetic variation was present as variation within populations, while 21 percent of the variation was

attributable to differences between populations (Birchenko 2001, p. 29). While these results alone do not demonstrate that genetic variability in white fringeless orchid populations has been eroded by restricted gene flow, Birchenko (2001, pp. 34–40) cautioned that interactions between demographic and ecological factors could be a cause for some observed population declines and could ultimately cause declines in the species' genetic variation and increase differentiation among white fringeless orchid populations.

Summary of Factors Affecting the Species

Under section 4(a)(1) of the Act, we may list a species based on: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

Information pertaining to white fringeless orchid in relation to the five factors provided in section 4(a)(1) of the Act is discussed below. In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat, and we then attempt to determine if that factor rises to the level of a threat, meaning that it may drive or contribute to the risk of extinction of the species such that the species warrants listing as an endangered or threatened as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors are operative threats that act on the species to the point that the species meets the definition of an endangered or threatened species under the Act.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Habitat modification caused by development, silvicultural practices, invasive plant species, disturbance by feral hogs, shading due to understory and canopy closure, altered hydrology, and right-of-way maintenance have impacted the range and abundance of white fringeless orchid.

Development

One white fringeless orchid occurrence was extirpated from a site in Henderson County, North Carolina, which Shea (1992, p. 15) reported had been nearly completely destroyed by construction of a building. Another occurrence in Tishomingo County, Mississippi, was extirpated from a site that was disturbed by construction of the Yellow Creek Nuclear Power Plant (Shea 1992, p. 15). A third site from which the species is considered extirpated, in Roane County, Tennessee, was severely disturbed during highway construction (Shea 1992, p. 15). One extant occurrence in Carroll County, Georgia, is located within a subdivision where restrictions have been put in place to protect the wetland habitat. Another extant occurrence in Pickens County, Georgia, is located within a subdivision, but the wetland habitat where white fringeless orchid occurs is located within an area protected by a conservation easement held by the North American Land Trust. There is one occurrence of uncertain status that is located on an as yet undeveloped lot in a subdivision in Grundy County, Tennessee. Potential future residential development at this site could directly impact white fringeless orchid due to habitat conversion or ground disturbance, or could indirectly affect the species by altering hydrology, increasing shading, or introducing invasive, nonnative plants.

Based on our review of the best commercial and scientific data available, development is a threat of low magnitude with potential to affect few white fringeless orchid populations in the foreseeable future.

Silvicultural Practices

Direct and indirect effects of silvicultural practices have adversely affected habitat conditions and abundance of many white fringeless orchid populations. Incompatible silviculture has taken the form of clearcutting, both of swamps occupied by the species and of surrounding upland forests. Shea (1992, p. 15) reported that white fringeless orchid had been extirpated from two Alabama sites where logging had disturbed the habitat. At one of these sites, the loss was attributed to impacts from logging and removal of beaver dams.

While white fringeless orchid has sometimes shown short-term increases in flower production following canopy removal, the longer-term response typically is a decline in abundance as vegetation succession ensues (Shea 1992, pp. 26, 96; Birchenko 2001, p. 33). Forests have been clearcut at nine extant occurrences and two of uncertain status in Tennessee, two extant sites and one of uncertain status in Alabama, and one extant site in Georgia. Of these, there is evidence for declines in white fringeless orchid abundance following timber harvests at five extant occurrences and two of uncertain status in Tennessee (TDEC 2014) and one extant occurrence in Alabama (Birchenko 2001, p. 33; ANHP 2014). At some sites, the timber harvests were too recent to know yet how white fringeless orchid will respond.

In many cases, native forests surrounding white fringeless orchid sites have been clearcut and replaced by intensively managed pine plantations, often consisting solely of *Pinus taeda* (loblolly pine), where intensive mechanical or chemical site preparation before planting occurs in order to reduce seedling competition with other tree species (Clatterbuck and Ganus 1999, p. 4). Plantation forestry generally causes reductions in streamflow as compared to native forest vegetation (Scott 2005, p. 4204), and research from the Cumberland Plateau comparing calcium stores in soils and trees of native hardwood forests to mature pine on converted hardwood sites revealed calcium loss from the system after a single pine rotation that could impede future regrowth of the native oak-hickory forest (McGrath *et al.* 2004, p. 21). The fact that plantation forests are implicated in reduced streamflow suggests that they could reduce the hydroperiod (seasonal pattern of the water level that results from the combination of the water budget and the storage capacity of a wetland) in wetlands located at the heads of streams, such as those typically occupied by white fringeless orchids, when they are embedded in a matrix of pine plantations. While more information on indirect effects of pine plantations on hydroperiods of wetlands occupied by white fringeless orchid is needed, evidence suggests that restoring native hardwood forest vegetation may be needed to restore wetland hydrology in some sites, and that this would be a challenging and long-term process.

At least four extant occurrences in Alabama, two in Georgia, and four in Tennessee are located in wetlands that are either located in pine plantations or bordered by them in surrounding uplands; one Tennessee occurrence of uncertain status is similarly situated. Fourteen percent of native forest, in seven counties of the southern Cumberland Plateau in Tennessee that are occupied by white fringeless orchid, was lost between 1981 and 2000. The majority (74 percent) of this lost native forest was converted to nonnative loblolly pine plantations, and the annual rate of conversion doubled during the last 3 years (1997–2000) (McGrath *et al.* 2004, p. 13). Given that there are three extant Tennessee occurrences and two of uncertain status that are located on private industrial forest lands, which have not yet been converted to nonnative pine plantations, conversion of lands surrounding additional white fringeless orchid occurrences represents a foreseeable future threat to the species.

Based on our review of the best commercial and scientific data available, silvicultural practices are a threat of moderate magnitude to white fringeless orchid populations.

Invasive Plant Species

The presence of invasive, nonnative plant species, including *Microstegium vimineum* (Japanese stiltgrass), *Ligustrum sinense* (Chinese privet), and *Perilla frutescens* (beefsteak plant), has been documented at 10 extant white fringeless orchid occurrences and one of unknown status (U.S. Forest Service (USFS) 2008, p. 53; Richards 2013, pers. comm.; KSNPC 2014; TDEC 2014). Chinese privet has been negatively correlated with cover, abundance, and richness of native herbaceous species in riparian wetlands of the Piedmont physiographic province (Greene and Blossey 2012, p. 143). Japanese stiltgrass has been shown to increase pH and phosphorous availability in Cumberland Plateau forest soils (McGrath and Binkley 2009, pp. 145–153) and to increase abundance of vesicular arbuscular mycorrhiza (VAM; mycorrhizal fungi that grow into the roots of host plants and form specialized structures called arbuscules and vesicles) in other sandstone-derived soils (Kourtev *et al.* 2002, p. 3163) as compared to native vegetation. While the effect of these soil alterations on white fringeless orchid has not been investigated, the species is associated with acidic (*i.e.,* lower pH) soils (Zettler and Fairey 1990, p. 213) and is dependent upon a specific mycorrhizal fungus that is not a VAM (Currah *et al.* 1997, p. 340). To the extent that increases in VAM might lead to decreases in abundance of the orchid's mycorrhizal fungus, *Epulorhiza inquilina,* negative effects on germination and growth would be expected for white fringeless orchid.

In addition to threats posed by nonnative plant species, at two extant white fringeless orchid sites, a native species, *Lygodium palmatum* (American climbing fern), has demonstrated invasive tendencies. Both sites are on public lands, and USFS attempts to control spread of the species at one of the sites met limited success. At the site on National Park Service lands, American climbing fern blankets vegetation along both sides of a dirt road that is in close proximity to a white fringeless orchid site, and the fern vines have spread into adjacent forests, including the wetland where white fringeless orchid occurs. Left unmanaged, encroachment of nonnative plants and American climbing fern could reduce potential for exposure of seeds to light before being incorporated into the soil, which enhances germination rates (Zettler and McInnis 1994, p. 137).

Based on available data, encroachment by native and nonnative invasive plants is a threat of moderate magnitude to white fringeless orchid populations.

Feral Hogs

Ground disturbance by rooting of feral hogs has been observed at 13 extant white fringeless orchid occurrences, in Georgia and Tennessee, including two of the largest known occurrences, both on protected lands (Zettler 1994, p. 687; USFS 2008, p. 54; Richards 2013 pers. comm.; Richards 2014, pers. comm.; Tackett 2015, pers. comm.). These disturbances have affected specific microsites where white fringeless orchid had previously been observed growing, as well as surrounding wetland habitat. Disturbance by feral hogs has been shown to affect plant communities by causing decreases in plant cover, diversity, and regeneration; effects to fungi from feral hogs are also known to occur (Barrios-Garcia and Ballari 2012, p. 2295), suggesting potential for adverse effects to white fringeless orchid via disruption of the symbiotic interactions with mycorrhizal fungi that enhance seed germination and promote seedling development and establishment (Zettler and McInnis 1992, pp. 157–160; Rasmussen and Whigham 1993, p. 1374).

Based on our review of the best commercial and scientific data available, feral hogs are a threat of moderate magnitude to white fringeless orchid populations.

Excessive Shading

Despite the fact that white fringeless orchid habitat has been described as shaded (Luer 1975, p. 186; Zettler and Fairey 1990, p. 212; Shea 1992, p. 19), excessive shading due to vegetation succession has been recognized as a factor associated with population declines (Shea 1992, pp. 26, 55, 61, 69; Richards 2013, pers. comm.; Schotz 2015, p. 4), and succession of woody vegetation has been named as the primary factor in the decline of Tennessee populations (TDEC 2012, p. 3). One Tennessee occurrence was extirpated due to woody vegetation succession in a right-of-way that occurred following removal of a powerline (TDEC 2014). Available data indicate that this threat has been noted at 19 extant occurrences and 5 of uncertain status across the species' geographic range (Richards 2013, pers. comm.; Sullivan 2014, pers. comm.; KSNPC 2014; TDEC 2014; Schotz 2015, pp. 10–35). The threat of shading has been most often noted in instances where woody succession followed logging in or adjacent to sites occupied by white fringeless orchid. As noted above, white fringeless orchid occurrences often exhibit short-term increases in flower production following canopy removal, but the longer-term response typically is a decline in abundance as woody vegetation succession ensues (Shea 1992, pp. 26, 96; Birchenko 2001, p. 33; TDEC 2012, pp. 2–3). It has been suggested that fire could play a role in regulating woody vegetation growth in uplands surrounding white fringeless orchid habitats, allowing greater light penetration into swamps where the species grows (Schotz 2015, p. 4).

Based on our review of the best commercial and scientific data available, excessive shading is a threat of moderate magnitude to white fringeless orchid populations.

Altered Hydrology

Several factors have been identified as causes for altered hydrology in white fringeless orchid habitat, including pond construction (TDEC 2008, p. 4), ditching (Sullivan 2014, pers. comm.), development, logging (Shea 1992, p. 26; Taylor 2014, pers. comm.), and woody vegetation succession following logging (Hoy 2012, p. 13). In Tennessee, three white fringeless orchid sites have been destroyed by pond construction, one as recently as 2006 (TDEC 2008, p. 4). One site in Cobb County, Georgia, was destroyed by pond construction

(Richards 2014, pers. comm.). In Winston County, Alabama, hydrology was altered by the removal of beaver dams to facilitate a logging operation, causing the extirpation of a white fringeless orchid occurrence (Shea 1992, p. 25).

Altered hydrology has been noted as a threat at five extant occurrences and four of unknown status (Taylor 2014, pers. comm.; Sullivan 2014, pers. comm.; GDNR 2014; KSNPC 2014; TDEC 2014). Conversion of surrounding uplands to a pine plantation was noted as the cause for hydrologic alteration at one extant site in Georgia (GDNR 2014), and as noted above, is a condition that is present at nine other extant occurrences and one of unknown status. Logging in surrounding uplands is suspected of contributing to altered hydrology at two Kentucky occurrences, one extant and one of uncertain status (Taylor 2014, pers. comm.; KSNPC 2014), by causing increased surface runoff during heavy precipitation events and accelerating channel development in wetlands at stream heads. In addition to loss of white fringeless orchid habitat and occurrences due to pond construction at the three Tennessee sites discussed above, hydrology has been altered in wetland habitats down slope of ponds at two other Tennessee sites, where white fringeless orchid's status is now uncertain (TDEC 2014). In Mississippi, ditching has altered hydrology at a site where white fringeless orchid was discovered in 2011, leaving the species' status uncertain at this location (Sullivan 2014, pers. comm.). Ditching has also altered hydrology at an extant occurrence located adjacent to a State highway in Tennessee. Disturbance by heavy equipment in an adjacent powerline right-of-way is thought to have altered hydrology at an extant site in Kentucky, by causing rutting of soils and hastening channel development at the stream head (Taylor 2014, pers. comm.).

While most observations of threats related to logging activity have concerned habitat disturbance or increased shading caused by woody vegetation regrowth, Hoy (2012, p. 26) suggests that high stem densities that occur during succession following canopy removal shorten the hydroperiod of wetlands at an extant white fringeless orchid site in Kentucky. This results from increased evapotranspiration, due to greater leaf surface area, causing faster rates of water loss. While only empirically documented in wetlands where a single white fringeless orchid occurrence is located, this process likely has affected numerous other sites where canopy removal has occurred due to logging.

Based on our review of the best commercial and scientific data available, altered hydrology is a threat of moderate magnitude to white fringeless orchid populations.

Right-of-Way Maintenance

Eleven extant white fringeless orchid occurrences and one of uncertain status are located in transportation or utility rights-of-way (Richards 2013, pers. comm.; KSNPC 2014; TDEC 2014). Vegetation management practices in such habitats prevent advanced succession of woody vegetation, which can benefit white fringeless orchid by periodically reducing shading. On the other hand, mechanical clearing in these habitats can alter hydrology by causing rutting of soils and hastening channel development, as discussed in the preceding section (Taylor 2014, pers. comm.). Mowing during the flowering period for white fringeless orchid is detrimental, given the low flowering rates that have been observed in this species and the fact that individual plants will not regenerate flowers during a growing season once they are lost to herbivory or other causes (Sheviak 1990, p. 195). Also, it is likely that indiscriminate herbicide application would cause mortality of white fringeless orchid plants. However, we have knowledge of one event in which the species responded favorably following selective herbicide application to control woody plant succession in a Tennessee Valley Authority transmission line right-of-way, reaching record numbers of flowering plants documented at the site within 2 years following the herbicide treatment. The lack of adverse effect to white fringeless orchid in this instance is likely attributable to the targeted application of herbicides to woody plants only.

Based on our review of the best commercial and scientific data available, right-of-way maintenance is a threat of moderate magnitude to white fringeless orchid populations.

Conservation Efforts To Reduce Habitat Destruction, Modification, or Curtailments of Its Range

The USFS has undertaken efforts to restore or protect habitat at a number of white fringeless orchid sites located on National Forest (NF) lands. At the Cherokee NF, the USFS constructed fences to exclude feral hogs at two sites, one of which is the largest known occurrence of the species. These fences are effective when maintained; however, only the main concentration of plants is protected at the site where the largest occurrence is present. At the Daniel Boone NF, the installation of check dams (small, often temporary, dam constructed across a swale, drainage ditch, or waterway to counteract erosion by reducing water flow velocity) in 2005 has been somewhat effective in restoring suitable conditions for white fringeless orchid at a site where wetland hydrology had been altered. Efforts to control invasion by Japanese stiltgrass by repeatedly weeding at one site on Daniel Boone NF have been hampered by a seed source that exists on private lands upslope of the site (Taylor 2014, pers. comm.).

Efforts have been made to restore suitable habitat conditions at one site on KSNPC lands, by reducing woody stem encroachment in 2012, following a timber harvest, and by placing log dams to slow surface runoff and minimize channel development. To date, white fringeless orchid has not shown a measureable response to this management effort; despite large numbers of vegetative *Platanthera* spp. leaves being present, fewer than 30 flowering plants per year have been observed in recent years at this site, where 530 plants were observed flowering in 1998 (KSNPC 2014).

Summary of Factor A

The threats to white fringeless orchid from habitat destruction and modification are occurring throughout much of the species' range. These threats include development, silvicultural practices, invasive plant species, disturbance by feral hogs, shading due to understory and canopy closure, altered hydrology, and right-of-way maintenance. While the species is present in a number of sites on conservation lands, few conservation actions have been undertaken to address these threats to the species' habitat, and those that are described above have met with limited success. The population-level impacts of habitat destruction and modification are expected to continue. Threats related to silvicultural practices could increase in the future, given that some occurrences are located on private industrial forest lands, where logging and future conversion of native hardwood forests to pine plantation are likely to occur. In addition to physical disturbances that alter hydrology, predicted changes in precipitation and drought frequency and severity (see Factor E, below) may contribute to increased loss of suitable habitat in the future.

Based on our review of the best commercial and scientific data available, we conclude that the present

or threatened destruction, modification, and curtailment of its habitat or range is currently a threat to white fringeless orchid and is expected to continue and possibly increase in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

White fringeless orchid was first collected from a site in McCreary County, Kentucky, but had disappeared from the site by the 1940s, apparently due to the collection of hundreds of specimens to be deposited in herbaria (Ettman and McAdoo 1979 cited in Zettler and Fairey 1990, p. 212). Shea (1992, p. 27) cites personal communications from R. Smartt and P. Somers, the latter of whom was a botanist with Tennessee's Natural Heritage Program, reporting that two nurseries in Tennessee had collected white fringeless orchid plants for resale. While we are not able to independently verify these historical reports, they suggest that collecting for various purposes has long been a threat to white fringeless orchid. Evidence of recent plant collecting (for unknown purposes), at two separate locations, is presented below.

The first of these occurred in 2004, alongside a State highway in Chattooga County, Georgia. Botanists discovered many flowering plants at the site, but when they later returned to the site they found that most of the plants had been dug out and removed. During 2014, only a single non-flowering white fringeless orchid was seen at this site (Richards 2014, pers. comm.). The second incident took place during 2014, alongside a State highway in Sequatchie County, Tennessee. A Service biologist observed 83 flowering white fringeless orchids at this site on August 13, 2014, but 2 weeks later only 31 plants bearing flowers or fruiting capsules were found during a survey with TDEC botanists. In the location where the greatest concentration of flowering plants had been observed on August 13, there were areas where mats of sphagnum moss and roots of woody plants had been scraped away from the surface and shallow depressions were present in the mineral soil beneath. Because no wildlife tracks were present in the area where the surface disturbance had occurred and no partial stems were present to indicate that the loss resulted from herbivory, the Service and TDEC botanists concluded that the plants had been collected.

While the fate of plants that have been collected is not known, we received information about white fringeless orchids having been purchased via an online vendor in 2004 (Richards 2014, pers. comm.). The plants were sold as nursery grown *Platanthera blephariglottis* (white fringed orchid), a taxon of which white fringeless orchid was once treated as a variety (Correll 1941, pp. 153–157); however, when the plants later flowered in a greenhouse, it was apparent they were white fringeless orchids. When the seller was questioned about the origin of the plants, she initially insisted they had come from a friend's private lands. The seller later refused to respond to additional inquiries from the buyer. A recent online search for commercially available, native *Platanthera* orchids revealed that three species, which often co-occur with white fringeless orchid, were being offered for sale on the online auction and shopping Web site eBay (*www.ebay.com,* accessed on September 17, 2014). The unintended purchase of white fringeless orchid from an online vendor, combined with the offering of three other *Platanthera* orchids for sale via eBay, provides additional evidence that demand exists for native orchids of this genus.

Due to the species' rarity, the small sizes of most known populations, and the fact that most of the populations are located in remote sites that are infrequently monitored by conservation organizations or law enforcement, collection is a threat to *P. integrilabia.* In small populations, the collection of even a few individuals would diminish reproductive output and likely reduce genetic diversity.

Based on our review of the best commercial and scientific data available, overutilization for commercial, scientific, or recreational purposes is currently a threat of low magnitude to white fringeless orchid and is expected to continue in the future. If the Service were to publish a proposal to designate critical habitat for this species, which would include detailed maps and descriptions of locations where the species is present, the magnitude and severity of this activity would increase, and it would become a threat of moderate to high magnitude.

Factor C. Disease or Predation

Zettler and Fairey (1990, p. 214) reported that both herbivory and disease affected two white fringeless orchid populations they studied in Georgia and South Carolina. At the Georgia site, 16.5 percent of the white fringeless orchids suffered from herbivory and 11.5 percent from disease; at the South Carolina site, herbivory and disease were evident on 22.5 and 23.9 percent of the plants, respectively. The specific herbivores were not discussed, but disease was attributed to pathogenic fungi that were isolated from necrotic tissue, including species of *Alternaria, Pestalotia, Nigrospora,* and *Cercospora* (Zettler and Fairey 1990, p. 214).

Zettler (1994, p. 687) also reported observations of tuber herbivory by feral hogs at the largest white fringeless orchid occurrence in McMinn County, Tennessee. The USFS constructed fences to exclude hogs from the greatest concentration of plants at this site and at a smaller occurrence in Polk County, but found the fence at the McMinn County site in need of repair in 2002, when they discovered that approximately half of the flowering white fringeless orchids and many vegetative orchids had been uprooted (USFS 2008, p. 54). As noted above, evidence of feral hog disturbance has been observed at 10 extant white fringeless orchid sites.

Numerous observers have reported herbivory by deer as a threat to white fringeless orchids, specifically removal of inflorescences from white fringeless orchid plants (Zettler and Fairey 1990, p. 212; Shea 1992, pp. 27, 61, 71–77, 95–97; TDEC 2012, p. 3; KSNPC 2014; TDEC 2014). From these sources, we found observations of inflorescence herbivory at 21 extant occurrences and 5 where the status is now uncertain. It is likely that this threat affects most white fringeless orchid occurrences (TDEC 2012, p. 3), despite not having been specifically documented in every instance.

Using material supplied by the Service, TDEC biologists installed plastic deer control fencing around two areas with concentrations of white fringeless orchids at a site on Tennessee State Park lands in 2013. During 2014, there were 105 flowering plants at the site, plus 31 plants with browsed inflorescences found outside of the fenced enclosures and one browsed plant inside one of the enclosures where the fence had partially collapsed. Inside of the enclosures were 45 flowering plants that were unharmed. Approximately one-third of the flowering plants outside of the fenced areas suffered inflorescence herbivory.

The high frequency at which inflorescence herbivory has been observed at white fringeless orchid occurrences likely contributes to population declines in this species. Orchid growth is initiated each spring from overwintered buds, similar to most perennial plants; however, orchids differ from most other plants by lacking the capacity to replace tissues lost to herbivory or other causes until the following year. In addition, in several

species of *Platanthera,* the usual response to loss of the shoot is death of the plant (Sheviak 1990, p. 195).

Based on our review of the best commercial and scientific data available, predation is a threat of moderate to high magnitude to white fringeless orchid and is expected to continue in the future. Pathogenic fungi have been documented in only two populations, though their presence has likely been overlooked by most observers, and therefore they are a low magnitude threat.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Section 4(b)(1)(A) of the Act requires the Service to take into account ''those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species. . . .'' In relation to Factor D under the Act, we interpret this language to require the Service to consider relevant Federal, State, and tribal laws, plans, regulations, and other such mechanisms that may minimize any of the threats we describe in threat analyses under the other four factors, or otherwise enhance conservation of the species. We give strongest weight to statutes and their implementing regulations and to management direction that stems from those laws and regulations. An example would be State governmental actions enforced under a State statute or constitution, or Federal action under statute.

Having evaluated the significance of the threat as mitigated by any such conservation efforts, we analyze under Factor D the extent to which existing regulatory mechanisms are inadequate to address the specific threats to the species. Regulatory mechanisms, if they exist, may reduce or eliminate the impacts from one or more identified threats. In this section, we review existing State and Federal regulatory mechanisms to determine whether they effectively reduce or remove threats to the white fringeless orchid.

The white fringeless orchid is listed as special concern, with historical status, by the State of North Carolina, as threatened by the State of Georgia, and as endangered by the Commonwealth of Kentucky and State of Tennessee.

The North Carolina Plant Protection and Conservation Act (NCPPCA; North Carolina General Statutes 106–202) authorizes the North Carolina Plant Conservation Board, within the Department of Agriculture and Consumer Services, to among other things: Maintain a list of protected plant species; adopt regulations to protect, conserve, or enhance protected plant species; and regulate the sale or distribution of protected plant species. The NCPPCA forbids any person from uprooting, digging, taking or otherwise disturbing or removing protected plant species from the lands of another without a written permit and prescribes penalties for violations.

The law that provides official protection to designated species of plants in Georgia is known as the Wildflower Preservation Act of 1973. Under this State law, no protected plant may be collected without written landowner permission. No protected plant may be transported within Georgia without a transport tag with a permit number affixed. Permits are also used to regulate a wide array of conservation activities, including plant rescues, sale of protected species, and propagation efforts for augmenting natural populations and establishing new ones. No protected plants may be collected from State-owned lands without the express permission of the GDNR. The Georgia Environmental Policy Act (GEPA), enacted in 1991, requires that impacts to protected species be addressed for all projects on State-owned lands, and for all projects undertaken by a municipality or county if funded half or more by State funds, or by a State grant of more than $250,000. The provisions of GEPA do not apply to actions of non-governmental entities. On private lands, the landowner has ultimate authority on what protection efforts, if any, occur with regard to protected plants (Patrick *et al.* 1995, p. 1 of section titled ''Legal Overview'').

The Kentucky Rare Plants Recognition Act, Kentucky Revised Statutes (KRS), chapter 146, sections 600–619, directs the KSNPC to identify plants native to Kentucky that are in danger of extirpation within Kentucky and report every 4 years to the Governor and General Assembly on the conditions and needs of these endangered or threatened plants. This list of endangered or threatened plants in Kentucky is found in Kentucky Administrative Regulations, title 400, chapter 3:040. The statute (KRS 146:600–619) recognizes the need to develop and maintain information regarding distribution, population, habitat needs, limiting factors, other biological data, and requirements for the survival of plants native to Kentucky. This statute does not include any regulatory prohibitions of activities or direct protections for any species included in the list. It is expressly stated in KRS 146.615 that this list of endangered or threatened plants shall not obstruct or hinder any development or use of public or private land. Furthermore, the intent of this statute is not to ameliorate the threats identified for the species, but it does provide information on the species.

The Tennessee Rare Plant Protection and Conservation Act of 1985 (TRPPCA; Tennessee Code Annotated 11–26–201) authorizes the Tennessee Department of Environment and Conservation (TDEC) to, among other things: Conduct investigations on species of rare plants throughout the State of Tennessee; maintain a listing of species of plants determined to be endangered, threatened, or of special concern within the State; and regulate the sale or export of endangered species via a licensing system. The TRPPCA forbids persons from knowingly uprooting, digging, taking, removing, damaging, destroying, possessing, or otherwise disturbing for any purpose, any endangered species from private or public lands without the written permission of the landowner, lessee, or other person entitled to possession and prescribes penalties for violations. The TDEC may use the list of threatened and special concern species when commenting on proposed public works projects in Tennessee, and the department encourages voluntary efforts to prevent the plants on this list from becoming endangered species. This authority is not, however, to be used to interfere with, delay, or impede any public works project.

Thus, despite the fact that the white fringeless orchid is listed as special concern, threatened, or endangered by the States of Georgia, North Carolina, and Tennessee and the Commonwealth of Kentucky, these designations confer no guarantee of protection to the species' habitat, whether on privately owned or State-owned lands, unless such protections are voluntarily extended to the species, and only prohibit unauthorized collection in Georgia, North Carolina, and Tennessee.

Section 404 of the Clean Water Act (CWA; 33 U.S.C. 1251 *et seq.*) establishes a Federal program for regulating the discharge of dredged or fill material into waters of the United States, including wetlands. Additionally, section 401 of the CWA forbids Federal agencies from issuing a permit or license for activities that may result in a discharge to waters of the United States until the State or Tribe where the discharge would originate has granted or waived certification. All of the States where white fringeless orchid occurs maintain regulatory programs providing a framework for issuance of section 401 certifications related to applications for section 404 permits.

This legislation does not prohibit the discharge of these materials into wetlands; rather, it provides a regulatory framework that requires permits prior to such action being taken. The U.S. Army Corps of Engineers (Corps) reviews individual permits for potentially significant impacts; however, most discharges are considered to have minimal impacts and may be covered by a general permit that does not require individual review.

Due to their typical position in non-navigable heads of streams located remotely from traditional navigable waters, where flow is ephemeral or intermittent and channels are poorly defined, if present at all, wetlands where white fringeless orchid occurs have been considered to not exhibit a significant nexus with traditional navigable waters. Therefore, these types of wetlands typically do not meet the definition of waters of the United States given in the Environmental Protection Agency (EPA) and Corps joint memorandum *Clean Water Act Jurisdiction Following the U.S. Supreme Court's Decision in Rapanos* v. *United States & Carabell* v. *United States* (December 2, 2008). However, on June 29, 2015, the EPA and Corps published a final rule (80 FR 37054) that revises the definition of ''Waters of the United States.'' Specific guidance on implementation of this revised definition is currently lacking, but it appears that the revised definition now includes the habitats where white fringeless orchid occurs among waters of the United States.

While the wetland habitats occupied by white fringeless orchid are now likely to be included within the definition of waters of the United States, as noted above, section 404 of the CWA does not necessarily prevent degradation to such habitats from the discharge of dredge or fill material. It simply provides a regulatory program for permitting activities that would result in such a discharge. Further, discharges associated with normal farming, ranching, and forestry activities, such as plowing, cultivating, minor drainage, and harvesting for the production of food, fiber, and forest products are exempt from the requirement to obtain a permit. Thus, potential impacts to wetland habitats from silvicultural activities such as those described above in the Factor A discussion are not regulated under section 404 of the CWA.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Small Population Size

The low number of individuals that have been seen at most white fringeless orchid occurrences (Figure 1, above) increases the species' vulnerability to threats, discussed under Factors A through D, above, by diminishing its resilience to recover from demographic reductions caused by habitat disturbance or modification, collecting, or herbivory. Despite the fact that white fringeless orchid has been shown to be self-compatible, higher rates of fruit set have been observed in larger populations, presumably due to higher rates of cross-pollination (Zettler and Fairey 1990, p. 214; Zettler *et al.* 1996, p. 20). Zettler *et al.* (1996, p. 22) attributed the lower fruiting rates in the smaller populations to inbreeding depression, noting that in a separate study both germination rates and propagation success were greater in white fringeless orchid seeds collected from the largest of the three populations they studied (Zettler and McInnis 1992, p. 160). Johnson *et al.* (2009, p. 3) found that higher proportions of self-pollination occurred in smaller populations of a moth-pollinated orchid, *Satyrium longicauda* (no common name), presumably due to pollinators visiting more flowers per plant in smaller populations and more frequently transferring pollen among flowers within a single inflorescence, rather than frequently moving among separate inflorescences on different individuals. To the extent that rates of cross-pollination, fruit set, germination, and propagation success are lower for white fringeless orchid populations of small size, demographic reductions resulting from other threats place the species at greater risk of localized extinctions.

While the results of genetic analyses did not demonstrate that genetic variability in populations of white fringeless orchid has been eroded by restricted gene flow, Birchenko (2001, pp. 34–40) cautioned that interactions between demographic and ecological factors could be a cause for some of the declines in white fringeless orchid population sizes and could ultimately cause declines in the species' genetic variation and increase differentiation among its populations. The ability of populations to adapt to environmental change is dependent upon genetic variation, a property of populations that derives from its members possessing different forms (*i.e.,* alleles) of the same gene (Primack 1998, p. 283). Small populations occurring in isolation on the landscape can lose genetic variation due to the potentially strong influence of genetic drift, *i.e.,* the random change in allele frequency from generation to generation (Barrett and Kohn 1991, p. 8). Smaller populations experience greater changes in allele frequency due to drift than do larger populations (Allendorf and Luikart 2007, pp. 121–122). Loss of genetic variation due to genetic drift heightens susceptibility of small populations to adverse genetic effects, including inbreeding depression and loss of evolutionary flexibility (Primack 1998, p. 283). Deleterious effects of loss of genetic variation through drift have been termed drift load, which is expressed as a decline in mean population performance of offspring in small populations (Willi *et al.* 2005, p. 2260).

Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate. The terms ''climate'' and ''climate change'' are defined by the Intergovernmental Panel on Climate Change (IPCC). ''Climate'' refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2014, pp. 119–120). The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (*e.g.,* temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (IPCC 2014, pp. 119–120). A recent compilation of climate change and its effects is available from reports of the IPCC (IPCC 2014, entire).

Various types of changes in climate can have direct or indirect effects on species. These effects may be positive, neutral, or negative and they may change over time, depending on the species and other relevant considerations, such as the effects of interactions of climate with other variables (*e.g.,* habitat fragmentation) (IPCC 2007, pp. 8–14, 18–19). Projected changes in climate and related impacts can vary substantially across and within different regions of the world (*e.g.,* IPCC 2014, pp. 11–13). Therefore, we use ''downscaled'' projections when they are available and have been developed through appropriate scientific procedures (see Glick *et al.* 2011, pp. 58–61, for a discussion of downscaling). In our analyses, we use our expert judgment to weigh relevant information, including uncertainty, in our

consideration of various aspects of climate change.

The IPCC concluded that evidence of warming of the climate system is unequivocal (IPCC 2014, pp. 2, 40). Numerous long-term climate changes have been observed including changes in arctic temperatures and ice, widespread changes in precipitation amounts, ocean salinity, and aspects of extreme weather including heavy precipitation and heat waves (IPCC 2014, pp. 40–44). While continued change is certain, the magnitude and rate of change is unknown in many cases. Species that are dependent on specialized habitat types, are limited in distribution, or have become restricted to the extreme periphery of their range will be most susceptible to the impacts of climate change.

Estimates of the effects of climate change using available climate models lack the geographic precision needed to predict the magnitude of effects at a scale small enough to discretely apply to the range of white fringeless orchid (*i.e.,* there are no ''downscaled'' projections available). However, data on recent trends and predicted changes for the Southeast United States (Karl *et al.* 2009, pp. 111–122) provide some insight for evaluating the potential threat of climate change to the species. White fringeless orchid's geographic range lies within the geographic area included by Karl *et al.* (2009, pp. 111–116) in their summary of regional climate impacts affecting the Southeast region.

Since 1970, the average annual temperature across the Southeast has increased by about 2 degrees Fahrenheit (°F), with the greatest increases occurring during winter months. The geographic extent of areas in the Southeast region affected by moderate to severe spring and summer drought has increased over the past three decades by 12 and 14 percent, respectively (Karl *et al.* 2009, p. 111). These trends are expected to increase. Rates of warming are predicted to more than double in comparison to what the Southeast has experienced since 1975, with the greatest increases projected for summer months. Depending on the emissions scenario used for modeling change, average temperatures are expected to increase by 4.5 °F to 9 °F by the 2080s (Karl *et al.* 2009, p. 111). While there is considerable variability in rainfall predictions throughout the region, increases in evaporation of moisture from soils and loss of water by plants in response to warmer temperatures are expected to contribute to increased frequency, intensity, and duration of drought events (Karl *et al.* 2009, p. 112).

Depending on timing and intensity of drought events, white fringeless orchid occurrences could be adversely affected by increased mortality rates, reduced reproductive output due to loss or reduced vigor of mature plants, and reduced rates of seed germination and seedling recruitment. Further, white fringeless orchid's dependence upon a limited number of large Lepidoptera for pollination (Zettler *et al.* 1996, pp.16–22) and, potentially, on a single species of mycorrhizal fungi to complete its life cycle (Currah *et al.* 1997, p. 340) place the species at higher risk of extinction due to environmental changes that could diminish habitat suitability for it or the other species upon which it depends (Swarts and Dixon 2009, p. 546).

While climate has changed in recent decades in the southeastern United States and the rate of change likely will continue to increase into the future, we do not have data to determine specifically how the habitats where white fringeless orchid occurs will be affected by, or how the species will respond to, these changes. However, the potential for adverse effects to white fringeless orchid, either through changes in habitat suitability or by affecting populations of pollinators or mycorrhizal fungi, is likely to increase as climate continues to change at an accelerating rate.

Based on our review of the best commercial and scientific data available, diminished resilience of many occurrences due to small population sizes and the species' dependence on a limited number of Lepidoptera and a single species of fungi to complete its life cycle are currently threats of moderate magnitude to white fringeless orchid. These threats are expected to continue and, in light of climate change projections, possibly increase in the future.

Proposed Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the white fringeless orchid. Habitat destruction and modification (Factor A) from development, silvicultural practices, excessive shading, and altered hydrology (*i.e.,* pond construction, beaver dam removal) have resulted in extirpation of the species from 10 sites. These threats, in addition to invasive plant species, feral hogs, and right-of-way maintenance, are associated with habitat modifications affecting dozens of other occurrences that are extant or of uncertain status. Collecting for scientific, recreational, or commercial purposes (Factor B) has been attributed as the cause for extirpation of white fringeless orchid at its type locality, and recent evidence demonstrates that this activity remains a threat to this species. Fungal pathogens have been identified as a threat to white fringeless orchid, but a threat with potentially greater impact associated with Factor C is inflorescence herbivory, presumably by deer, which has been reported at over one-third of extant occurrences and likely is a factor threatening most white fringeless orchid occurrences, especially where low numbers of plants are present. Tuber herbivory by feral hogs has been reported at the largest known white fringeless orchid occurrence. The effects of these threats are intensified by the small population sizes that characterize a majority of occurrences throughout the species' geographic range (Factor E), due to their diminished resilience to recover from demographic reductions caused by loss of individuals or low reproductive output from other threats. Further, the species' dependence on a limited number of Lepidoptera and a single species of fungi to complete its life cycle, make it vulnerable to disturbances that diminish habitat suitability for these taxa as well (Factor E). Existing regulatory mechanisms have not led to a reduction or removal of threats posed to the species from these factors (see Factor D discussion).

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that white fringeless orchid is likely to become endangered throughout all or a significant portion of its range within the foreseeable future based on the low to moderate threats currently impacting the species. The species is known to be extant at 58 locations, but low numbers of individuals have been observed at more than half of these (see Figure 1, above), distributed across the species' range, and their persistence into the future is uncertain. Furthermore, the threats of habitat destruction or modification and herbivory are present throughout the species' geographic range. Left unmanaged, these threats will likely lead to further reductions in the species' geographic range and abundance at individual sites, increasing the risk of extinction to the point of endangerment. Therefore, on the basis of the best available scientific and commercial information, we

propose listing the white fringeless orchid as threatened in accordance with sections 3(20) and 4(a)(1) of the Act. The species does not currently meet the definition of endangered, because a sufficient number of robust populations are present on publicly owned or managed lands. Conservation efforts have been initiated that could be effective in reducing threats by increasing population sizes and improving habitat conditions across much of the species' geographic range.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. The threats to the survival of white fringeless orchid occur throughout the species' range and are not restricted to any particular significant portion of that range. Accordingly, our assessment and proposed determination applies to the species throughout its entire range. Therefore, because we have determined that white fringeless orchid is threatened throughout all of its range, no portion of its range can be ''significant'' for purposes of the definitions of ''endangered species'' and ''threatened species.'' See the Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578; July 1, 2014).

Critical Habitat and Prudency Determination

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographic area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features:

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist:

(1) The species is threatened by taking, collection, or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or

(2) Such designation of critical habitat would not be beneficial to the species.

We have determined that white fringeless orchid is threatened by taking, collection, or other human activity and that identification of critical habitat would be expected to increase this threat. We also have determined that little measurable benefit to the species would result from designation of critical habitat. This determination involves weighing the expected increase in threats associated with a critical habitat designation against the benefits gained by a critical habitat designation. An explanation of this ''balancing'' evaluation follows.

Increased Threat to the Species by Designating Critical Habitat

Designation of critical habitat requires publication of maps and a narrative description of specific critical habitat areas in the **Federal Register**. The degree of detail in those maps and boundary descriptions is far greater than the general location descriptions provided in this listing proposal. Also, while general location data (*e.g.,* names of administrative units of the National Park Service (NPS), USFS, or State conservation agencies where the species occurs) concerning white fringeless orchid are available, maps or detailed descriptions are not found in scientific or popular literature, current agency management plans, or other readily available sources. One exception is the availability online of a now expired management plan for a site in Alabama with maps depicting two locations of the species. Location information can also be found in a journal article for a site in North Carolina, where the species is no longer extant. Designation of critical habitat would more widely announce the exact location of the white fringeless orchid to poachers, collectors, and vandals and further facilitate unauthorized collection. Due to its rarity (low numbers of individuals in most populations), this orchid is highly vulnerable to collection. Removal of individuals from extant populations would have devastating consequences in terms of reducing their viability, if not causing outright extirpation. These threats would be exacerbated by the publication of maps and descriptions outlining the specific locations of this imperiled orchid in the **Federal Register** and local newspapers. Maps and descriptions of critical habitat, such as those that would appear in the **Federal Register** if critical habitat were designated, are not now available to the general public.

We have discussed evidence related to poaching and commercial sale of white fringeless orchid and other congeners above (see Factor B, above). Due to the species' rarity, the small sizes of most known populations, and the fact that most of the populations are located in remote sites that are infrequently monitored by conservation organizations or law enforcement, collection is a threat to white fringeless orchid. In small populations, the collection of even a few individuals would diminish reproductive output and likely reduce genetic diversity. Identification of critical habitat would increase the magnitude and severity of this threat by spatially depicting exactly where the species may be found and widely publicizing this information, exposing these fragile populations and their habitat to greater risks. We have reviewed management plans and other documents produced by Federal and State conservation agencies and scientific literature, and detailed information on the specific locations of white fringeless orchid sites is not currently available.

Benefits to the Species From Critical Habitat Designation

It is true that designation of critical habitat for endangered or threatened species could have some beneficial effects. Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of that species' critical habitat. Critical habitat only provides protections where there is a Federal nexus, that is, those actions that come under the purview of section 7 of the Act. Critical habitat designation has no application to actions that do not have a Federal nexus. Section 7(a)(2) of the Act mandates that Federal agencies, in consultation with the Service, evaluate the effects of its proposed action on any designated critical habitat. Similar to the Act's requirement that a Federal agency action not jeopardize the

continued existence of listed species, Federal agencies have the responsibility not to implement actions that would destroy or adversely modify designated critical habitat. Critical habitat designation alone, however, does not require that a Federal action agency implement specific steps toward species recovery.

Available data indicate that white fringeless orchid is known from 58 extant occurrences and from 22 others whose current status is uncertain. Of these 80 occurrences, 17 are located on Federal lands managed by the USFS (12), NPS (3), and the Service (2), where they currently receive protection from adverse effects of management actions and, in some cases, receive management specifically to benefit the species and its habitat. Management efforts have taken place to control feral hogs and invasive plants, increase light availability by reducing woody vegetation cover, and restore hydrology. In addition, the USFS recently entered a Master Stewardship Agreement with the Atlanta Botanical Garden to provide for habitat management, captive propagation, and reintroduction or augmentation of populations on USFS lands, where appropriate. Some of the populations on Federal lands are the largest known, and any future activity involving a Federal action that would destroy or adversely modify critical habitat at these sites would also likely jeopardize the species' continued existence. Consultation with respect to critical habitat would provide additional protection to a species only if the agency action would result in the destruction or adverse modification of the critical habitat but would not jeopardize the continued existence of the species. In the absence of a critical habitat designation, areas that support white fringeless orchid will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard, as appropriate.

Another possible benefit to white fringeless orchid from designating critical habitat would be that it could serve to educate landowners; State and local government agencies; visitors to National Forests, National Parks, and National Wildlife Refuges; and the general public regarding the potential conservation value of the areas. However, through the process of recognizing white fringeless orchid as a candidate for Federal listing, much of this educational benefit has already been realized and designating critical habitat would do little to increase awareness about the species' presence and need for conservation among affected land managers. Agencies, organizations, and stakeholders are actively engaged in efforts to raise awareness for the orchid and its conservation needs. For example, the Atlanta Botanical Garden received a Five Star Urban Habitat Restoration grant to improve habitat at several white fringeless orchid sites in Georgia, propagate the species for reintroductions or augmentations, and establish educational bog gardens at Chattahoochee Nature Center and the Atlanta Botanical Garden. This project, which is separate from the USFS agreement discussed above, involves seven official partners, including two local high schools and Georgia State University. In addition, designation of critical habitat could inform State agencies and local governments about areas that could be conserved under State laws or local ordinances. However, as awareness and education involving white fringeless orchid is already well underway and the species currently receives protection from adverse effects of management activities where it occurs on public and privately owned conservation lands, designation of critical habitat would likely provide only minimal incremental benefits.

Increased Threat to the Species Outweighs the Benefits of Critical Habitat Designation

Upon reviewing the available information, we have determined that the designation of critical habitat would increase the threat to white fringeless orchid from unauthorized collection and trade. At the same time, designation of critical habitat is likely to confer little measurable benefit to the species beyond that provided by listing. Overall, the risk of increasing significant threats to the species by publishing detailed location information in a critical habitat designation greatly outweighs the benefits of designating critical habitat.

In conclusion, we find that the designation of critical habitat is not prudent, in accordance with 50 CFR 424.12(a)(1), because white fringeless orchid is threatened by collection, and designation can reasonably be expected to increase the degree of this threat to the species and its habitat. However, we seek public comment on our determination that designation of critical habitat is not prudent.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for downlisting or delisting, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. If the species is listed, the recovery outline, draft recovery plan, and the final recovery plan, when completed, would be available on our Web site (*http://www.fws.gov/endangered*), or from our Tennessee Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other

Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands. If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the State(s) of Georgia, South Carolina, and Tennessee and the Commonwealth of Kentucky would be eligible for Federal funds to implement management actions that promote the protection or recovery of the white fringeless orchid. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the white fringeless orchid is only proposed for listing under the Act at this time, please let us know if you are interested in participating in conservation efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for conservation planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the U.S. Fish and Wildlife Service, USFS, and NPS; issuance of section 404 CWA permits by the Corps; powerline right-of-way construction and maintenance by the Tennessee Valley Authority; and construction and maintenance of roads or highways by the Federal Highway Administration.

With respect to threatened plants, 50 CFR 17.71 provides that all of the provisions at 50 CFR 17.61 shall apply to threatened plants. These provisions make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale in interstate or foreign commerce, or to remove and reduce to possession any such plant species from areas under Federal jurisdiction. In addition, the Act prohibits malicious damage or destruction of any such species on any area under Federal jurisdiction, and the removal, cutting, digging up, or damaging or destroying of any such species on any other area in knowing violation of any State law or regulation, or in the course of any violation of a State criminal trespass law. However, there is the following exception for threatened plants. Seeds of cultivated specimens of species treated as threatened shall be exempt from all the provisions of 50 CFR 17.61, provided that a statement that the seeds are of ''cultivated origin'' accompanies the seeds or their container during the course of any activity otherwise subject to these regulations. Exceptions to these prohibitions are outlined in 50 CFR 17.72.

We may issue permits to carry out otherwise prohibited activities involving threatened plants under certain circumstances. Regulations governing permits are codified at 50 CFR 17.72. With regard to threatened plants, a permit issued under this section must be for one of the following: Scientific purposes, the enhancement of the propagation or survival of threatened species, economic hardship, botanical or horticultural exhibition, educational purposes, or other activities consistent with the purposes and policy of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of species proposed for listing.

Based on the best available information, the following activities may potentially result in a violation of section 9 the Act; this list is not comprehensive:

(1) Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of white fringeless orchid, including import or export across State lines and international boundaries, except for properly documented antique specimens of this species at least 100 years old, as defined by section 10(h)(1) of the Act;

(2) Unauthorized removal, damage, or destruction of white fringeless orchid plants from populations located on Federal land (USFS, NPS, and Service lands); and

(3) Unauthorized removal, damage, or destruction of white fringeless orchid plants on private land in violation of any State regulation, including criminal trespass.

At this time, we are unable to identify specific activities that would not be considered to result in a violation of section 9 of the Act because white fringeless orchid occurs in a variety of habitat conditions across its range and it is likely that site-specific conservation measures may be needed for activities that may directly or indirectly affect the species.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Tennessee Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one

of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the Tennessee Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Tennessee Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.12(h), add an entry for *Platanthera integrilabia* (white fringeless orchid) to the List of Endangered and Threatened Plants in alphabetical order under FLOWERING PLANTS to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*	*	
Platanthera integrilabia	White fringeless orchid.	U.S.A. (AL, GA, KY, MS, NC, SC, TN).	Orchidaceae	T		NA	NA
*	*	*	*	*	*	*	

* * * * *

Dated: August 14, 2015.

Stephen Guertin,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2015–22973 Filed 9–14–15; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 80, No. 178
Tuesday, September 15, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Economic Research Service

Notice of Intent To Request New Information Collection

AGENCY: Economic Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Economic Research Service (ERS) invites the general public and other Federal agencies to take this opportunity to comment on a proposed new information collection, the Generic Clearance for Survey Research Studies.

DATES: Comments on this notice must be received by November 16, 2015 to be assured of consideration.

ADDRESSES: Address all comments concerning this notice to Pheny Weidman, ERS Clearance Officer, Economic Research Service, Room 4–163B, 1400 Independence Ave. SW., Mail Stop 1800, Washington, DC 20050–1800. Submit electronic comments to *pweidman@ers.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Pheny Weidman at the address in the preamble. Tel. 202–694–5013.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for Survey Research Studies.

OMB Number: 0536–NEW.

Expiration Date of Approval: Three years from the date of approval.

Type of Request: New collection.

Abstract: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and OMB regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the ERS' intention to request approval from the Office of Management and Budget (OMB) for a generic clearance that will allow ERS to rigorously develop, test, and evaluate its survey methodologies, instruments, and administration. The mission of ERS is to provide economic and other social science information and analysis for public and private decisions on agriculture, food, natural resources, and rural America. This request is part of an on-going initiative to improve ERS data product quality, as recommended by both its own guidelines and those of OMB.

The purpose of this generic clearance is to allow ERS to evaluate, adopt, and use state-of-the-art and multi-disciplinary research to improve and enhance the quality of its current data collections. This clearance will also be used to aid in the development of new surveys. It will help to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

ERS envisions using a variety of survey improvement techniques, as appropriate to the individual project under investigation. These include focus groups, cognitive and usability laboratory and field techniques, exploratory interviews, behavior coding, and respondent debriefing.

Following standard OMB requirements, ERS will inform OMB individually in writing of the purpose, scope, time frame, and number of burden hours used for each survey improvement or development project it undertakes under this generic clearance. ERS will also provide OMB with a copy of the data collection instrument (if applicable), and all other materials describing the project.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a).

ERS intends to protect respondent information under the Privacy Act of 1974, Section 1770 of the Food Security Act of 1985, and 7 U.S.C. 2276. ERS has decided not to invoke the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA). The complexity and cost necessary to invoke CIPSEA is not justified given the nature of the collection; the collections would generally be conducted by ERS' contractors and designed to be hosted in non-government owned computer systems, where CIPSEA compliance could not be assured.

Specific details regarding information handling will be specified in individual submissions under this generic clearance.

Estimate of Burden: Public reporting burden for these collections of information is estimated to average from 1 to 2 hours per respondent, depending upon the information collection and the technique used to test for that particular collection.

Respondents: Individuals or households, farms, and businesses or other for-profits.

Estimated Total Number of Respondents: 3,500.

Estimated Total Annual Burden on Respondents: 5,600 hours. Public reporting burden for these collections of information is estimated to average from 1 to 2 hours per respondent, dependent upon the survey and the technique used to test for that particular survey.

Copies of this information collection can be obtained from Pheny Weidman at the address in the preamble.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to the address in the preamble. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: September 3, 2015.

Mary Bohman,

Administrator, Economic Research Service.

[FR Doc. 2015–23123 Filed 9–14–15; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF AGRICULTURE

Forest Service

Shasta-Trinity National Forest; California; Highway 89 Safety Enhancement and Forest Ecosystem Restoration Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: With the Highway 89 Safety Enhancement and Forest Ecosystem Restoration Project (Highway 89 project), the Shasta-Trinity National Forest (Forest) is proposing to improve public safety along California State Highway 89 (Highway 89) and restore forest health throughout approximately 13,514 acres of forest by:

Addressing infrastructure needs (National Forest System roads and helispot, developed recreation areas);

Reducing the risk of uncharacteristic wildfire by reducing fuel loads, thinning overstocked stands, and gradually returning fire to the landscape both along the highway corridor and within the surrounding forest; and

Restoring resilient forest structures, patterns, and disturbance regimes by reducing stand densities, retaining and releasing larger trees, increasing under-represented forest vegetation such as aspen and oak, and providing forest structural diversity across the landscape.

The 13,514 acre project area is located in Siskiyou County, California, north and south of Highway 89, from near the junction of Highway 89 with Interstate 5 (Mount Shasta, California area), east to the Cattle Camp turnoff (Forest Roads 43N19 and 40N44). The project boundary extends up to 2.5 miles from the highway and is bounded by the McCloud River, private property, and major Forest roads. The large landscape selected encompasses both complex natural forest stands that retain more spatial heterogeneity combined with simplified forest stands that are typically homogeneous in structure and include uniform stands of small and medium-sized trees within plantations. Using logical landscape boundaries, including the river, private property, roads, and other restored landscapes (Algoma Vegetation Management Project) fosters restoration of resilient forest structures, patterns, and disturbance regimes which are lacking.

The legal location is: Township 39 North, Range 1 West, Sections 2–10, 17–18; Township 39 North, Range 2 West, Sections 1–3, 12; Township 40 North, Range 1 West, Sections 27, 28, 31–34; Township 40 North, Range 2 West, Sections 34–36; Township 40 North, Range 3 West, Sections 32–33; Township 40 North, Range 4 West, Sections 22–26, 34, Mt. Diablo Meridian. Elevations range from 3,200 to 4,400 feet.

Project treatments include thinning along the Highway 89 corridor, thinning in plantations and in natural forest stands throughout the 13,514 acres, hazard tree removal, prescribed burning, Forest road management, and developing a helispot.

DATES: Comments concerning this scope of the analysis must be received by October 15, 2015. The draft environmental impact statement is expected in December, 2015 and the final environmental impact statement is expected in May 2016.

ADDRESSES: Send written comments to Carolyn Napper, District Ranger, Shasta-McCloud Management Unit, 204 W. Alma St., Mt. Shasta, California 96067, Attn. Heather McRae. Comments may also be sent via email to: *comments-pacificsw-shasta-trinity-mtshasta-mccloud@fs.fed.us,* or via facsimile to (530) 926–5120.

FOR FURTHER INFORMATION CONTACT: Heather McRae, Fuels Specialist, at (530) 964–3770 or *hmcrae@fs.fed.us,* or Ann Glubczynski, Natural Resource Planner, at (530) 964–3717 or *aglubczynski@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The project purpose and need for action is generated by looking at the difference between the existing conditions and the desired conditions [as identified in the Shasta-Trinity National Forest Land Resource Management Plan (Forest Plan)] in the project area.

Highway 89 Corridor

Existing Conditions: The Highway 89 corridor is defined as the area that extends up to 275 feet out from the edge of the pavement on both sides of the two-lane highway. This corridor is composed of three sections between Interstate 5 (I–5) and Cattle Camp (Forest roads 43N19 and 40N44), for a total of 10.2 miles. The California Department of Transportation (CalTrans) right of way (ROW) along the highway varies from 80 to 200 feet from the roadway centerline through the project area.

The vegetation along portions of the Highway 89 corridor includes tall, dense forest stands that are close to the road shoulder and cast shadows on the pavement. During the winter months, the shade on the roadway keeps snow and ice from melting for up to several weeks following a storm. Trees immediately adjacent to the highway with overhanging branches can drop snow loads onto the highway and passing vehicles. These branches collect snow, until the snow becomes too heavy, and drops onto the roadway. Snow from overhanging branches has been known to hit the windshields of vehicles as it falls, even breaking some windshields. In many areas, the trees and brush are very dense, growing within the ROW, which makes snow removal from the paved traffic lanes difficult.

During the entire year, vegetation along the highway also limits visibility for drivers to see wildlife moving from the forest onto the highway. Numerous animal and vehicle collisions have occurred along the highway in the project area, because drivers are not able to see animals entering the roadway until they are so close that it is difficult to stop or even slow down.

Dense vegetation, tree mortality, and large amounts of dead vegetation and debris along Highway 89 have increased the likelihood that a fire starting or burning along the highway could spread quickly to threaten surrounding forests and communities, or allow for a fire to cross the highway, and be difficult to control during dry summer conditions. Highway 89 also serves as an evacuation route for residents to leave and emergency personnel to access the area.

Desired Future Conditions: Sunlight is able to reach the Highway 89 road surface during winter months, enabling snow and ice to melt from the roadway more quickly. There are fewer trees with branches hanging over Highway 89.

Drivers along Highway 89 have adequate sight distance and an open view of wildlife entering the roadway to respond as necessary.

Sufficient gaps in vegetation exist along Highway 89 to allow for efficient snow removal during heavy snowfalls.

Vegetation conditions and predicted fire behavior along Highway 89 are such that a wildfire during summer months is less likely to spread along or across the highway, is less likely to threaten surrounding forests and communities, and would not limit access for firefighters, or egress for citizens.

Forest Roads, Powerline Corridors and Helispot

Existing Conditions: There are many Forest roads within the project area. The conditions of these roads vary, from

well maintained to nearly undrivable. Brush and trees encroach on some roadways making them undrivable or difficult to drive on and therefore unsafe for users. Many Forest roads are used frequently by Forest visitors to access areas where they recreate, or for recreation activities such as biking, horse-back riding, or driving off highway vehicles (OHVs). Some of these roads have reduced access for recreational opportunities due to their poor condition or being overgrown.

Some roads that are open are not heavily used, nor are they needed for resource management activities. There are many user-created routes in the project area that are not part of the Forest transportation system (unauthorized routes) and not needed for resource management activities. But several Forest Transportation System roads and one unauthorized route in the project area that are currently closed or inaccessible do provide critical access for resource management activities.

Powerlines crossing through the project area are maintained by the power companies, who currently remove vegetation within the power line corridor ROW. However, in some areas, such as near the community of Mount Shasta, dense forest stands on NFS lands are growing right up to the powerline corridors. The safety of firefighters responding to a fire near these powerlines is at risk. There is no break in the vegetation sufficient to safely put firefighters near the powerlines during a wildfire to protect them.

There is an existing helispot located behind the Ash Creek Guard Station where trees are obstructing the take-off and landing paths for helicopters. These trees are part of a seed orchard of specially bred trees. Cutting these trees would result in the loss of valuable genetic research. The effectiveness of the helispot is increasingly hazardous due to the height of adjacent trees, and we expect that within 10 years the helispot will no longer be usable. There is currently no other suitable landing spot for helicopters in the general vicinity.

Desired Future Conditions: Roads on the Forest transportation system that are needed for current and future resource management or recreation access have been maintained to provide safe access for forest management and recreation activities, including: OHV riding, horseback riding, and biking (activities the public has indicated are important to them). Forest transportation system roads used for Forest resource management are closed when not in use. Unauthorized routes that do not meet management needs are decommissioned and become revegetated. Forest system roads and trails that access rivers and streams for water-oriented recreation activities are improved, and roads and trails to hunting, fishing and wildlife viewing areas are maintained at an appropriate maintenance level.

Vegetation on both sides of the powerline ROW is managed to reduce potential impacts during wildfire. Overstory, ladder, and surface fuels would be reduced such that the potential for crown fire during summer conditions is unlikely. Anticipated fire behavior during summer conditions is such that firefighters can safely manage a fire in the vicinity of the powerlines.

A new helispot is located east of McCloud, with sufficient clearance to allow a medical evacuation (medevac) helicopter to land and transport a patient. This helispot is also available to support fire operations.

Developed Recreation Areas

Existing Conditions: Developed recreation areas within the project boundary include those within the McCloud River Loop area, specifically: Fowlers, Cattle Camp and Camp 4 Campgrounds, Lower, Middle, and Upper Falls picnic areas, Lakin Dam and Cattle Camp Swimming Hole day use sites, the McCloud River Trail, and the Vista Point along Highway 89.

Many of the forest stands in the recreation areas are overly dense and at risk of density-related mortality. Evidence of root disease and insect damage has been observed, and high fuel loading from mortality is present throughout the area, increasing the likelihood of undesirable effects in the event of a wildfire.

In the Cattle Camp Campground, there has been an increase in tree mortality over the past five years. Within the developed campgrounds and other recreation sites in the McCloud River corridor, hazard trees continue to be a concern for public safety. Excessive hazardous fuel accumulations can increase the potential for intense wildfires.

Vegetation is blocking views of the McCloud River from many of the developed recreation sites such as Fowlers Campground and views of Mount Shasta from the Vista Point.

Desired Future Conditions: Hazardous fuels are reduced to the standards under the Forest Plan, allowing fire managers to effectively protect life, property, and natural resources during a wildfire. Hazard trees in developed recreation sites, along trails, and in campgrounds are removed for forest health and public safety. Forest stands within and surrounding campgrounds are healthy. Opportunities exist to view the McCloud River within the developed recreation sites and trails, and to view Mount Shasta from the Vista Point on Highway 89.

Wildland Urban Interface Defense Zones (Defined as Areas Up to ¼ Mile From Structures)

Existing Conditions: Fuels have been reduced in a portion of the Wildland Urban Interface (WUI) in recent years around the communities of McCloud and Mount Shasta. However, there are numerous forest stands and brushy areas where fuels have not been reduced. Some of the treated stands are still in a condition that could sustain a wildfire with potential impacts to homes and private property, especially in the WUI defense zones near Mount Shasta and on Snowman's Hill.

Desired Future Conditions: In the WUI defense zones around the community of Mt. Shasta and Snowman's Hill, fuel loading has been managed and reduced to the Forest Plan standards. Vegetation is managed to achieve 4-foot flame lengths or less during 97th percentile weather conditions. There is sufficient ingress/egress clearance and limited chances of crown fire.

Forest Ecosystem Health

Existing Conditions: The project area is a combination of plantations and natural (non-plantation) forest stands. The primarily ponderosa pine plantations range in age from less than 10 years to over 70 years. Some of the plantations have had recent treatments (brush mastication, thinning, pruning). Others have not and are overstocked, with interlocking tree crowns and decadent woody shrubs, making them vulnerable to mortality from insects and fire. Mortality has occurred within some of the plantations, resulting in pockets of dead trees. The plantations lack age, structure, and species diversity, and some were subject to windrowing (a site preparation method which resulted in piles of topsoil) and mechanical planting in the past.

Most of the natural forest stands are overly dense and at risk of density-related mortality. Mortality pockets are starting to occur across the project area. Root diseases, such as black stain and Heterobasidion, along with evidence of insect damage, have been observed in many locations. Dense and dying knobcone pine stands are far outside of their natural range of variation both in overall numbers as well as percent composition and are creating unnaturally large fuel loads.

Windrows were created in several plantations prior to planting as a way to remove competing vegetation. Windrowing reduced overall soil productivity by scalping and piling nutrient rich topsoil, which displaced nutrients and soil organic matter in the piles and left poorer quality subsoil exposed for tree planting.

Areas dominated by bitterbrush, individual black oak trees, and stands of aspen and oak (important for vegetative diversity and wildlife habitat) are being encroached on by conifers, which are shading out these shrubs/trees. Due to a lack of disturbance, forest stands have followed a process of succession in which conifers grow taller than aspen and oak, blocking the sunlight these species need. Conifers are competing for soil nutrients and water with the other tree and shrub species. Aspen stands are declining at a rapid rate due to past management such as fire suppression, timber management (removing aspen and planting conifers), livestock grazing and site conversion. Bitterbrush stands are mostly even-aged and decadent with limited regeneration or new growth, and there are encroaching conifers at the edges of and within the bitterbrush stands.

Some Riparian Reserve areas located within the McCloud River corridor (inner gorge) contain dense pockets of young conifers encroaching on the riparian vegetation as well as dead and dying trees. Some of these areas are adjacent to trails, such as the McCloud River Trail, and recreation sites.

Effective fire suppression in the last century has greatly reduced the total area burned when compared to pre-historic levels. Approximately 73% of the project area historically experienced a high frequency (0–35 year return interval), low to mixed severity fire regime. Approximately 6% of the project area historically experienced a high frequency (0–35 year return interval), high severity fire regime, while 6% of the project area evolved under a low frequency (35–100 year) high severity fire regime (non-burnable area accounts for the remaining 15%).

Based on the historic fire return intervals and fire history data, the project area is outside the historical range for fire occurrence. Approximately 80% of the project area is designated as a high departure from the historical fire return interval range. These areas have missed multiple fire return intervals. The remaining 4% of burnable area is at a moderate departure, missing one or more return intervals. This departure has resulted in changes to vegetation characteristics (species composition, structural stages, stand age, canopy closure, and mosaic pattern); fuel composition; fire frequency, severity, and pattern; and insect and disease activity. The risk of losing key ecosystem components is high.

Desired Future Conditions: Plantations with trees primarily 10 inches diameter at breast height (dbh) or greater have a more multi-aged structure with variable sizes and spacing, and plantations with trees primarily less than 10 inches dbh are moving toward stands with larger sized trees. Natural stands have densities at levels that improve and protect forest health and vigor. The stands have structural diversity with varied species, multiple canopy layers, other types of vegetation, and appropriate levels of coarse woody debris and snags. Plantations and natural stands are resilient to epidemic insect or disease attack. Knobcone pine dominated stands more closely resemble their historic conditions of other species such as ponderosa pine, incense cedar and white fir mixed in with the knobcone.

In plantations with windrows, the windrows have been respread, redistributing the topsoil and nutrients throughout the plantation. Overall soil quality and productivity are improved in the plantations providing more nutrients to the trees.

Hardwoods, especially oaks and aspen, remain a healthy and vigorous component of forest stands where they are naturally located. In hardwood-dominated stands, there are fewer conifers competing for resources (sunlight, nutrients, water) with the hardwoods. Bitterbrush stands have a mix of age and condition classes and also have limited competition from conifers. In riparian areas, the species composition and structural diversity of the native vegetation maintain a healthy riparian ecosystem, without excess competition for resources from conifers.

All stands and vegetation types experience fires at intervals that are historic to the area, have appropriate coarse woody debris and snag levels, but do not have excess fuel loads. Wildfires that occur within the project area during dry summer conditions are beneficial to the ecosystem, as occurred historically.

Purpose and Need

For the Highway 89 corridor, there is a need to:

(1) Cut vegetation throughout the highway corridor, so that the forest canopy is more open, allowing increased winter sunlight on the roadway and faster melting of snow and ice on the pavement.

(2) Manage vegetation along the highway for increased driver sight distance to reduce the risk of vehicle-wildlife collisions.

(3) Remove vegetation along the road shoulders for space to place plowed/blown snow during storms.

(4) Reduce fuels along Highway 89 to allow for a more effective fire response during summer conditions.

For Forest roads, powerline corridors and helispot facilities, there is a need:

(1) To ensure that roads needed for Forest resource management are maintained or repaired to meet Forest standards and closed when not in use. Roads needed fror recreation access are maintained and repaired to meet Forest standards and public safety needs. Roads not needed for Forest management or recreation access are decommissioned. Roads are added or removed from the Forest transportation system as appropriate.

(2) For a helispot east of McCloud to facilitate a medical evacuation and an appropriate fire management response.

(3) To reduce hazardous fuels levels (surface fuel loadings, ladder fuels, and vegetation densities) along powerlines, to increase firefighter safety during a wildfire.

For developed recreation areas, there is a need to:

(1) Increase visitor safety from hazard trees and the risk of wildfires, including along the McCloud River Trail, and improve access within and surrounding the developed recreation sites.

(2) Improve the views throughout the project area, including Mt. Shasta, the McCloud River, and the natural landscape.

For the WUI defense zones, there is a need to:

(1) Reduce hazardous fuel levels (surface fuel loadings, ladder fuels, and vegetation densities) within the defense zones to achieve 4-foot flame lengths or less during 97th percentile weather conditions.

For forest and ecosystem health, there is a need to:

(1) Increase the diversity of species composition, age, and structure in plantations and natural forest stands.

(2) Increase resilience to fire, insects and disease in all stands.

(3) Reduce competition by conifers in hardwood stands, bitterbrush areas, and riparian vegetation to ensure their growth and vigor.

(4) Respread existing windrowed topsoil in several plantations to redistribute soil nutrients and organic matter and improve overall soil productivity.

(5) Restore the natural role of fire in the ecosystem to facilitate vegetative and other fire-related processes.

Proposed Alternative 3

The project area was divided into treatment areas based on vegetation type, use, and areas with special conditions. Activities include Forest road management, and construction of a new helispot for medical air evacuation and firefighting support. Silviculture treatments such as tree thinning, sanitation thinning and hazard tree removal, along with fuels treatments such as underburning, hand or machine piling, and mastication will be implemented to improve resilience and health in forest stands, and improve safety along the Highway 89 corridor, in WUI defense zones and in developed recreation areas.

A complete description of alternative 3, including resource protection measures and treatment maps, can be found in the Highway 89 Safety Enhancement and Forest Ecosystem Restoration Project Scoping Document on the Shasta-Trinity National Forest Web site at *http://www.fs.usda.gov/project/?project=43770.*

In summary, to meet the purpose and need the following treatments have been identified (all acreages and miles are approximate, some treatments will overlap, occurring in the same areas).

Thinning (variable density across all diameter classes, including understory vegetation) of trees will be implemented throughout the project area to reduce relative stand densities and meet other objectives. In some areas thinning will create small gaps/openings in the canopy (such as the WUI defense zone). In other areas, clumps of trees with wildlife sheltering structure will be retained.

Sanitation (removing dead and dying clumps of trees) will be implemented in areas of disease, insect damage, and ongoing mortality. Group selections will be installed in larger areas of mortality to try and slow rate of progression.

Hazard tree removal will occur throughout the project area. Encroaching conifers will be removed to release riparian vegetation along the McCloud River Corridor and from bitterbrush fields.

These treatments will occur in:

- 3,376 acres of plantations with trees 10 inches or greater,
- 617 acres of plantations with trees less than 10 inches dbh,
- 1,241 acres of mixed conifer natural stands,
- 3,794 acres of pine dominated natural stands,
- 653 acres of knobcone pine dominated stands,
- 212 acres of the McCloud River Corridor area,
- 212 acres of the Big Canyon Creek area,
- 61 acres of bitterbrush fields, and
- 16 acres of black oak stands.

Fuels treatments will include mastication, machine and hand piling and pile burning, and thinning for fuel reduction. The entire project area (with the exception of specific sensitive areas) will be underburned.

The treatments will yield renewable forest by-products of both sawtimber (logs) and biomass (chips), firewood, and special forest products. Treatments will be accomplished through a variety of methods including service contacts, force account, commercial timber harvest, and stewardship contracts.

In addition to vegetation treatments, a 550-foot x 550-foot helispot will be constructed across the highway from the Ash Creek Work Station (total area of approximately 14 acres). Forest road management activities will include 78 miles of road maintenance, 2.8 miles of reconstruction, 4 miles of new temporary road construction, 7.9 miles road/route decommissioning, 11.25 miles of road closures, 3 miles of road openings, and 0.25 miles of road (access to the new helispot) added to the Forest Transportation System.

Highway 89 is designated as a Forest Service Scenic Byway. Visual quality objectives for the highway corridor through National Forest land call for retention, meaning human activities are not visually evident to the casual forest visitor. Trees will be removed along the highway in view of the roadway and the resulting changes in vegetation will be visually evident. Depending on the results of the scenery analysis, a Forest Plan amendment may be required for the project activities along the Highway 89 corridor.

Responsible Official

Forest Supervisor, Shasta-Trinity National Forest.

Nature of Decision To Be Made

The Forest Supervisor will decide whether to implement the proposed alternative 3, take an alternative action that meets the purpose and need, or take no action.

Permits or Licenses Required

A permit would be required from the State of California prior to burning piles. The appropriate regulatory agencies will be consulted regarding national or state required permits associated with roads used during project implementation. All rquired permits will be obtained prior to implementation.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement.

Early in the project development process, meetings were held with local stakeholders, including representatives from the California Department of Transportation, the local timber industry and American Forest Resources Council, local fire safe and watershed councils, environmental and citizens' organizations, and the Pit River Tribe. It was anticipated at that time that an environmental assessment would be written for the project.

The project was originally scoped in June, 2014. The project was posted on the Forest Schedule of Proposed Actions (SOPA) On June 30, 2014. The Legal Notice was published in the newspaper of record (Record Searchlight, Redding, California) on June 30, 2014. A notice was also published in the Mount Shasta Herald (Mount Shasta, California). A scoping letter was mailed or emailed to 168 individuals, organizations, and government agencies. The scoping document and was posted to the Shasta-Trinity National Forest Web site. The scoping period was 30 days. Comments were received from nine individuals, organizations, and agencies.

In addition to the written request for comments, the scoping phase included two public meetings and field trips for interested members of the public and other government agencies. A public meeting/field trip was held on October 4, 2014 with 11 attendees. A field trip with representatives of the U.S. Fish and Wildlife Service was held on October 31, 2014. The comments from the scoping period and public meetings/field trips have become part of the Highway 89 Safety Enhancement and Forest Ecosystem Restoration Project record, and were considered when developing this new alternative (alternative 3), which is referred to as alternative 3 in this notice of intent.

Based on the public involvement since scoping as well as new information, the line officer has chosen to evaluate and document project effects on the environment in an environmental impact statement.

For the scoping period initiated by this notice of intent, it is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and

contentions. Comments submitted during the first scoping period will continue to be considered and need not be resubmitted. This project would implement the Forest Plan and is subject to 36 CFR 218 subparts A and B. All persons who provided comment in past designated comment periods associated with this project will have standing to object on comment issues previously provided however, those interested in the project are encouraged to review the scoping package and provide comments. Please note that to object per 36 CFR 218, a commenter must have provided specific written comments regarding the proposed project or activity during scoping or another designated opportunity for public comment (in other words objection issues must be based on previously submitted specific written comments except for issues that arose after the opportunities for comment). Please refer to 36 CFR 218.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however anonymous comments will not provide the Agency with the ability to provide the respondent with subsequent environmental documents and may preclude their ability to object.

Dated: September 8, 2015.

David R. Myers,

Forest Supervisor.

[FR Doc. 2015–23157 Filed 9–14–15; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended), the Rural Utilities Service, a Rural Development agency of the United States Department of Agriculture invites comments on the following information collections for which the Agency intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by November 16, 2015.

FOR FURTHER INFORMATION CONTACT: Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492. Fax: (202) 720–8435.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies information collections that RUS is submitting to OMB for extension.

Comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology. Comments may be sent to Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, STOP 1522, 1400 Independence Ave. SW., Washington, DC 20250–1522. (202) 690–4492. Fax: (202) 720–8435.

Title: Request for Approval to Sell Capital Assets.

OMB Control Number: 0572–0020.

Type of Request: Extension of a currently approved collection.

Abstract: A borrower's assets provide the security for a government loan. The selling of assets reduces the security and increases the risk to the government. RUS Form 369 allows the borrower to seek agency permission to sell some of its assets. The form collects detailed information regarding the proposed sales of a portion of the borrower's systems. USDA Rural Development electric utility borrowers complete this form to request USDA Rural Development approval in order to sell capital assets when the fair market value exceeds 10 percent of the borrower's net utility plant.

Estimate of Burden: Public Reporting burden for this collection of information is estimated to average 3 hours per response.

Respondents: Not-for-profit institutions; Business or other for profit.

Estimated Number of Respondents: 5.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 15 hours.

Dated: September 5, 2015.

Brandon McBride,

Administrator, Rural Utilities Service.

[FR Doc. 2015–23087 Filed 9–14–15; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

[Docket No.: 150720626–5831–02]

Privacy Act of 1974, Amended System of Records

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of Proposed Amendment to Privacy Act System of Records: COMMERCE/NOAA–19, Permits and Registrations for United States Federally Regulated Fisheries.

SUMMARY: The Department of Commerce publishes this notice to announce the effective date of a Privacy Act System of Records notice entitled Notice of Proposed Amendment to Privacy Act System of Records: COMMERCE/NOAA–19, Permits and Registrations for United States Federally Regulated Fisheries.

DATES: The system of records becomes effective on September 15, 2015.

ADDRESSES: For a copy of the system of records please mail requests to: Sarah Brabson, NOAA Office of the Chief Information Officer, Room 9856, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Erin Steiner, NOAA Fisheries, Northwest Fisheries Science Center, FRAM Division, 2725 Montlake Boulevard East, Seattle, WA 98112.

SUPPLEMENTARY INFORMATION: On August 7, 2015 (80 FR 47457), the Department of Commerce published a notice in the **Federal Register** requesting comments on a proposed new Privacy Act System of Records notice entitled Notice of Proposed Amendment to Privacy Act System of Records: COMMERCE/NOAA–19, Permits and Registrations for United States Federally Regulated

Fisheries. No comments were received in response to the request for comments. By this notice, the Department of Commerce is adopting the proposed new system as final without changes effective September 15, 2015.

Dated: September 9, 2015.

Michael J. Toland,

Department of Commerce, Acting Freedom of Information and Privacy Act Officer.

[FR Doc. 2015–23131 Filed 9–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

[Docket No.: 150720624–5832–02]

Privacy Act of 1974, New System of Records

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of Privacy Act System of Records: ''COMMERCE/NOAA–23; Economic Data Collection Program for West Coast Groundfish Trawl Catch Share Program off the coast of Washington, Oregon, and California.''

SUMMARY: The Department of Commerce publishes this notice to announce the effective date of a Privacy Act System of Records notice entitled COMMERCE/NOAA–23; Economic Data Collection Program for West Coast Groundfish Trawl Catch Share Program off the coast of Washington, Oregon, and California.

DATES: The system of records becomes effective on September 15, 2015.

ADDRESSES: For a copy of the system of records please mail requests to: Sarah Brabson, NOAA Office of the Chief Information Officer, Room 9856, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Erin Steiner, NOAA Fisheries, Northwest Fisheries Science Center, FRAM Division, 2725 Montlake Boulevard East, Seattle, WA 98112.

SUPPLEMENTARY INFORMATION: On August 7, 2015 (80 FR 47454), the Department of Commerce published a notice in the **Federal Register** requesting comments on a proposed new Privacy Act System of Records notice entitled COMMERCE/NOAA–23; Economic Data Collection Program for West Coast Groundfish Trawl Catch Share Program off the coast of Washington, Oregon, and California. No comments were received in response to the request for comments. By this notice, the Department of Commerce is adopting the proposed new system as final without changes effective September 15, 2015.

Dated: September 9, 2015.

Michael J. Toland,

Department of Commerce, Acting Freedom of Information and Privacy Act Officer.

[FR Doc. 2015–23127 Filed 9–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–802]

Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review, 2013–2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 9, 2015, the Department of Commerce (''Department'') published in the **Federal Register** the *Preliminary Results* of the ninth administrative review of the antidumping duty *Order*[1] on certain warmwater shrimp from the Socialist Republic of Vietnam (''Vietnam'').[2] Based upon our analysis of the comments and information received, we determine that Minh Phu Group[3] and Thuan Phuoc[4] sold subject merchandise at less than normal value (''NV'') during the period of review (''POR''), February 1, 2013, through January 31, 2014. The Department determines that sales of subject merchandise by Fimex VN[5] were not made below NV.

DATES: Effective Date: September 15, 2015.

FOR FURTHER INFORMATION CONTACT: Bob Palmer, Irene Gorelik, or Alexis Polovina, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–9068, (202) 482–6905, (202) 482–3927, respectively.

SUPPLEMENTARY INFORMATION: On March 9, 2015, the Department published the *Preliminary Results.* On March 10, 2015, VASEP[6] filed surrogate value information rebutting certain surrogate values we applied in the *Preliminary Results.* Between April 20, 2015, and May 4, 2015, the Department conducted verification of Fimex VN and Thuan Phuoc. On June 5, 2015, the Department extended the time limit for these final results by 60 days. We gave interested parties an opportunity to comment on the *Preliminary Results.* On June 8, 2015, Petitioner[7] and VASEP submitted their case briefs. On June 13, 205, Petitioner, Domestic Processors,[8] and VASEP filed their rebuttal briefs.

Scope of the Order

The merchandise subject to the order is certain frozen warmwater shrimp. The product is currently classified under the following Harmonized Tariff Schedule of the United States item numbers: 0306.17.00.03, 0306.17.00.06, 0306.17.00.09, 0306.17.00.12, 0306.17.00.15, 0306.17.00.18, 0306.17.00.21, 0306.17.00.24, 0306.17.00.27, 0306.17.00.40, 1605.21.10.30, and 1605.29.10.10. The written description of the scope of the order is dispositive. A full description of the scope of the *Order* is available in the accompanying Issues and Decision Memorandum.[9]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this review are addressed in the accompanying Issues and Decision Memorandum.[10] A list of the issues which parties raised, and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam,* 70 FR 5152 (February 1, 2005) (''*Order*'').

[2] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review; 2013–2014,* 80 FR 12441 (March 9, 2015) (''*Preliminary Results*'').

[3] Minh Phu Seafood Export Import Corporation (and affiliated Minh Qui Seafood Co., Ltd. and Minh Phat Seafood Co., Ltd.); Minh Phu Seafood Corporation, Minh Phu Seafood Corp., Minh Qui Seafood Co., Ltd., Minh Qui Seafood, Minh Phat Seafood Co., Ltd., Minh Phat Seafood, and Minh Phu Hau Giang Seafood Joint Stock Company Co., Ltd. (collectively, the ''Minh Phu Group'').

[4] Thuan Phuoc Seafoods and Trading Corporation (''Thuan Phuoc'').

[5] Sao Ta Foods Joint Stock Company (''Fimex VN'').

[6] Vietnam Association of Seafood Exporters and Producers (''VASEP'')

[7] The Ad Hoc Shrimp Trade Action Committee (''Petitioner'').

[8] American Shrimp Processors Association (''Domestic Processors'').

[9] *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, From Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Issues and Decision Memorandum for the Final Results, (''Issues and Decision Memorandum'') dated concurrently and hereby adopted by this notice.

[10] *Id.*

Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and electronic versions of the Issues and Decision Memorandum are identical in content.

Final Determination of No Shipments

In the *Preliminary Results,* the Department determined the following companies did not have any reviewable transactions during the POR: (1) Bien Dong Seafood Co., Ltd.; (2) BIM Foods Joint Stock Company; (3) Cafatex Fishery Joint Stock Corporation; (4) Camau Seafood Processing and Service Joint-stock Corporation; (5) Camranh Seafoods Co., Ltd.; (6) Nhat Duc Co., Ltd.; (7) Phu Cuong Jostco Seafood Corporation; and (8) Seavina Joint Stock Company. As we have not received any information to contradict this determination, the Department determines that the above-named companies did not have any reviewable entries of subject merchandise during the POR, and will issue appropriate instructions that are consistent with our ''automatic assessment'' clarification, for these final results.

Changes Since the Preliminary Results

The Department has made changes to a surrogate value and to the company-specific margin calculation programs since the *Preliminary Results.* For detailed information, *see* the Issues and Decision Memorandum and the company-specific final results analysis memoranda.

Separate Rates

In the *Preliminary Results,* we determined that 32 companies [11] (''Separate Rate Respondents'') in addition to Minh Phu Group, Fimex VN, and Thuan Phuoc met the criteria for separate rate status. We have not received any information since the issuance of the *Preliminary Results* that provides a basis for reconsidering this preliminary determination. Therefore, the Department continues to find that these companies meet the criteria for a separate rate for the final results.

Rate for Non-Selected Companies

For the final results, the calculated rates for the mandatory respondents have changed from the *Preliminary Results.* Therefore, we recalculated the sample rate assigned to the Separate Rate Respondents for the final results of this review, and we continue to determine that a ''reasonable method for determining the weighted-average dumping margins for the non-selected respondents in this review is to average the weighted-average dumping margins calculated for the mandatory respondents,'' as noted in the *Preliminary Results.*[12]

Final Results of Review

In the *Preliminary Results,* we found that 56 companies for which a review was requested have not established eligibility for a separate rate and, thus, we considered them to be part of the Vietnam-wide entity.[13] The Department's change in policy regarding conditional review of the Vietnam-wide entity applies to this administrative review.[14] Under this policy, the Vietnam-wide entity will not be under review unless a party specifically requests, or the Department self-initiates, a review of the entity. Because no party requested a review of the Vietnam-wide entity, the entity is not under review and the entity's rate is not subject to change. For companies for which a review was requested and that have established eligibility for a separate rate, the Department determines that the following weighted-average dumping margins exist:

Exporter [15]	Weighted-average margin (percent)
Minh Phu Group: [16]	
Minh Phu Seafood Corp., aka Minh Phu Seafood Corporation, aka Minh Phu Seafood Pte, aka Minh Phat Seafood Co., Ltd., aka Minh Qui Seafood Co., Ltd., aka Minh Qui Seafood, aka Minh Phu Hau Giang Seafood Joint Stock Company	1.39
Sao Ta Foods Joint Stock Company (''Fimex VN''), aka Sao Ta Foods Joint Stock Company, aka Fimex VN aka Sao Ta Seafood Factory aka Saota Seafood Factory	0.00
Thuan Phuoc Seafoods and Trading Corporation, aka Thuan Phuoc Corp., aka Frozen Seafoods Factory No. 32, aka Seafoods and Foodstuff Factory, aka Seafoods and Foodstuff Factory Vietnam, aka My Son Seafoods Factory	1.16
Bac Lieu Fisheries Joint Stock Company, aka Bac Lieu Fisheries Company Limited, aka Bac Lieu Fisheries Co., Ltd., aka Bac Lieu Fisheries Limited Company, aka Bac Lieu Fis	0.91
Bentre Forestry and Aquaproduct Import-Export Joint Stock Company, aka FAQUIMEX	0.91
Camau Frozen Seafood Processing Import Export Corporation, aka Camimex, aka Camau Seafood Factory No. 4, aka Camau Seafood Factory No. 5, aka Camau Frozen Seafood Processing Import Export Corp. (CAMIMEX–FAC 25), aka Frozen Factory No. 4	0.91
C.P. Vietnam Corporation, aka C.P. Vietnam Livestock Corporation, aka C.P. Vietnam Livestock Company Limited, aka C.P. Vietnam	0.91
Cadovimex Seafood Import-Export and Processing Joint Stock Company, aka Cai Doi Vam Seafood Import-Export Company, aka Caidoivam Seafood Company (Cadovimex), aka Cadovimex-Vietnam	0.91
Can Tho Import Export Fishery Limited Company, aka CAFISH	0.91
Fine Foods Co., aka FFC	0.91
Cuu Long Seaproducts Company, aka Cuulong Seaproducts Company Cuu Long Seaproducts Limited, aka Cuulong Seapro aka Cuu Long Seapro	0.91
Gallant Ocean (Vietnam) Co., Ltd.	0.91
Gallant Dachan Seafood Co., Ltd.	0.91
Goldenquality Seafood Corporation	0.91
Hai Viet Corporation, aka HAVICO	0.91

[11] *See* Issues and Decision Memorandum at Appendix I.

[12] *See Preliminary Results,* and accompanying Preliminary Decision Memorandum.

[13] *See Preliminary Results,* 80 FR 12442 and Appendix II for a full list of the 56 companies; *see also* Preliminary Decision Memorandum, at 9–10.

[14] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

Exporter [15]	Weighted-average margin (percent)
Investment Commerce Fisheries Corporation, aka Investment Commerce Fisheries Corp., aka Investment Commerce Fisheries, aka Incomfish, aka Incomfish Corp., aka Incomfish Corporation	0.91
Kim Anh Company Limited, aka Kim Anh Co, Ltd.	0.91
Minh Cuong Seafood Import Export Frozen Processing Joint Stock Co, aka Minh Cuong Seafood Import- Export Processing, aka MC Seafood	0.91
Minh Hai Export Frozen Seafood Processing Joint-Stock Company, aka Minh Hai Jostoco	0.91
Minh Hai Joint-Stock Seafoods Processing Company, aka Seaprodex Minh Hai, aka Sea Minh Hai, aka Seaprodex Min Hai, aka Seaprodex Minh Hai-Factory No. 78, aka Seaprodex Minh Hai (Minh Hai Joint Stock Seafoods Processing Co.), aka Seaprodex Minh Hai Workshop 1, aka Seaprodex Minh Hai Factory No. 69	0.91
Minh Hai Sea Products Import Export Company, aka Ca Mau Seafood Joint Stock Company, aka Seaprimexco Vietnam, aka Seaprimexco	0.91
Nha Trang Fisheries Joint Stock Company, aka Nha Trang Fisco aka Nhatrang Fisco, aka Nha Trang Fisheries, Joint Stock	0.91
Nha Trang Seafoods Group: Nha Trang Seaproduct Company, aka Nha Trang Seafoods, aka NT Seafoods Corporation, aka NT Seafoods, aka Nha Trang Seafoods—F89 Joint Stock Company, aka Nha Trang Seafoods—F89, aka NTSF Seafoods Joint Stock Company, aka NTSF Seafoods	0.91
Ngoc Tri Seafood Joint Stock Company, aka Ngoc Tri Seafood Company	0.91
Phuong Nam Foodstuff Corp. aka Phuong Nam Co., Ltd., aka Phuong Nam Foodstuff Product Processing Joint Stock Corporation, aka Phuong Namco-Ltd	0.91
Quoc Viet Seaproducts Processing Trading and Import-Export Co., Ltd.	0.91
Soc Trang Seafood Joint Stock Company, aka Stapimex, aka Soc Trang Aquatic Products and General Import Export Company, aka Soc Trang Aquatic Products and General Import Export Company (''Stapimex''), aka Stapmex	0.91
Tacvan Frozen Seafood Processing Export Company, aka Tacvan Seafoods Co.	0.91
Tan Phong Phu Seafoods Co., Ltd.	0.91
Thong Thuan Company Limited, aka T&T Co., Ltd	0.91
UTXI Aquatic Products Processing Corporation, aka UT XI Aquatic Products Processing Corporation, aka UTXI Aquatic Products Processing Company, aka UT XI Aquatic Products Processing Company, aka UTXI Co. Ltd., aka UTXI, aka UTXICO, aka Hoang Phuong Seafood Factory, aka Hoang Phong Seafood Factory	0.91
Viet Foods Co., Ltd., aka Nam Hai Foodstuff and Export Company Ltd.	0.91
Vietnam Clean Seafood Corporation, aka Vina Cleanfood	0.91
Viet Hai Seafood Co., Ltd., aka Vietnam Fish One Co., Ltd.	0.91
Viet I-Mei Frozen Foods Co., Ltd.	0.91

Disclosure and Public Comment

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

For any individually examined respondent whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), the Department will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of sales. Where we do not have entered values for all U.S. sales to a particular importer/customer, we calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer).[17] To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer- (or customer-) specific *ad valorem* ratios based on the estimated entered value. Where either a respondent's weighted average dumping margin is zero or *de minimis,* or an importer- (or customer-) specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[18]

Additionally, consistent with its assessment practice in non-market economy (NME) cases, if the Department continues to determine that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered

[15] Due to the issues we have had in the past with variations of exporter names related to this *Order,* we remind exporters that the names listed below are the exact names, including spelling and punctuation which the Department will provide to CBP and which CBP will use to assess POR entries and collect cash deposits.

[16] The Department previously collapsed the companies within the Minh Phu Group in the sixth administrative review. *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Preliminary Results of Administrative Review,* 77 FR 13547, 13549 (March 7, 2012), unchanged in *Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 77 FR 55800 (September 11, 2012). In the *Preliminary Results,* the Department reevaluated the collapsed entity based on a corporate structure and name change of one of the collapsed companies, Minh Phu Hau Giang Seafood Co., Ltd. *See* ''Memorandum to the File, through Catherine Bertrand, Program Manager, Office V, from Irene Gorelik, Senior Analyst, Office V, re; Collapsing Determination for the Minh Phu Seafood Corporation and its Affiliates, with Minh Phu Hau Giang Seafood Joint Stock Company,'' dated March 2, 2015. We have made no changes since the *Preliminary Results* with respect to Minh Phu Hau Giang Seafood Joint Stock Company being part of the Minh Phu Group single entity. Thus, for the final results, we continue to find that Minh Phu Hau Giang Seafood Joint Stock Company is affiliated with the Minh Phu Group group of companies, and that they comprise a single entity, to which we will assign a single rate. The company name and trade names formerly used by Minh Phu Hau Giang Seafood Joint Stock Company have not been included above, for cash deposit purposes, based on the information submitted on the record. However, the former names will be included for liquidation purposes.

[17] *See* 19 CFR 351.212(b)(1).

[18] *See* 19 CFR 352.106(c)(2); *Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012) (''*Final Modification for Reviews*'').

under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the NME-wide rate.[19]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from Vietnam entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For the companies listed above, which have a separate rate, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Vietnam and non-Vietnam exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Vietnam exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the Vietnam-wide entity; and (4) for all non-Vietnam exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Vietnam exporter that supplied that non-Vietnam exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: September 8, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Appendix II

Companies Subject to Review Determined To Be Part of the Vietnam-Wide Entity

1. An Giang Coffee JSC
2. Agrex Saigon
3. Amanda Foods (Vietnam) Ltd., Amanda Seafood Co., Ltd.
4. Amanda Foods (Vietnam) Ltd. Ngoc Tri Seafood Company (Amanda's affiliate)
5. Anvifish Joint Stock Co.
6. Binh An Seafood Joint Stock Company
7. Camimex Seafood Company Limited
8. Ca Mau Foods and Fishery Export Joint Stock Company
9. Can Tho Agricultural and Animal Products Import Export Company, aka, Can Tho Agricultural Products, aka, Can Tho Agricultural and Animal Products Imex Company, aka, CATACO, aka, Can Tho Agricultural and Animal Product Import Export Company (''CATACO''), aka, Can Tho Agricultural and Animal Product Import Export Company (''CATACO'') and/or Can Tho Agricultural and Animal Products Import Export Company (''CATACO'''), aka, Can Tho Agricultural & Animal Product Import Export Company (''CATACO''') and/or Can Tho Agricultural and Animal Products Import Export Company (''CATACO'')
10. Can Tho Import Export Seafood Joint Stock Company, aka, CASEAMEX
11. Cau Tre Enterprise (C.T.E.)
12. Cautre Export Goods Processing Joint Stock Company
13. Chang Shin Vietnam Co., Ltd.
14. CL Fish Co., Ltd. (Cuu Long Fish Company)
15. Cautre Export Goods Processing Joint Stock Company
16. Coastal Fisheries Development Corporation, Coastal Fisheries Development Corporation (''COFIDEC''), Coastal Fisheries Development Corporation (''Cofidec''), Coastal Fishery Development, COFIDEC
17. D & N Foods Processing (Danang Company Ltd.)
18. Danang Seaproduct Import-Export Corporation (''Seaprodex Danang'') (and its

[19] For a full discussion of this practice, see *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

affiliates), Danang Seaproducts Import Export Corporation, Danang Seaproducts Import Export Corporation (''Seaprodex Danang''), Danang Seaproducts Import-Export Corporation (and its affilliate, Tho Quang Seafood Processing and Export Com-pany) (collectively ''Seaprodex Danang''), Tho Quang, Tho Quang Co., Tho Quang Seafood Processing and Export Company, Tho Quang Seafood Processing & Export Company, Seaprodex Danang
19. Duy Dai Corporation
20. Gallant Ocean (Quang Ngai) Co., Ltd.
21. Gn Foods
22. Hai Thanh Food Company Ltd.
23. Hai Vuong Co., Ltd.
24. Hoa Phat Aquatic Products Processing And Trading Service Co., Ltd.
25. Hoang Hai Company Ltd.
26. Hua Heong Food Industries Vietnam Co. Ltd.
27. Interfood Shareholding Co.
28. Khanh Loi Seafood Factory
29. Kien Long Seafoods Co. Ltd.
30. Luan Vo Fishery Co., Ltd.
31. Lucky Shining Co., Ltd.
32. Minh Chau Imp. Exp. Seafood Processing Co., Ltd.
33. Mp Consol Co., Ltd.
34. Ngoc Chau Co., Ltd. and/or Ngoc Chau Seafood Processing Company
35. Ngoc Sinh, Ngoc Sinh Seafoods Processing and Trading Enterprise, Ngoc Sinh Fisheries, Ngoc Sinh Private, Ngoc Sinh Private Enterprises, Ngoc Sinh Seafood Processing Company, Ngoc Sinh Seafood Trading & Processing, Ngoc Sinh Seafood Trading & Processing Enterprise, Ngoc Sinh Seafoods, Ngoc Sinh Seafoods (Private Enterprise), Ngoc Sinh Seafoods Processing and Trading Enterprises
36. Ngo Bros Seaproducts Import-Export One Member Company Limited (''Ngo Bros'')
37. Quang Ninh Export Aquatic Products Processing Factory
38. Quang Ninh Seaproducts Factory
39. S.R.V. Freight Services Co., Ltd.
40. Sustainable Seafood
41. Tai Kim Anh Seafood Joint Stock Company
42. Tan Thang Loi Frozen Food Co., Ltd.
43. Thanh Doan Seaproducts Import & Export Processing Joint-Stock Company (THADIMEXCO)
44. Thanh Hung Frozen Seafood Processing Import Export Co., Ltd.
45. Thanh Tri Seafood Processing Co. Ltd.
46. The Quang Co.
47. The Quang Seafood Processing & Export Company
48. Thong Thuan-Cam Ranh Seafood Joint Stock Company
49. Tien Tien Garment Joint Stock Company
50. Tithi Co., Ltd.
51. Trang Corporation
52. Viet Cuong Seafood Processing Import Export Joint-Stock Company, Viet Cuong Seafood Processing Import Export
53. Vietnam Northern Viking Technologies Co. Ltd.
54. Vinatex Danang
55. Vinh Hoan Corp.
56. Vinh Loi Import Export Company (''Vimexco''), aka, Vinh Loi Import Export Company (''VIMEX''), aka, VIMEXCO aka, VIMEX aka, Vinh Loi Import/Export Co., aka, Vinhloi Import Export Company aka, Vinh Loi Import-Export Company, Vinh Loi Import Export Company (''Vimexco'') and/or Vinh Loi Import Export Company (''VIMEX'')

[FR Doc. 2015–23159 Filed 9–14–15; 8:45 a.m.]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–810]

Stainless Steel Bar From India: Final Results of Antidumping Duty Administrative Review; 2013–2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 9, 2015, the Department of Commerce (Department) published the preliminary results of the administrative review of the antidumping duty order on stainless steel bar (SSB) from India.[1] The period of review (POR) is February 1, 2013, through January 31, 2014. Based on comments received from Bhansali Bright Bars Pvt. Ltd., (Bhansali) and the petitioner,[2] we have made certain changes to our preliminary results. The final dumping margin for this review is listed in the ''Final Results of the Review'' section below.

DATES: Effective Date: September 15, 2015.

FOR FURTHER INFORMATION CONTACT: Joseph Shuler, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–1293.

SUPPLEMENTARY INFORMATION:

Background

Following the *Preliminary Results,* the Department issued an additional supplemental questionnaire to Bhansali, the only respondent in this administrative review, on March 20, 2015, and received a response on April 2, 2015. We received timely filed case and rebuttal briefs from Bhansali and the petitioner.

Scope of the Order

The merchandise subject to the order is SSB. The SSB subject to the order is currently classifiable under subheadings 7222.10.00, 7222.11.00, 7222.19.00, 7222.20.00, 7222.30.00 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes. The written description is dispositive.[3]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum, which is incorporated herein by reference. A list of the issues which parties raised, and to which we respond in the Issues and Decision Memorandum, is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and it is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic versions of the Issues Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of the comments received, we have made certain changes to the *Preliminary Results.* For a discussion of these changes, see Issues and Decision Memorandum.

Final Results of the Review

As a result of this review, we determine the following weighted-average dumping margin exists for the respondent for the period February 1, 2013, through January 31, 2014.

Producer/exporter	Weighted-average dumping margin (percent)
Bhansali Bright Bars Pvt. Ltd	0.00

[1] *See Stainless Steel Bar From India: Preliminary Results, and Rescission, in Part, of Antidumping Duty Administrative Review; 2013–2014,* 80 FR 12439 (March 9, 2015) (*Preliminary Results*).

[2] The petitioner is Valbruna Slater Stainless, Inc.

[3] For a full description of the scope of the order, see the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Stainless Steel Bar from India'' dated concurrently with this notice (Issues and Decision Memorandum), which is hereby adopted by this notice.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b), the Department determines, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

For assessment purposes, because Bhansali's weighted-average dumping margin remains zero or *de minimis* (*i.e.,* less than 0.5 percent) in these final results, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). Our instructions will be on an importer-specific basis, where the importer is known, or on a customer-specific basis, where the importer is not known.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the POR produced by Bhansali for which it did not know its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for Bhansali will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which that manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the manufacturer of subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 12.45 percent, the ''all others'' rate established in the order.[4] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These final results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 8, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Issues Discussed in the Issues and Decision Memorandum

[FR Doc. 2015–23161 Filed 9–14–15; 8:45 am]

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[4] *See Notice of Final Determination of Sales at Less Than Fair Value: Stainless Steel Bar from India,* 59 FR 66915, 66921 (December 28, 1994).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–814]

Utility Scale Wind Towers From the Socialist Republic Vietnam: Final Results of Antidumping Duty Administrative Review; 2013–2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 9, 2015, the Department of Commerce (''the Department'') published the preliminary results of the administrative review of the antidumping duty order on utility scale wind towers from the Socialist Republic of Vietnam (''Vietnam'').[1] The period of review is February 13, 2013, through January 31, 2014. The review covers one respondent, CS Wind Vietnam and CS Wind Corporation (collectively, ''CS Wind Group''). We continue to find that CS Wind Group has sold subject merchandise in the United States at below normal value during the POR.

DATES: Effective Date: September 15, 2015.

FOR FURTHER INFORMATION CONTACT: Trisha Tran AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4852.

Background

On March 9, 2015, the Department published the *Preliminary Results*.[2] On June 3, 2015, the Department extended the deadline for issuing the final results by 60 days, until September 8, 2015. CS Wind Group, and the Wind Tower Trade Coalition (''Petitioner'') submitted case and rebuttal briefs on April 15, 2013 and April 23, 2015, respectively.

[1] *See Utility Scale Wind Towers From the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review; 2013–2014,* 80 FR 12449 (March 9, 2015) (''*Preliminary Results*'').

[2] *Id.*

Both parties participated in a public hearing on July 16, 2015.

Scope of the Order

The merchandise covered by this order is certain wind towers, whether or not tapered, and sections thereof. Imports of the subject merchandise are provided for under the following subheadings of the Harmonized Tariff Schedule of the United States (''HTSUS''): 7308.20.00.20 [3] or 8502.31.00.00.[4] Prior to 2011, merchandise covered by the order was classified in the HTSUS under subheading 7308.20.00.00 and may continue to be to some degree. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive. A full description of the scope of the order is contained in the Issues and Decision Memorandum, dated concurrently with and hereby adopted by this notice.[5]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues raised in the briefs and addressed in the Issues and Decision Memorandum is attached to this notice as an appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made revisions to CS Wind Group's margin calculations. These changes are discussed in the Issues and Decision Memorandum and CS Wind Group's analysis memorandum.

Final Results of the Review

We determine that the following weighted-average dumping margin exists for the period of review from February 13, 2013 through January 31, 2014.

Exporter	Weighted-average dumping margin (percent)
The CS Wind Group	0.00

Assessment Rates

The Department shall determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of these final results of this review pursuant to section 751(a)(2)(C) of the Tariff Act of 1930, as amended (''Act'') and 19 CFR 351.212(b). In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer-) specific assessment rates for the merchandise subject to this review.[6] Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[7] For CS Wind Group, whose weighted average dumping margin is zero, the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[8]

On October 24, 2011, the Department announced a refinement to its assessment practice in NME cases.[9] Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by the company individually examined during this review, the Department will instruct CBP to liquidate such entries at the rate applicable to the Vietnam-wide entity (*i.e.,* 58.54 percent). In addition, for companies for which the Department determined that the exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the Vietnam-wide rate.

In accordance with section 751(a)(2)(C) of the Act, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of these final results of this administrative review for all shipments of the subject merchandise from Vietnam, entered or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is zero or *de minimis,* then a cash deposit rate of zero will be established for that company); (2) for previously investigated or reviewed Vietnam or non-Vietnam exporters not listed above that currently have a separate rate, the cash deposit rate will continue to be the exporter-specific rate published for the most the recently completed segment of this proceeding where the exporter received that separate rate; (3) for all Vietnam exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the Vietnam-wide entity, 58.54 percent; and (4) for all non-Vietnam exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the Vietnam exporter that supplied that non-Vietnam exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed regarding these administrative review final results within five days of the date of publication of this notice in this proceeding in accordance with 19 CFR 351.224(b).

[3] Wind towers are classified under HTSUS 7308.20.0020 when imported as a tower or tower section(s) alone.

[4] Wind towers may also be classified under HTSUS 8502.31.0000 when imported as part of a wind turbine (*i.e.,* accompanying nacelles and/or rotor blades.

[5] *See* Memorandum from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, regarding ''Issues and Decision Memorandum for the Final Results of the 2013–2014 Administrative Review of the Antidumping Duty Order on Utility Scale Wind Towers from the Socialist Republic of Vietnam'' issued concurrently with this notice (''Issues and Decision Memorandum'').

[6] *See Antidumping Proceedings: Calculation of the Weighted Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[7] *See* 19 CFR 351.106 (c)(2).

[8] *See* 19 CFR 351.212(b)(1).

[9] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order (''APO'')

This notice also serves as a final reminder to parties subject to APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the final results of this review and notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213.

Dated: September 8, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in Issues and Decision Memorandum

[FR Doc. 2015–23155 Filed 9–14–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–842]

Large Residential Washers From Mexico: Final Results of the Antidumping Duty Administrative Review; 2012–2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 9, 2015, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty (AD) order on large residential washers (LRWs) from Mexico.[1] The review covers two producers/exporters of the subject merchandise: Electrolux Home Products Corp. N.V. and Electrolux Home Products de Mexico, S.A. de C.V. (collectively, Electrolux) and Samsung Electronics Co., Ltd. (Samsung). The period of review (POR) is August 3, 2012, through January 31, 2014. We gave interested parties an opportunity to comment on the *Preliminary Results.* After reviewing the comments received and making corrections to the margin calculation, we continue to find that Electrolux made sales of subject merchandise to the United States at prices below normal value. We also find that Samsung made no shipments of subject merchandise during the POR. Electrolux's final dumping margin is listed below in the section entitled ''Final Results of the Review.''

DATES: *Effective Date:* September 15, 2015.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Brandon Custard, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–1823, respectively.

SUPPLEMENTARY INFORMATION:

Background

For a complete description of the events that following the publication of the *Preliminary Results,* see the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's AD and Countervailing Duty (CVD) Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

The Department conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the order are all large residential washers and certain subassemblies thereof from Mexico. The products are currently classifiable under subheadings 8450.20.0040 and 8450.20.0080 of the Harmonized Tariff System of the United States (HTSUS). Products subject to this order may also enter under HTSUS subheadings 8450.11.0040, 8450.11.0080, 8450.90.2000, and 8450.90.6000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.[3]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as Appendix I.

Final Determination of No Shipments

In the *Preliminary Results,* based on our analysis of U.S. Customs and Border Protection (CBP) information and information provided by Samsung, we determined that Samsung had no shipments of the subject merchandise,

[1] *See Large Residential Washers From Mexico: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2012–2014,* 80 FR 12436 (March 9, 2015) (*Preliminary Results*).

[2] *See* memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Large Residential Washers from Mexico,'' dated concurrently with and adopted by this notice (Issues and Decision Memorandum).

[3] A full description of the scope of the order is contained in the Issues and Decision Memorandum. The HTSUS numbers are revised from the numbers previously stated in the scope. *See* Memorandum to The File entitled ''Changes to the HTS Numbers to the ACE Case Reference Files for the Antidumping Duty Orders,'' dated January 6, 2015.

and, therefore, no reviewable transactions, during the POR.[4] No party commented on our preliminary results with respect to Samsung, and no additional information has been placed on the record to call into question those preliminary results. Accordingly, for the final results of this review, we continue to find that Samsung made no shipments of the subject merchandise during the POR.

Final Results of the Review

Based on our analysis of the comments received, we made changes to the weighted-average dumping margin calculation for Electrolux. Therefore, we are assigning the following weighted-average dumping margins for the period August 3, 2012, through January 31, 2014:

Manufacturer/exporter	Weighted-average dumping margin (percent)
Electrolux Home Products Corp. NV/Electrolux Home Products de Mexico, S.A. de C.V.	6.45

Disclosure and Public Comment

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), the Department has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review.

For Electrolux, the Department calculated *ad valorem* importer-specific assessment rates equal to the total amount of dumping calculated for the importer's examined sales and the total entered value of those sales. Where an importer-specific assessment rate is zero or *de minimis* (*i.e.,* less than 0.5 percent), the Department will instruct CBP to liquidate these entries without regard to antidumping duties pursuant to 19 CFR 351.106(c)(2).

The Department clarified its ''automatic assessment'' regulation on May 6, 2003.[5] If applicable, this clarification will apply to entries of subject merchandise during the POR produced by Electrolux or Samsung, for which the company did not know that its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate these entries at the all-others rate established in the less-than fair-value (LTFV) investigation, 36.52 percent,[6] if there is no rate for the intermediary involved in the transaction. *See Assessment Policy Notice* for a full discussion of this clarification.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Electrolux will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 36.52 percent, the all-others rate determined in the LTFV investigation.[7] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is published in accordance with section 751(a)(1) and 777(i)(1) of the Act.

Dated: September 8, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

Summary
Background
Margin Calculations
Scope of the Order
Discussion of Issues
1. Clerical Errors in Electrolux's Preliminary Dumping Margin
2. Electrolux's Affiliated Party Transactions
3. Methodological Issues in the Differential Pricing Analysis
4. Zeroing and Differential Pricing
5. Monthly Time Periods in Differential Pricing Analysis

[FR Doc. 2015–23158 Filed 9–14–15; 8:45 a.m.]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–869]

Large Residential Washers From the Republic of Korea: Final Results of Countervailing Duty Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 11, 2015, the Department published the preliminary results of the administrative review of the countervailing duty order on large residential washers from Korea.[1] The

[4] *See Preliminary Results,* 80 FR at 12347.

[5] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

[6] *See Large Residential Washers From Mexico and the Republic of Korea: Antidumping Duty Orders,* 78 FR 11148 (February 15, 2013) (*AD Order*).

[7] *Id.*

[1] *See Large Residential Washers From the Republic of Korea: Preliminary Results of the*

review covers two producers/exporters of the subject merchandise, Samsung Electronics Co., Ltd. (Samsung) and Daewoo Electronics Corporation (Daewoo). The period of review (POR) is June 5, 2012, through December 31, 2013. Based on an analysis of the comments received, the Department has not made changes to the subsidy rates calculated for Daewoo and Samsung in the *Preliminary Results.* The final subsidy rates are listed in the ''Final Results of Administrative Review'' section below.

DATES: Effective Date: September 15, 2015.

FOR FURTHER INFORMATION CONTACT: Toni Page AD/CVD Operations, Office VII, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1398.

Scope of the Order

The products covered by the order are all large residential washers and certain subassemblies thereof from Korea. The products are currently classifiable under subheadings 8450.20.0040 and 8450.20.0080 of the Harmonized Tariff System of the United States (HTSUS). Products subject to this order may also enter under HTSUS subheadings 8450.11.0040, 8450.11.0080, 8450.90.2000, and 8450.90.6000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.[2]

Analysis of Comments Received

The issues raised by Whirlpool Corporation (Petitioner), the only interested party to submit comments, are addressed in the Issues and Decision Memorandum.[3] The issues are identified in the Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the memorandum are identical in content.

Methodology

The Department is conducting this countervailing duty review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit to the recipient, and that the subsidy is specific.[4] Additionally, for certain subsidy programs, we are relying on the facts available, with adverse inferences, pursuant to sections 776(a) and (b) of the Act. For further information, see the Issues and Decision Memorandum.

Final Results of Administrative Review

As a result of this review, we determine the countervailable subsidy rates during the POR for the mandatory respondents to be:

Company	Subsidy rate (percent)
Samsung Electronics Co., Ltd	34.77
Daewoo Electronics Corporation	81.91

Assessment and Cash Deposit Requirements

In accordance with 19 CFR 351.212(b)(2), the Department intends to issue appropriate instructions to U.S. Customs and Border Protection (CBP) 15 days after publication of the final results of this review. The Department will instruct CBP to liquidate shipments of subject merchandise produced and/or exported by Daewoo and Samsung, entered or withdrawn from warehouse, for consumption from June 5, 2012, through December 31, 2013.

Pursuant to section 751(a)(2)(C) of the Act, the Department also intends to instruct CBP to collect cash deposits of estimated CVDs, in the amounts shown above for each of the respective companies shown above, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 8, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

APPENDIX I

Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Use of Facts Otherwise Available and Adverse Inferences
V. Analysis of Programs
VI. Analysis of Comments
VII. Recommendation

[FR Doc. 2015–23163 Filed 9–14–15; 8:45 am]

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Countervailing Duty Administrative Review; 2012–2013, 80 FR 12803 and accompanying Preliminary Decision Memorandum (PDM) (March 11, 2015) (*Preliminary Results*).

[2] For a full description of the scope, *see* the Department Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review: Large Residential Washers from the Republic of Korea'' (Issues and Decision Memorandum) (September 8, 2015).

[3] *Id.*

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and, section 771(5A) of the Act regarding specificity.

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, October 21, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, Thursday, October 22, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, and Friday, October 23, 2015, from 8:30 a.m. until 12:00 p.m. Eastern Time. All sessions will be open to the public.

DATES: The meeting will be held on Wednesday, October 21, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, Thursday, October 22, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, and Friday, October 23, 2015, from 8:30 a.m. until 12:00 p.m. Eastern Time.

ADDRESSES: The meeting will take place at the U.S. Access Board, 1331 F Street NW., Suite 800, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Annie Sokol, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930, telephone: (301) 975–2006, or by email at: *annie.sokol@nist.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, October 21, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, Thursday, October 22, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, and Friday, October 23, 2015, from 8:30 a.m. until 12:00 p.m. Eastern Time. All sessions will be open to the public. The ISPAB is authorized by 15 U.S.C. 278g–4, as amended, and advises the National Institute of Standards and Technology (NIST), and the Director of the Office of Management and Budget (OMB) on information security and privacy issues pertaining to Federal government information systems, including thorough review of proposed standards and guidelines developed by NIST. Details regarding the ISPAB's activities are available at *http://csrc.nist.gov/groups/SMA/ispab/index.html.*

The agenda is expected to include the following items:

—Presentation from U.S. Department of Homeland Security, National Protection and Programs Directorate,

—Updates from Deputy Undersecretary for Cybersecurity and Communications, U.S. Department of Homeland Security,

—Presentation from U.S. Department of Justice and Federal Bureau of Investigation on Information Collection—Going Dark Initiative—Overview, Challenges and Gaps,

—Updates on OMB Circular No. A–130 Revised, Management of Federal Information Resources,

—Discussion on cybersecurity from Federal Energy Regulatory Commission,

—Updates from Government Accountability Office on information security and privacy reports,

—Presentation from Federal Bureau of Investigation on information collection,

—Presentation from the Communications Security, Reliability and Interoperability Council (CSRIC) on Cybersecurity,

—Legislative Updates relating to cybersecurity,

—FedRAMP Updates on ''High'' baseline security controls,

—Presentation from U.S. Department of Justice on Cyber Norms,

—Discussion on Government adoption of Internet of Things,

—Follow-up discussion with National Telecommunication and Information Administration (NTIA) on Drones and Privacy,

—Discussion on Prevention of large-scale breaches in Federal Databases containing Personally Identifiable Information (PII), and

—Updates on NIST Computer Security Division.

Note that agenda items may change without notice. The final agenda will be posted at *http://csrc.nist.gov/groups/SMA/ispab/index.html.* Seating will be available for the public and media. No registration is required to attend this meeting.

Public Participation: The ISPAB agenda will include a period of time, not to exceed thirty minutes, for oral comments from the public (Friday, October 23, 2015, between 10:00 a.m. and 10:30 a.m.). Speakers will be selected on a first-come, first-served basis. Each speaker will be limited to five minutes. Questions from the public will not be considered during this period. Members of the public who are interested in speaking are requested to contact Annie Sokol at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements. In addition, written statements are invited and may be submitted to the ISPAB at any time. All written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory, 100 Bureau Drive, Stop 8930, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930.

Richard Cavanagh,

Acting Associate Director for Laboratory Programs.

[FR Doc. 2015–23081 Filed 9–14–15; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council, NEFMC) will hold a three-day meeting to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, Wednesday and Thursday, September 29–October 1, 2015, starting at 8:30 a.m. on each of the meeting days.

ADDRESSES: The meeting will be held at the Radisson Plymouth Harbor Hotel, 180 Water St, Plymouth, MA 02360; telephone: (508) 747–4900; fax: (508) 746–2609; or online at *www.radisson.com/plymouth-hotel-ma-02360/maplyhar.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; phone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, September 29, 2015

After introductions and any announcements, the Council meeting will open with the swearing-in of new and reappointed Council members by the Regional Administrator of NOAA's Greater Atlantic Regional Fisheries Office (GARFO). The full Council will then elect its 2015–16 officers to be followed by brief reports from the NEFMC Chairman and Executive Director, the GARFO Regional Administrator, the Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, NOAA General Counsel and its Office of Law Enforcement, and representatives of the Atlantic States Marine Fisheries Commission, and U.S Coast Guard. Next, the public will have an opportunity to make brief comments on items that are relevant to Council business but otherwise not listed on the published agenda.

Following a break at 12 p.m., the NEFMC will receive reports from its oversight committees. The Atlantic

Herring Committee will provide recommendations and the Council will take final action on the fishery's 2016–18 specifications. These will include an overfishing level (OFL) and acceptable biological catch (ABC) based on Scientific and Statistical Committee advice, quotas for each of the four Atlantic herring management areas as well as monthly quota allocations, research set-asides, and annual gear/area-specific catch caps for river herring and shad. The day will conclude with the Council's Observer Committee report. This group will ask for approval of a Draft Environmental Assessment and draft omnibus amendment that would establish provisions for industry-funded monitoring (IFM) across all federally-managed fisheries in the Greater Atlantic region and address monitoring requirements on Atlantic herring vessels. Additionally, the discussion will include consideration of Observer Committee and Herring Committee recommendations regarding the inclusion of any additional management measures in the action, the selection of preferred alternatives, and approval of the Draft Omnibus IFM Amendment for public comment.

Wednesday, September 30, 2015

Wednesday's session will begin with the receipt of recommendations from the Council's Scientific and Statistical Committee on a Georges Bank yellowtail flounder OFL and ABC for fishing years 2016–17; and an ABC recommendation for the species in the Northeast skate complex for fishing years 2016–18. Next, a summary of the 2015 Transboundary Resources Assessment Committee's recent stock assessments for Eastern Georges Bank cod, Eastern Georges Bank haddock, and Georges Bank yellowtail flounder will be presented. This will be followed by a discussion of and a decision on the Transboundary Management Guidance Committee's (TMGC) recommendations for the 2016 quotas for these same stocks. The Council may also discuss other TMGC issues. The Council's Groundfish Committee report will follow and will contain a number of elements: (1) Final Council action on Amendment 18 to the Northeast Multispecies Fishery Management Plan (FMP), which focuses on accumulation limits and fleet diversity; (2) an update on the development of Framework Adjustment 55 to the Northeast Multispecies (Groundfish) Plan, which would set specifications for all groundfish stocks for fishing years 2016–18, and include the quotas for the three U.S./Canada stocks mentioned above for 2016 only; and (3) relative to Framework 55, consider including a proposal to establish a new sector in the groundfish fishery and possible changes that might streamline the current at-sea monitoring program.

Thursday, October 1, 2015

The final meeting day will begin with a briefing by Dr. Jason Link of NOAA Fisheries on the agency's Ecosystem-Based Fisheries Management Strategy. The Council's Habitat Committee will discuss the possibility of initiating a framework adjustment that would allow hydraulic clam dredging in some portions of the Great South Channel and the Georges Shoal Habitat Management Areas approved by the Council in Omnibus EFH Amendment 2 and review the status of and new information associated with the development of an Omnibus Deep-Sea Coral Amendment. A discussion of management priorities for 2016 will occur just prior to a lunch break.

After the break, the Scallop Committee will ask the Council to identify preferred alternatives in Amendment 19 to the Sea Scallop FMP. The action is intended to expedite the implementation date of the sea scallop fishery specifications each year. An update on the development of fishing year 2016 specifications and default measures for fishing year 2017 is also scheduled. The Council will spend the remainder of the day on its Small Mesh Multispecies Program and the Northeast skate complex. During the Small Mesh Program agenda item the Council will: (1) Receive a summary of the annual monitoring report for the three species in this group, red, silver, and offshore hake, all of which are managed via the Groundfish Plan; (2) consider an interim adjustment to the fishery specifications for red hake; and (3) review and approve a draft scoping document for Amendment 22 to the Groundfish Plan, which would address limited access in this fishery. During the skate discussion, the Council will receive an update on the status of the seven skate species in the complex and recent catches. A decision may also be made about initiating a framework adjustment that would allow the Skate Committee to take the lead in developing specifications for fishing years 2016–17.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: September 10, 2015.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–23107 Filed 9–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2015–0062]

Streamlined, Expedited Patent Appeal Pilot for Small Entities

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) has a procedure under which an application will be advanced out of turn (accorded special status) for examination if the applicant files a petition to make special with the appropriate showing. The USPTO is providing a temporary basis (the Streamlined, Expedited Patent Appeal Pilot for Small Entities) under which a small or micro entity appellant may have an *ex parte* appeal to the Patent Trial and Appeal Board (Board) accorded special status if the appellant has only a single appeal pending before the Board and the appellant agrees to streamline the appeal. Specifically, the appeal must not involve any claim subject to a rejection for lack of written description, enablement, or best mode, or for indefiniteness, and the appellant must agree to the disposition of all claims subject to each ground of rejection as a single group and waive any request for an oral hearing. The Streamlined, Expedited Patent Appeal Pilot for Small Entities will allow small or micro entity appellants who streamline their appeals to have greater control over the priority with which their appeals are decided.

DATES: *Effective Date:* September 18, 2015.

Duration: The Streamlined, Expedited Patent Appeal Pilot for Small Entities is being adopted on a temporary basis and

will run until two thousand (2,000) appeals have been accorded special status under the pilot, or until September 16, 2016, whichever occurs earlier. The USPTO may extend the Streamlined, Expedited Patent Appeal Pilot for Small Entities (with or without modification) on either a temporary or permanent basis, or may discontinue this pilot after September 16, 2016, depending upon the results.

FOR FURTHER INFORMATION CONTACT: Steven Bartlett, Patent Trial and Appeal Board, by telephone at 571–272–9797, or by electronic mail message at *expeditedpatentappealspilot@uspto.gov.*

SUPPLEMENTARY INFORMATION: Appeals to the Board are normally taken up for decision by the Board in the order in which they are docketed. The USPTO has a preexisting procedure under which an application will be advanced out of turn (accorded special status) if the applicant files a petition to make special with the appropriate showing. *See* 37 CFR 1.102 and MPEP section 708.02. The USPTO recently adopted the Expedited Patent Appeal Pilot, under which an appellant may have an *ex parte* appeal to the Board in an application accorded special status if the appellant withdraws the appeal in another application or *ex parte* reexamination with an *ex parte* appeal also pending before the Board. *See Expedited Patent Appeal Pilot,* 80 FR 34145 (June 15, 2015). The USPTO is now adopting, on a temporary basis, the Streamlined, Expedited Patent Appeal Pilot for Small Entities, under which a small or micro entity appellant may have an *ex parte* appeal to the Board accorded special status if the appellant has only a single appeal pending before the Board as of September 18, 2015 and the appellant agrees to streamline the appeal. The Streamlined, Expedited Patent Appeal Pilot for Small Entities will permit small or micro entity appellants to accelerate the Board decision on an appeal, possibly hastening the pace at which the invention is patented and brought to the marketplace, and thus spurring follow-on innovation, economic growth, and job creation. The streamlining of appeals under this pilot also will assist the Board to more efficiently reduce the overall inventory of pending appeals.

The USPTO will accord special status to an appeal pending before the Board under the Streamlined, Expedited Patent Appeal Pilot for Small Entities under the following conditions:

(1) A certification and petition under 37 CFR 41.3 must be filed by the USPTO's electronic filing system (EFS-Web) in the application involved in the *ex parte* appeal for which special status is sought (''appeal to be made special''), identifying that application and appeal by application and appeal number, respectively. In addition, the appeal to be made special must be the appellant's only appeal pending before the Board as of September 18, 2015, and the appeal to be made special must have been docketed with the PTAB on or before September 18, 2015.

(2) The appellant must certify that the appellant has established status as a small entity or micro entity in the application underlying the appeal to be made special and also must certify that status as a small entity or micro entity is still appropriate. *See* 37 CFR 1.27 and 1.28 concerning small entity status and see 37 CFR 1.29 concerning micro entity status.

(3) The appellant must agree that, for each ground of rejection applying to two or more claims, the PTAB may select a single claim from the claims subject to each ground of rejection and decide the appeal to be made special with respect to every claim subject to that ground of rejection on the basis of the selected claim alone. *See* 37 CFR 41.37(c)(1)(iv) concerning the treatment of claims subject to the same ground of rejection argued together as a group.

(4) The appellant must certify that the appeal to be made special does not involve any claim subject to a rejection under 35 U.S.C. 112. If an appeal made special under the Streamlined, Expedited Patent Appeal Pilot for Small Entities is found to involve one or more claims subject to a rejection under 35 U.S.C. 112, the appeal normally will be removed from the pilot at the discretion of the Board.

(5) The appellant must agree to waive any oral hearing in the appeal to be made special, and acknowledge that any oral hearing fees paid in connection with the appeal to be made special will not be refunded.

(6) The petition under 37 CFR 41.3 must be signed by a registered practitioner who has a power of attorney under 37 CFR 1.32, or has authority to act under 37 CFR 1.34, for the application involved in the appeal to be made special.

The USPTO has created a form-fillable Portable Document Format (PDF) ''Petition to Make Special—the Streamlined, Expedited Patent Appeal Pilot for Small Entities'' (Form PTO/SB/441) for use in filing a certification and petition under 37 CFR 41.3 under the Streamlined, Expedited Patent Appeal Pilot for Small Entities. Form PTO/SB/441 is available on the USPTO's Internet Web site on the micro site for USPTO patent-related forms (*http://www.uspto.gov/patent/patents-forms*). Form PTO/SB/441 does not collect ''information'' within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). *See* 5 CFR 1320.3(h). Therefore, this notice does not involve information collection requirements which are subject to review by OMB.

No petition fee is required. The $400.00 fee for a petition under 37 CFR 41.3 is hereby *sua sponte* waived for any petition to make an appeal special under the Streamlined, Expedited Patent Appeal Pilot for Small Entities.

MPEP section 1203 provides that an application made special and advanced out of turn for examination will continue to be special throughout its entire course of prosecution in the Office, including appeal, if any, to the Board. An appeal that is accorded special status for decision on an appeal to the Board under the Streamlined, Expedited Patent Appeal Pilot for Small Entities will be advanced out of turn for a decision on the appeal by the Board. The difference between the Streamlined, Expedited Patent Appeal Pilot for Small Entities and an application made special under 37 CFR 1.102 and MPEP section 708.02 is that an application in which an appeal is accorded special status for decision on an appeal to the Board under the Streamlined, Expedited Patent Appeal Pilot for Small Entities will not have a special status under CFR 1.102 and MPEP section 708.02 after the decision on the appeal.

The goal for handling an application in which a petition to make an appeal special under the Streamlined, Expedited Patent Appeal Pilot for Small Entities is filed is as follows: (1) rendering a decision on the petition to make the appeal special no later than two months from the filing date of the petition; and (2) rendering a decision on the appeal no later than four months from the date a petition to make an appeal special under the Streamlined, Expedited Patent Appeal Pilot for Small Entities is granted. The current pendency of decided appeals in applications, for those appeals decided this fiscal year, ranges between an average of 24.9 months for appeals from applications assigned to Technology Center 1700 and an average of 32.5 months for appeals from applications assigned to Technology Center 1600, and is shown for each Technology Center in the following table:

Technology center	Average months from docketing notice to board decision
1600	32.5
1700	24.9
2100	31.6
2400	31.2
2600	31.2
2800	27.0
2900	26.2
3600	31.7
3700	30.1

Ex parte reexamination proceedings, including any appeal to the Board, are conducted with special dispatch within the USPTO. *See* 35 U.S.C. 305. The current average pendency of appeals in *ex parte* reexaminations, for those appeals decided this fiscal year, is 6.0 months. The USPTO is not making the Streamlined, Expedited Patent Appeal Pilot for Small Entities applicable to appeals in *ex parte* reexaminations as these appeals already are handled with special dispatch, and the petition evaluation process only would delay the Board decision in an appeal in an *ex parte* reexamination.

The Streamlined, Expedited Patent Appeal Pilot for Small Entities is being adopted on a temporary basis until two thousand (2,000) appeals have been accorded special status under the pilot, or until September 16, 2016, whichever occurs earlier. The USPTO may extend the Streamlined, Expedited Patent Appeal Pilot for Small Entities (with or without modification) on either a temporary or permanent basis, or may discontinue the pilot after September 16, 2016, depending upon the results. Additional information concerning the Streamlined, Expedited Patent Appeal Pilot for Small Entities, including statistical information and pendency of appeals before the Board, can found on the USPTO Internet Web site at: *https://www-cms.uspto.gov/patents-application-process/patent-trial-and-appeal-board/expedited-patent-appeal-pilot.*

Dated: September 8, 2015.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2015–23090 Filed 9–14–15; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2015–0014]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form And OMB Number: U.S. Army Corps of Engineers, Instrument for Hurricane Evacuation Behavioral Survey; Generic Collection for OMB Control Number 0710–XXXX.

Type of Request: New.

Number of Respondents: 6000.

Responses per Respondent: 1.

Annual Responses: 6000.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 1500.

Needs and Uses: USACE is preparing a Hurricane Evacuation Study to identify clearance times for the evacuations of coastal areas in advance of a hurricane or tropical storm threat. Part of the evacuation study is a behavioral assessment, which identifies the factors and decision points for individuals who are evacuation from areas vulnerable to the storm. The proposed behavioral assessment will use phone interviews to determine the likelihood of evacuation, the method of evacuation, and the number of vehicles and individuals that will be evacuated for all contacted individuals.

Affected Public: Individuals or Households.

Frequency: Annual.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Stuart Levenbach.

Comments and recommendations on the proposed information collection should be emailed to Mr. Stuart Levenbach, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: September 9, 2015.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2015–23069 Filed 9–14–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2015–0005]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by October 15, 2015.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: U.S. Army Corps of Engineers Flood Risk Management Surveys; Generic Collection for OMB Control Number 0710–XXXX.

Type of Request: New.

Number of Respondents: 7,000.

Responses per Respondent: 1.

Annual Responses: 7,000.

Average Burden per Response: 43 minutes.

Annual Burden Hours: 5,000.

Needs and Uses: The Corps of Engineers uses public surveys for collecting data for planning, formulation, and evaluation of projects. Floodplain residents, property owners, businesses, and nonprofit organizations, who are flood victims, are interviewed along with state and local officials and other affected individuals.

Affected Public: Individuals or Households, Business or Other For-Profit, Not-For-Profit Institutions, Farms, State, Local, or Tribal Government.

Frequency: Annual.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Stuart Levenbach.

Comments and recommendations on the proposed information collection should be emailed to Mr. Stuart Levenbach, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: September 9, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–23091 Filed 9–14–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Annual Notice of Interest Rates of Federal Student Loans Made Under the Federal Family Education Loan Program Prior to July 1, 2010

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.032.

SUMMARY: In accordance with section 427A of the Higher Education Act of 1965, as amended, the Chief Operating Officer for Federal Student Aid announces the interest rates for the period July 1, 2015, through June 30, 2016, for certain loans made under the Federal Family Education Loan (FFEL) Program prior to July 1, 2010. The Chief Operating Officer takes this action to give notice of FFEL Program loan interest rates to the public.

DATES: This notice is effective September 15, 2015.

FOR FURTHER INFORMATION CONTACT: Ian Foss, U.S. Department of Education, 830 First Street NE., Room 114I1, Washington, DC 20202. Telephone: (202) 377–3681 or by email: *ian.foss@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Section 427A of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1077a), provides formulas for determining the interest rates charged to borrowers on loans made under the Federal Family Education Loan (FFEL) Program, including Federal Subsidized and Unsubsidized Stafford Loans, Federal PLUS Loans, and Federal Consolidation Loans.

The FFEL Program includes loans with variable interest rates and loans with fixed interest rates. Most loans made under the FFEL Program before July 1, 2006, have variable interest rates that change each year. In most cases, the variable interest rate formula that applies to a particular loan usually depends on the date of the first disbursement of the loan. The variable rates are determined annually and are effective for each 12-month period beginning July 1 of one year and ending June 30 of the following year.

Under section 427A(k) of the HEA, FFEL Program loans first disbursed on or after July 1, 2006, have a fixed interest rate.

In the case of some Federal Consolidation Loans, the interest rate is determined by the date on which the Federal Consolidation Loan application was received. Federal Consolidation Loans for which the application was received on or after October 1, 1998, have a fixed interest rate. This fixed rate is based on the weighted average of the loans that are consolidated, rounded up to the nearest higher 1/8 of one percent up to a maximum rate of 8.25 percent.

FFEL variable interest rates are based on formulas that use the bond equivalent rate of the 91-day Treasury bills auctioned at the final auction held before June 1 of each year plus a statutorily established add-on. These formulas apply to: All Federal Subsidized and Unsubsidized Stafford Loans first disbursed before October 1, 1992, that have been converted to variable rate loans; all Federal Subsidized and Unsubsidized Stafford Loans first disbursed on or after October 1, 1992, and before July 1, 2006; Federal PLUS Loans first disbursed on or after July 1, 1998, and before July 1, 2006; and Federal Consolidation Loans for which the Federal Consolidation Loan application was received on or after November 13, 1997, and before October 1, 1998. In each case, the calculated rate is capped by a maximum interest rate. The bond equivalent rate of the 91-day Treasury bills auctioned on May 26, 2015, which is used to calculate the interest rates on these loans, is 0.02 percent.

For Federal PLUS loans first disbursed before July 1, 1998, the interest rate is based on the weekly average of the one-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System on the last day of the calendar week ending on or before June 26 of each year, plus a statutory add-on percentage. The calculated rate is capped by a maximum interest rate. The weekly average of the one-year constant maturity Treasury yield published on June 29, 2015, which is used to calculate the interest rate on these loans, is 0.29 percent.

This notice includes five charts containing specific information on the calculation of interest rates for loans made under the FFEL Program:

Chart 1 contains information on the interest rates for Federal Subsidized and Unsubsidized Stafford Loans that were made as fixed-rate loans, but were subsequently converted to variable-rate loans.

Chart 2 contains information on the interest rates for variable-rate Federal Subsidized and Unsubsidized Stafford Loans.

Chart 3 contains information on the interest rates for variable-rate Federal PLUS Loans.

Chart 4 contains information on the interest rates for fixed-rate Federal Consolidation Loans.

Chart 5 contains information on the interest rates for fixed-rate Federal Subsidized and Unsubsidized Stafford and PLUS Loans.

CHART 1—"CONVERTED" VARIABLE-RATE FEDERAL SUBSIDIZED AND UNSUBSIDIZED STAFFORD LOANS

Cohort		Original fixed interest rate	Max. rate (%)	91-Day T-Bill rate (%)	Margin (%)	Total rate (%)
First disbursed on or after	First disbursed before					
7/1/1988	7/23/1992	8.00%, increasing to 10.00%	10.00	0.02	3.25	3.27
7/23/1992	10/1/1992	8.00%, increasing to 10.00%	10.00	0.02	3.25	3.27
7/23/1992	7/1/1994	7.00%	7.00	0.02	3.10	3.12
7/23/1992	7/1/1994	8.00%	8.00	0.02	3.10	3.12
7/23/1992	7/1/1994	9.00%	9.00	0.02	3.10	3.12
7/23/1992	7/1/1994	8.00%, increasing to 10.00%	10.00	0.02	3.10	3.12

Note: The FFEL Program loans represented by the second row of the chart were only made to ''new borrowers'' on or after July 23, 1992. Whether the FFEL Program loans represented by the third through sixth rows of the chart were made to a specific borrower depends on the interest rate on a borrower's existing loans at the time that the borrower received the loans on or after July 23, 1992 and prior to July 1, 1994.

In Charts 2 and 3, a dagger following a date in a cohort field indicates that the trigger for the rate to apply is a period of enrollment for which the loan was intended either ''ending before'' or ''beginning on or after'' the date in the cohort field.

CHART 2—VARIABLE-RATE FEDERAL SUBSIDIZED AND UNSUBSIDIZED STAFFORD LOANS

Cohort		Max. rate (%)	91-Day T-Bill rate (%)	Margin		Total rate	
First disbursed on or after	First disbursed before			In-school, grace, deferment (%)	All other periods (%)	In-school, grace, deferment (%)	All other periods (%)
10/1/1992	7/1/1994	9.00	0.02	3.10	3.10	3.12	3.12
7/1/1994	7/1/1994†	9.00	0.02	3.10	3.10	3.12	3.12
7/1/1994	7/1/1995	8.25	0.02	3.10	3.10	3.12	3.12
7/1/1995	7/1/1998	8.25	0.02	2.50	3.10	2.52	3.12
7/1/1998	7/1/2006	8.25	0.02	1.70	2.30	1.72	2.32

Note: The FFEL Program loans represented in the first row in Chart 2 were only made to ''new borrowers'' on or after October 1, 1992. The FFEL Program loans represented in the second row in Chart 2 were only made to ''new borrowers'' on or after July 1, 1994. The FFEL Program loans represented in the third row in Chart 2 must—in addition to having been first disbursed on or after July 1, 1994, and before July 1, 1995—have been made for a period of enrollment that began on or included July 1, 1994.

In Charts 3 and 4, an asterisk following a date in a cohort field indicates that the relevant trigger is an application for a Federal Consolidation Loan being received either ''on or after'' or ''before'' the date in the cohort field. For example, the sixth row in Chart 3 describes the interest rate for a Federal Consolidation Loan for which the application was received on or after November 13, 1997, but before October 1, 1998.

CHART 3—VARIABLE-RATE FEDERAL PLUS, SLS, AND CONSOLIDATION LOANS

Loan type	Cohort		Max. rate (%)	Index rate		Margin (%)	Total rate (%)
	First disbursed on or after	First disbursed before		91-Day T-Bill rate (%)	1-Year constant Treasury maturity (%)		
PLUS and SLS		10/1/1992	12.00		0.29	3.25	3.54
SLS	10/1/1992	7/1/1994†	11.00		0.29	3.10	3.39
PLUS	10/1/1992	7/1/1994	10.00		0.29	3.10	3.39
PLUS	7/1/1994	7/1/1998	9.00		0.29	3.10	3.39
PLUS	7/1/1998	7/1/2006	9.00	0.02		3.10	3.12
Consolidation	11/13/1997*	10/1/1998*	8.25	0.02		3.10	3.12
HHS Portion of Consolidation.				0.02		3.00	3.02

The last row in Chart 3 refers to portions of Federal Consolidation Loans attributable to loans made by the U.S. Department of Health and Human Services under subpart I of part A of title VII of the Public Health Service Act.

CHART 4—FIXED-RATE CONSOLIDATION LOANS

First disbursed on or after	First disbursed before	Max. rate (%)	Rate
	7/1/1994		Weighted average of rates on the loans included in the consolidation, rounded to nearest whole percent, but not less than 9.00%.
7/1/1994	11/13/1997*		Weighted average of rates on the loans included in the consolidation, rounded upward to nearest whole percent.
10/1/1998	7/1/2010	8.25	Weighted average of rates on the loans included in the consolidation, rounded to the nearest higher 1/8 of 1 percent.

CHART 5—FIXED-RATE FEDERAL SUBSIDIZED AND UNSUBSIDIZED STAFFORD AND PLUS LOANS

Loan type	Student grade level	First disbursed on or after	First disbursed before	Rate (%)
Subsidized	Undergraduate Students	7/1/2006	7/1/2008	6.80
Subsidized	Undergraduate Students	7/1/2008	7/1/2009	6.00
Subsidized	Undergraduate Students	7/1/2009	7/1/2010	5.60
Subsidized	Graduate/Professional Students	7/1/2006	7/1/2010	6.80
Unsubsidized	All Students	7/1/2006	7/1/2010	6.80
PLUS	Parents and Graduate/Professional Students	7/1/2006	7/1/2010	8.50

Note: No new loans have been made under the FFEL Program since June 30, 2010.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1071 *et seq.*

Dated: September 10, 2015.

James W. Runcie,

Chief Operating Officer, Federal Student Aid.

[FR Doc. 2015–23165 Filed 9–14–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Annual Notice of Interest Rates of Federal Student Loans Made Under the William D. Ford Federal Direct Loan Program Prior to July 1, 2013

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.268.

DATES: This notice is effective September 15, 2015.

SUMMARY: In accordance with section 455(b)(9) of the Higher Education Act of 1965, as amended, the Chief Operating Officer for Federal Student Aid announces the interest rates for the period July 1, 2015, through June 30, 2016, for loans made under the William D. Ford Federal Direct Loan (Direct Loan) Program prior to July 1, 2013. The Chief Operating Officer takes this action to give notice of Direct Loan interest rates to the public.

FOR FURTHER INFORMATION CONTACT: Ian Foss, U.S. Department of Education, 830 First Street NE., Room 114I1, Washington, DC 20202. Telephone: (202) 377–3681 or by email: *ian.foss@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Section 455(b) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1087e(b)), provides formulas for determining the interest rates charged to borrowers for loans made under the Direct Loan Program including: Federal Direct Subsidized Stafford Loans (Direct Subsidized Loans); Federal Direct Unsubsidized Stafford Loans (Direct Unsubsidized Loans); Federal Direct PLUS Loans (Direct PLUS Loans); and Federal Direct Consolidation Loans (Direct Consolidation Loans) (collectively, ''Direct Loans.'').

The Direct Loan Program includes loans with variable interest rates and loans with fixed interest rates. Most loans made under the Direct Loan Program before July 1, 2006, have variable interest rates that change each year. In most cases, the variable interest rate formula that applies to a particular loan depends on the date of the first disbursement of the loan. The variable rates are determined annually and are effective for each 12-month period beginning July 1 of one year and ending June 30 of the following year.

Under section 455(b) of the HEA, Direct Loans first disbursed on or after July 1, 2006, have a fixed interest rate.

In the case of some Direct Consolidation Loans, the interest rate is determined by the date on which the Direct Consolidation Loan application was received. Direct Consolidation Loans for which the application was received on or after February 1, 1999, have a fixed interest rate. This fixed rate is based on the weighted average of the loans that are consolidated, rounded up to the nearest higher 1/8 of one percent. Direct Consolidation Loans for which the application was received on or after February 1, 1999, and prior to July 1, 2013, have a maximum interest rate of 8.25 percent.

Under section 455(b) of the HEA, the Direct Loan variable interest rates are based on formulas that use the bond equivalent rates of the 91-day Treasury bills auctioned at the final auction held before June 1 of each year, plus a

statutory add-on percentage. These formulas apply to: All Direct Subsidized Loans and Direct Unsubsidized Loans; Direct Consolidation Loans for which the application was received on or after July 1, 1998, and before February 1, 1999; and Direct PLUS Loans disbursed on or after July 1, 1998. In each case, the calculated rate is capped by a maximum interest rate. The bond equivalent rate of the 91-day Treasury bills auctioned on May 26, 2015, which is used to calculate the interest rates on these loans, is 0.02 percent.

In addition, under section 455(b)(4) of the HEA, the interest rate for Direct PLUS Loans that were first disbursed on or after July 1, 1994, and before July 1, 1998, is based on the weekly average of the one-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System on the last day of the calendar week ending on or before June 26 of each year, plus a statutory add-on percentage. The calculated rate is capped by a maximum interest rate. The weekly average of the one-year constant maturity Treasury yield published on June 29, 2015, which is used to calculate the interest rate on these loans, is 0.29 percent.

This notice includes five charts containing specific information on the calculation of the interest rates for loans made under the Direct Loan Program prior to July 1, 2013. We published a separate notice containing the interest rates for Direct Loans made for the current award year on July 17, 2015 (See 80 FR 42488).

Chart 1 contains information on the interest rates for variable-rate Direct Subsidized and Direct Unsubsidized Loans.

Chart 2 contains information on the interest rates for variable-rate Direct PLUS Loans.

Chart 3 contains information on the interest rates for variable-rate Direct Subsidized Consolidation Loans and Direct Unsubsidized Consolidation Loans.

Chart 4 contains information on the interest rates for variable-rate Direct PLUS Consolidation Loans.

Chart 5 contains information on the interest rates for fixed-rate Direct Subsidized, Direct Unsubsidized, and Direct PLUS Loans, and Direct Consolidation Loans.

CHART 1—VARIABLE-RATE DIRECT SUBSIDIZED AND DIRECT UNSUBSIDIZED LOANS

Cohort		Max. rate (%)	Index rate	Margin		Total rate	
First disbursed on or after	First disbursed before		91-Day T-bill rate (%)	In-school, grace, deferment (%)	All other periods (%)	In-school, grace, deferment (%)	All other periods (%)
7/1/1994	7/1/1995	8.25	0.02	3.10	3.10	3.12	3.12
7/1/1995	7/1/1998	8.25	0.02	2.50	3.10	2.52	3.12
7/1/1998	7/1/2006	8.25	0.02	1.70	2.30	1.72	2.32

CHART 2—VARIABLE-RATE DIRECT PLUS LOANS

Cohort		Max. rate (%)	Index rate		Margin (%)	Total rate (%)
First disbursed on or after	First disbursed before		91-Day T-bill rate (%)	1-Year constant treasury maturity (%)		
7/1/1994	7/1/1998	9.00	.....	0.29	3.10	3.39
7/1/1998	7/1/2006	8.25	0.02	.....	3.10	3.12

In Charts 3 through 5, an asterisk following a date in a cohort field indicates that the trigger for the rate to apply is an application for a Direct Consolidation Loan being received either ''on or after'' or ''before'' the date in the cohort field. For example, the fourth row in Chart 3 describes the interest rate for Direct Subsidized and Unsubsidized Consolidation Loans for which the application was received before October 1, 1998, and that were first disbursed on or after October 1, 1998.

CHART 3—VARIABLE-RATE DIRECT SUBSIDIZED AND DIRECT UNSUBSIDIZED CONSOLIDATION LOANS

Cohort		Max. rate (%)	Index rate	Margin		Total rate	
First disbursed on or after	First disbursed before		91-Day T-bill rate (%)	In-school, grace, deferment (%)	All other periods (%)	In-school, grace, deferment (%)	All other periods (%)
7/1/1994	7/1/1995	8.25	0.02	3.10	3.10	3.12	3.12
7/1/1995	7/1/1998	8.25	0.02	2.50	3.10	2.52	3.12
7/1/1998	10/1/1998	8.25	0.02	1.70	2.30	1.72	2.32
10/1/1998	*10/1/1998	8.25	0.02	1.70	2.30	1.72	2.32
*10/1/1998	*2/1/1999	8.25	0.02	2.30	2.30	2.32	2.32

CHART 4—VARIABLE-RATE DIRECT PLUS CONSOLIDATION LOANS

Cohort		Max. rate (%)	Index rate		Margin		Total rate	
First disbursed on or after	First disbursed before		91-Day T-bill rate (%)	1-Year constant treasury maturity (%)	In-school, grace, deferment (%)	All other periods (%)	In-school, grace, deferment (%)	All other periods (%)
7/1/1994	7/1/1998	9.00		0.29	3.10	3.10	3.39	3.39
7/1/1998	10/1/1998	9.00	0.02		3.10	3.10	3.12	3.13
10/1/1998	*10/1/1998	9.00	0.02		3.10	3.10	3.12	3.12
*10/1/1998	*2/1/1999*	8.25	0.02		2.30	2.30	2.32	2.32

CHART 5—FIXED-RATE DIRECT SUBSIDIZED, DIRECT UNSUBSIDIZED, DIRECT PLUS LOANS, AND DIRECT CONSOLIDATION LOANS

Loan type	Student grade level	First disbursed on or after	First disbursed before	Rate
Subsidized	Undergraduates	7/1/2006	7/1/2008	6.80%
Subsidized	Undergraduates	7/1/2008	7/1/2009	6.00%
Subsidized	Undergraduates	7/1/2009	7/1/2010	5.60%
Subsidized	Undergraduates	7/1/2010	7/1/2011	4.50%
Subsidized	Undergraduates	7/1/2011	7/1/2013	3.40%
Subsidized	Graduate/Professional Students	7/1/2006	7/1/2012	6.80%
Unsubsidized	All	7/1/2006	7/1/2013	6.80%
PLUS	Parents and Graduate/Professionals	7/1/2006	7/1/2013	7.90%
Consolidation	All	2/1/1999	7/1/2013	Weighted average of rates on the loans included in the consolidation, rounded to 1/8 of 1 percent, up to 8.25 percent.

Note: Interest rates for Direct Loans first disbursed on or after July 1, 2013, are published in a separate **Federal Register** notices, as follows:

- For Direct Loans first disbursed on or after July 1, 2013, and prior to July 1, 2014, see 78 FR 59011.
- For Direct Loans first disbursed on or after July 1, 2014, and prior to July 1, 2015, see 79 FR 37301.
- For Direct Loans first disbursed on or after July 1, 2015, and prior to July 1, 2016, see 80 FR 42488.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1087 *et seq.*

Dated: September 10, 2015.

James W. Runcie,

Chief Operating Officer, Federal Student Aid.

[FR Doc. 2015–23160 Filed 9–14–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2015–ICCD–0091]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS–K:2011) Spring Fifth-Grade National Data Collection

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 15, 2015.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://wwww.regulations.gov* by searching the Docket ID number ED–2015–ICCD–0091. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E105, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, (202) 502–7411 or by email *kashka.kubzdela@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork

Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS–K:2011) Spring Fifth-Grade National Data Collection.

OMB Control Number: 1850–0750.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 99,576.

Total Estimated Number of Annual Burden Hours: 36,108.

Abstract: The Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS–K:2011), conducted by the National Center for Education Statistics (NCES) within the Institute of Education Sciences (IES) of the U.S. Department of Education (ED), is a survey that focuses on children's early school experiences beginning with kindergarten and continuing through the fifth grade. It includes the collection of data from parents, teachers, school administrators, and nonparental care providers, as well as direct child assessments. Like its sister study, the Early Childhood Longitudinal Study, Kindergarten Class of 1998–99 (ECLS–K), the ECLS–K:2011 is exceptionally broad in its scope and coverage of child development, early learning, and school progress, drawing together information from multiple sources to provide rich data about the population of children who were kindergartners in the 2010–11 school year. This submission requests OMB's clearance for the spring 2016 fifth-grade data collection, which will be the last data collection for the study.

Dated: September 10, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–23111 Filed 9–14–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Proposed Agency Information Collection

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy

ACTION: Agency Information Collection Activities: Proposed Extension with Changes; Notice and Request for Comments.

SUMMARY: The EIA invites public comment on the proposed three-year extension of the following Oil and Gas Reserves System Survey Forms that EIA is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995: Revision of Form EIA–23L, *Annual Survey of Domestic Oil and Gas Reserves, Field Level Report;* extension without changes of Form EIA–64A, *Annual Report of the Origin of Natural Gas Liquids Production;* and continued suspension of Form EIA–23S, *Annual Survey of Domestic Oil and Gas Reserves, Summary Level Report.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be filed by November 16, 2015. If you anticipate difficulty in submitting comments within that period, contact the person listed in the below **ADDRESSES** Section as soon as possible.

ADDRESSES: Written comments may be sent to Mr. Steven Grape, EI–24, U. S. Department of Energy, 1000 Independence Avenue SW., Washington DC 20585, by fax at (202) 586–4420, or by email at *steven.grape@eia.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Mr. Grape, as listed above. The information collection instrument and instructions are available on the EIA Web site at: Form EIA–23L, *http://wwwdev.eia.gov/survey/#eia-23l,* Form EIA–23S, *http://wwwdev.eia.gov/survey/#eia-23s,* Form EIA–64A, *http://wwwdev.eia.gov/survey/#eia-64a.*

SUPPLEMENTARY INFORMATION: Comments and feedback are requested on the following topics directly related to the proposed changes to Form EIA–23L:

- Field versus County Level Data Detail—EIA currently collects data on a field level basis, but publishes reserves estimates on a State and State subdivision level. Reporting burden to respondents may be reduced, depending on existing record keeping practices, if operators report proved reserves and production data aggregated at a county level. EIA is able to make accurate State and State subdivision level reserves estimates if proved reserves are reported at a county level. Abandoning field-level detail will result in some loss of detail for reserve estimates; however, it will increase the utility of the data by facilitating the matching of other economic data that are only published at the county level.
- Well Counts (by County)—EIA does not currently collect the number of producing wells on Form EIA–23L. EIA proposes to collect well counts by county on Form EIA–23L to assist data quality validation of the production data reported on the form. Collecting well count data by county is consistent with commercially-available production data that is based on well-level reporting in many States and will facilitate data comparisons and data quality evaluations.
- Type Code—EIA is considering deleting the Type Code ''CH'' for Chalk from Schedule B. EIA has Type Codes for certain reservoir types: CV for Conventional, SH for Shale, CB for Coalbed, CH for Chalk, and LP for Other Low Permeability Reservoirs. CH is currently underutilized and EIA proposes to delete Chalk as a reservoir Type Code. The two codes SH and LP have been used interchangeably by operators for tight oil reserves estimates and may be combined for crude oil into

a new reservoir Type Code title ''Tight.'' EIA requests comments on the proposal to delete Type Code ''CH'' for Chalk, and combine reservoir Type codes ''SH'' and ''LP'' into a single category ''Tight for crude oil only.''

• Fuel Types—EIA tracks the proved reserves of four fuel types—two types of liquids; crude oil and lease condensate; and two types of natural gas proved reserves; nonassociated (aka gas well gas) and associated-dissolved (aka casinghead or oil well gas). EIA proposes to continue collecting proved reserves estimates by these four types, instead of combining them into Total Liquids and Total Natural Gas.

• Producing versus Nonproducing Reserves—Currently operators report both producing and nonproducing proved reserves by field on Form EIA–23L. EIA requests comments on the ability to report these data on a county level basis.

• Extensions, New Field Discoveries, and New Reservoir Discoveries in Old Fields—EIA requests comments on the utility of collecting and publishing these three components of Total Discoveries or whether it is more useful to report and publish these components under one data category such as ''County level Discoveries.'' EIA also requests comments on the burden of reporting these three components separately.

• Field Code Master List—EIA proposes to delete the EIA Field Code Master List that is currently used to report data at the field level. Changing the reporting on Form EIA–23L from Field to County level would eliminate the need to publish or maintain the EIA Field Code Master List.

All of the proposed changes that are described above are shaded the color yellow on the draft Form EIA–23L to illustrate and facilitate the review of the data elements that are affected by these proposed changes.

This information collection request contains:

(1) OMB No. 1905–0057;

(2) Information Collection Request Title: Oil and Gas Reserves System.

(3) Type of Request: Revision of the currently approved Form EIA–23L; extension without changes of the currently approved Form EIA–64A; and continued suspension of collection of the currently approved Form EIA–23S (suspended).

(4) Purpose: In response to Public Law 95–91 Section 657, estimates of U.S. oil and gas reserves are to be reported annually. Many U.S. government agencies have an interest in the definitions of proved oil and gas reserves and the quality, reliability, and usefulness of estimates of reserves. Among these are the U.S. Energy Information Administration (EIA), Department of Energy; Bureau of Ocean Energy Management (BOEM), Department of Interior; Internal Revenue Service (IRS), Department of the Treasury; and the Securities and Exchange Commission (SEC). Each of these organizations has specific purposes for collecting, using, or estimating proved reserves. EIA has a congressional mandate to provide accurate annual estimates of U.S. proved crude oil, natural gas, and natural gas liquids reserves, and EIA presents annual reserves data in EIA Web reports to meet this requirement. The BOEM maintains estimates of proved reserves to carry out their responsibilities in leasing, collecting royalty payments, and regulating the activities of oil and gas companies on Federal lands and water. Accurate reserve estimates are important, as the BOEM is second only to the IRS in generating Federal revenue. For the IRS, proved reserves and occasionally probable reserves are an essential component of calculating taxes for companies owning or producing oil and gas. The SEC requires publicly traded petroleum companies to annually file a reserves statement as part of their 10–K filing. The basic purpose of the 10–K filing is to provide public investors with a clear and reliable financial basis to assess the relative value, as a financial asset, of a company's reserves, especially in comparison to other similar oil and gas companies.

The Government also uses the resulting information to develop national and regional estimates of proved reserves of domestic crude oil, natural gas, and natural gas liquids to facilitate national energy policy decisions. These estimates are essential to the development, implementation, and evaluation of energy policy and legislation. Data are used directly in EIA Web reports concerning U.S. crude oil, natural gas, and natural gas liquids reserves, and are incorporated into a number of other Web reports and analyses.

EIA proposes to make the following changes to Form EIA–23L, *Annual Survey of Domestic Oil and Gas Reserves, Field Level Report:*

• Change the title of Form EIA–23L to *Annual Survey of Domestic Oil and Gas Reserves, County Level Report;*

• Change the title of Schedule A to Operated Proved Reserves, Production, and Related Data by County;

• Operators will be instructed to file their proved reserves by county rather than by field. Line Item 2.0 will be named ''County Data (operated basis);''

• Line Item 2.1.4 ''Field Code'', will be changed to ''County Name;''

• Line Item 2.1.5 ''MMS Code'' will be changed to ''Type Code;''

• Line Item 2.1.6. ''Field Name'' will be changed to ''Field, Play, or Prospect Name (Optional);''

• Line Items 2.1.9 ''water depth'' and 2.1.10 ''field discovery year'' will be replaced with 2.1.9 ''# of producing wells'', 2.1.10 ''# of wells added [in survey year];'' and

• Line Item 2.1.11, ''Prospect Name (optional) will be replaced with ''# of wells sold [in survey year].''

Comments and Feedback are requested on these proposed changes to Form EIA–23L.

Secondary reports that use the data include EIA's *Annual Energy Review, Annual Energy Outlook, Petroleum Supply Annual,* and *Natural Gas Annual;*

(5) Annual Estimated Number of Respondents:

Forms EIA–23L/23S/64A: 1,450.

(6) Annual Estimated Number of Total Responses:

Forms EIA–23L/23S/64A: 1,450.

(7) Annual Estimated Number of Burden Hours: 41,210.

Form EIA–23L *Annual Survey of Domestic Oil and Gas Reserves, County Level Report:* 38 hours (420 intermediate-size operators); 110 hours (160 large operators); 15 hours (270 small operators): 37,610 hours.

Form EIA–23S *Annual Survey of Domestic Oil and Gas Reserves, Summary Level Report:* 4 hours (small operators): 0 hours (Currently suspended)

Form EIA–64A *Annual Report of the Origin of Natural Gas Liquids Production:* 6 hours (600 natural gas plant operators): 3,600 hours.

(8) Annual Estimated Reporting and Recordkeeping Cost Burden:

Forms EIA–23L/23S/64A: EIA estimates that there are no capital and start-up costs associated with this data collection. The information is maintained in the normal course of business. The cost of burden hours to the respondents is estimated to be $2,965,884 (41,210 burden hours times $71.97 per hour). Therefore, other than the cost of burden hours, EIA estimates that there are no additional costs for generating, maintaining and providing the information.

Statutory Authority: Section 13(b) of the Federal Energy Administration Act of 1974, Public Law 93–275, codified at 15 U.S.C. 772(b).

Issued in Washington, DC, September 9, 2015.

Nanda Srinivasan,

Director, Office of Survey Development and Statistical Integration, U.S. Energy Information Administration.

[FR Doc. 2015–23136 Filed 9–14–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meeting related to the transmission planning activities of the Midcontinent Independent System Operator, Inc. (MISO):

MISO Planning Advisory Committee
September 16, 2015, 9 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be held at:

MISO Headquarters, 720 City Center Drive, Carmel, IN 46032

Further information may be found at *www.misoenergy.org.*

The discussions at the meeting described above may address matters at issue in the following proceedings:

Docket Nos. ER13–1944, *et al., PJM Interconnection, LLC*
Docket No. ER14–1174, *Southwest Power Pool, Inc.*
Docket No. ER14–1736, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–2445, *Midcontinent Independent System Operator, Inc.*
Docket No. ER13–1864, *Southwest Power Pool, Inc.*
Docket No. EL14–21, *Southwest Power Pool, Inc.* v. *Midcontinent Independent System Operator, Inc.*
Docket No. EL14–30, *Midcontinent Independent System Operator, Inc.* v. *Southwest Power Pool, Inc.*
Docket No. EL11–34, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER11–1844, *Midwest Independent Transmission System Operator, Inc.*
Docket No. EL13–88, *Northern Indiana Public Service Company* v. *Midcontinent Independent System Operator, Inc. and PJM Interconnection, L.L.C.*
Docket Nos. ER13–1923, *et al., Midcontinent Independent System Operator, Inc.*
Docket Nos. ER13–1937, *et al., Southwest Power Pool, Inc.*
Docket No. EL15–89, *Midcontinent Independent System Operator, Inc.*

For more information, contact Chris Miller, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5936 or *christopher.miller@ferc.gov;* or Jason Strong, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–6124 or *jason.strong@ferc.gov.*

Dated: September 9, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–23149 Filed 9–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14682–000]

Adam R. Rousselle II; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On June 17, 2015, Adam R. Rousselle II filed an application for a preliminary permit under section 4(f) of the Federal Power Act proposing to study the feasibility of the proposed Paint Creek Dam Water Power Project No. 14682–000, to be located at the existing U.S. Army Corps of Engineers' Paint Creek Lake, near the town of Bainbridge, Highland County, Ohio. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would be located completely within lands owned by the United States and use an existing concrete intake tower located in Paint Creek Lake and an existing 1,100-foot-long, 48-foot-diameter tunnel conveying the lake water from the intake tower to the outlet works downstream of the dam. The proposed project would consist of the following new facilities: (1) Two 80-foot-long, 8-foot-diameter steel penstocks attached to the outlet works and ending at the turbine assembly; (2) a 50-foot-long, 30-foot-wide, 30-foot-high concrete powerhouse located approximately 100 feet downstream of the outlet works and containing two Kaplan turbine-generators with a combined installed capacity of 2.14 megawatts; (3) a 500-foot-long, 14.7 kilovolt transmission line; and (4) appurtenant facilities. The project is estimated to generate 13,100 megawatt hours annually.

Applicant Contact: Adam R. Rousselle II, 104 Autumn Trace Drive, New Hope, PA 18938; phone: 215–485–1708.

FERC Contact: Sergiu Serban, (202) 502–6211.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14682–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14682) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: September 9, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–23151 Filed 9–14–15; 8:45 am]

BILLING CODE 6717–0–1P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1432–013]

PB Energy, Inc.; Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 1432–013.

c. *Date Filed:* August 31, 2015.

d. *Submitted By:* PB Energy, Inc.

e. *Name of Project:* Dry Spruce Bay Project.

f. *Location:* On an unnamed creek near Port Bailey in Kodiak Island Borough, Alaska. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. Potential *Applicant Contact:* Robert and Anita Shane, Director of Administration, PB Energy, Inc., PO Box KPY, Kodiak, Alaska 99697; (360) 633–3719; email—*anita99697@gmail.com.*

i. *FERC Contact:* Ryan Hansen at (202) 502–8074; or email at *ryan.hansen@ferc.gov.*

j. PB Energy, Inc. filed its request to use the Traditional Licensing Process on May 29, 2015. PB Energy, Inc. provided public notice of its request on June 8, 2015. In a letter dated July 22, 2015, the Director of the Division of Hydropower Licensing approved PB Energy, Inc.'s request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the Alaska State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. PB Energy, Inc. filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

m. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in paragraph h.

n. The licensee states its unequivocal intent to submit an application for a new license for Project No. 1432. Pursuant to 18 CFR 16.8, 16.9, and 16.10 each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by May 31, 2018.

o. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: September 9, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–23146 Filed 9–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14683–000]

Mr. Adam R. Rousselle, II; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On June 17, 2015, Mr. Adam R. Rousselle, II, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Blue Marsh Dam Water Power Project (project) to be located on Tulpehocken Creek, near the town of Reading, Berks County, Pennsylvania. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The project would consist of the following: (1) a proposed 6-foot-diameter penstock; (2) a proposed powerhouse containing two generating units having a total installed capacity of 2,500 kilowatts; (3) a tailrace returning flow to Tulpehocken Creek; (4) a proposed 0.9-mile-long, 12.47-kilovolt transmission line interconnecting with the Pennsylvania Power Company system; and (5) appurtenant facilities. The proposed project would have an average annual generation of about 9,943,000 kilowatt-hours, which would be sold to a local utility.

Applicant Contact: Mr. Adam R. Rousselle, II, 104 Autumn Trace Drive, New Hope, PA 18938; phone: (215) 485–1708.

FERC Contact: Tim Looney; phone: (202) 502–6096.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14683–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14683) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: September 9, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–23152 Filed 9–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. P–1256–031]

Loup River Hydroelectric Project; Notice of Technical Meeting

a. *Project Name and Number:* Loup River Hydroelectric Project No. 1256.

b. *Date and Time of Meeting:* September 30, 2015; 2:00 p.m. Eastern Time (1:00 p.m. Central Time).

c. *Place:* Telephone conference with U.S. Fish and Wildlife Service (FWS).

d. *FERC Contact:* Chelsea Hudock, *chelsea.hudock@ferc.gov* or (202) 502–8448.

e. *Purpose of Meeting:* To discuss the FWS revisions, filed on August 12, 2015, to its Incidental Take Statement regarding threatened and endangered species affected by the proposed Loup River Hydroelectric Project (project), the effects of the proposed project on the endangered whooping crane, and a timeframe by which we would provide the FWS with our evaluation of the project effects on the Northern long-eared bat and the red knot.

f. A summary of the meeting will be prepared and filed in the Commission's public file for the project.

g. All local, state, and federal agencies, Indian tribes, and other interested parties are invited to participate by phone. Please contact Chelsea Hudock at *chelsea.hudock@ferc.gov* or (202) 502–8448 by close of business September 22, 2015, to R.S.V.P. and to receive specific instructions on how to participate.

Dated: September 9, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–23150 Filed 9–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL15–68–000]

Midcontinent Independent System Operator, Inc.; Notice of Filing

On June 18, 2015, pursuant to section 206 of the Federal Power Act, 16 U.S.C. 824e, the Commission instituted an investigation in Docket No. EL15–68–000 to examine the justness and reasonableness of the *pro forma* Facilities Construction Agreement (FCA), Generator Interconnection Agreement (GIA), and Multi-Party Facilities Construction Agreement (MPFCA) contained in Midcontinent Independent System Operator, Inc.'s (MISO) Open Access Transmission, Energy and Operating Reserve Markets Tariff (Tariff). *Midcontinent Indep. Sys. Operator, Inc., et al.,* 151 FERC ¶ 61,220 (2015). The Commission found that, upon initial review, the *pro forma* FCA, GIA, and MPFCA may be unjust and unreasonable, and that the potentially unjust and unreasonable Tariff language could be remedied with certain revisions. The Commission required MISO to make a filing either to (1) report whether it will propose Tariff changes as suggested by the Commission or (2) explain why such changes are not necessary. Take notice that, on August 17, 2015, MISO submitted a filing in response to the Commission's directive.

The Commission is now providing an opportunity for other parties to comment on the Commission's preliminary findings in the section 206 proceeding in Docket No. EL15–68–000, as well as MISO's response to the Commission's directive. Any person desiring to comment must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Comments will be considered by the Commission in determining the appropriate action to be taken, but intervention is necessary to become a party to the proceeding.

The Commission encourages electronic submission of comments in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the comments to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

MISO's filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on September 30, 2015.

Dated: September 9, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–23148 Filed 9–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14241–000]

Alaska Energy Authority; Notice Soliciting Comments on Request To Lift the ILP Abeyance and Approve Proposed Modifications to the ILP Plan and Schedule

On August 26, 2015, Alaska Energy Authority (AEA), prospective license applicant for the proposed Susitna-Watana Hydroelectric Project No. 14241, requested that Commission staff: (1) Lift the Integrated Licensing Process (ILP) abeyance granted to AEA for its proposed project on January 8, 2015; and (2) approve AEA's proposed modifications to the ILP plan and schedule. These requests, including the proposed process plan and schedule modifications, can be viewed at *http://elibrary.ferc.gov/idmws/common/OpenNat.asp?fileID=13969092.*

The Commission is soliciting comments on these requests. Any comments should be filed within 30 days from the date of this notice. Comments may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14241–000.

For further information, contact Nick Jayjack at (202) 502–6073.

Dated: September 9, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–23147 Filed 9–14–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2015–0056; FRL–9934–08–OW]

National Advisory Council for Environmental Policy and Technology: Assumable Waters Subcommittee; Notice of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Federal Advisory Subcommittee Meetings.

SUMMARY: Consistent with the Federal Advisory Committee Act, Public Law 92–463, EPA is giving notice of two upcoming public meetings of the Assumable Waters Subcommittee convened under the National Advisory Council for Environmental Policy and Technology (NACEPT). The Assumable Waters Subcommittee will provide advice and recommendations as to how the EPA can best clarify assumable waters for dredge and fill permit programs pursuant to Clean Water Act section 404(g)(1). The EPA is undertaking this effort to support states and tribes that wish to assume the program. Similar to the parent NACEPT, the subcommittee represents a diversity of interests from academia, industry, non-governmental organizations, and local, State, and tribal governments. Meeting agendas and materials will be posted at *www2.epa.gov/cwa-404/assumable-waters-sub-committee.*

DATES: The Assumable Waters Subcommittee will hold two-day public meetings on:

- October 6–7, 2015, from 9:00 a.m. to 5:00 p.m., in the William Jefferson Clinton Building in Washington, DC.
- December 1–2, 2015, from 9:00 a.m. to 5:00 p.m., in the One Potomac Yard Building in Arlington, VA.

ADDRESSES:

- William Jefferson Clinton Building, Room B305 North, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- One Potomac Yard, Ground Floor, 2777 Crystal Dr. Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Laura Bachle, Designated Federal Officer, via Email at: Assumable, by phone: (202) 566–2468, via postal service at: U.S. EPA, Office of Wetlands Oceans and Watersheds, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: Requests to make oral comments or to provide written comments to the Assumable Waters Subcommittee should be sent to Laura Bachle via Email at: *assumablewaters@epa.gov* by September 25, 2015, for the October meeting and by November 16, 2015, for the December meeting. The meetings are open to the public, with limited seating available on a first-come, first-served basis. Members of the public wishing to attend should contact Laura Bachle via Email at: *assumablewaters@epa.gov* or by phone at: (202) 566–2468 by September 25, 2015, for the October meeting and by November 16, 2015, for the December meeting. Public comments will heard from 1:30 p.m. to 2:30 p.m. on October 7, 2015, and December 2, 2015.

Meeting Access: Information regarding accessibility and/or accommodations for individuals with disabilities should be directed to Laura Bachle at the email address or phone number listed above. To ensure adequate time for processing, please make requests for accommodations at least 10 days prior to the meeting.

Dated: September 9, 2015.

Benita Best-Wong,

Director, Office of Wetlands, Oceans, and Watersheds.

[FR Doc. 2015–23143 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2015–0628; FRL–9933–77–OECA]

Public Comment on EPA's National Enforcement Initiatives for Fiscal Years 2017–2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is soliciting public comment and recommendations on national enforcement initiatives (NEI) for fiscal years 2017–2019. EPA selects these initiatives every three years in order to focus federal resources on the most important environmental problems where noncompliance is a significant contributing factor and where federal enforcement attention can make a difference. The current initiatives as well as potential new initiatives under consideration are described in the **SUPPLEMENTARY INFORMATION** section, with additional descriptions and data on current initiatives available on our Web site: *http://www2.epa.gov/enforcement/national-enforcement-initiatives.*

DATES: Comments must be received on or before October 14, 2015.

ADDRESSES: Submit your comments via *www.regulations.gov,* identified by Docket ID No. EPA–HQ–OECA–2015–0628; FRL–9933–77–OECA. Follow the on-line instructions for submitting comments.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OECA–2015–0628. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov.* The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

FOR FURTHER INFORMATION CONTACT: Daniel Palmer, Deputy Director, Planning Measures and Oversight Division, Office of Enforcement and Compliance Assurance, Mail Code: M2221A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–564–5034; fax number: 202–564–0027; email address: *Palmer.Daniel@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What are EPA enforcement and compliance national initiatives?

EPA is soliciting public comment and recommendations on national enforcement initiatives to be undertaken in fiscal years 2017–2019. EPA selects these initiatives every three years in order to focus federal resources on the most important environmental problems

where noncompliance is a significant contributing factor and where federal enforcement attention can make a difference. This notice is an Agency planning document and does not impose any legally binding requirements on EPA or any outside parties.

II. On what is EPA requesting comment?

EPA's Office of Enforcement and Compliance Assurance is collecting comment on which of the current national enforcement initiatives should continue, be expanded or returned to the standard enforcement program. Current initiatives may be carried forward, refined or concluded for the FY 2017–2019 cycle. EPA is also seeking comment on the list of potential NEIs described above which are currently being considered for the FY 2017–2019 national enforcement cycle. The public is invited to propose any other areas for consideration, keeping in mind resource constraints.

III. What are the current FY 2014–2016 national enforcement initiatives (which can be extended)?

For the six current initiatives, EPA invites the public to comment on whether each NEI should continue into the FY 17–19 cycle or return to the standard enforcement program for completion of remaining work. EPA also invites comment on whether EPA should add new areas of focus within those NEIs that are recommended for extension.

(1) Reducing air pollution from the largest sources. This national enforcement initiative has focused on ensuring that large industrial facilities comply with the Clean Air Act when building new facilities or making modifications to existing facilities. In keeping with the purpose of NEIs to address the largest, highest impact sources of pollution, this NEI has been centered on industrial sectors with the largest amounts of air pollution that can significantly impact human health: Coal fired power plants, as well as acid, glass and cement manufacturing facilities. Large percentages of facilities in these sectors are now under enforceable commitments to reduce pollution, although there are still violating facilities with substantial pollution. For coal-fired power plants alone, the injunctive relief in these cases, when fully implemented, will mean reductions in serious air pollution of nearly 3 million tons each year. Although significant progress has been made to address noncompliance in several sub-categories of this initiative, more work may be needed on new cases and EPA has an on-going commitment to monitor progress under existing consent agreements to assure that the required actions are implemented and air pollution reductions from completed enforcement actions actually occur.

(2) Cutting toxic air pollution. Toxic air pollution from industrial facilities is a national problem, which is nowhere more urgent than in the fence line communities that bear the brunt of unlawful pollution. This national enforcement initiative has focused on the substantial illegal emissions of hazardous air pollutants (HAPs) from leaks, flares, and excess emissions at industrial facilities that are putting neighbors' health at risk. Through active investigations and use of innovative monitoring technologies, EPA has identified many violating facilities where toxic air pollution was much greater than what had previously been estimated. EPA has conducted hundreds of evaluations and brought numerous enforcement actions to require these facilities to reduce pollution and to comply with the law. Based on what we have learned about the sources of the largest toxic emissions and the causes of the releases, EPA is considering expanding this initiative into new focus areas and sources where noncompliance is a growing threat, as described further below.

(3) Assuring energy extraction and production activities comply with environmental laws. EPA has been working with states to assure that domestic land-based natural gas extraction and production is done in an environmentally protective manner and in compliance with environmental laws. Natural gas development activities in energy rich areas of the country have led to concerns about increases in air pollution levels, pollution of surface and ground waters, the safety of community drinking water supplies, and damage to ecosystems. EPA has brought a number of high impact enforcement actions to address serious violations in this industry. This sector continues to develop and change rapidly, and EPA is continuing to evaluate the best way to address pollution problems in this sector, including opportunities for greater use of advanced monitoring.

(4) Reducing pollution from mineral processing operations: Mining and mineral processing facilities generate more toxic and hazardous waste than any other industrial sector. Improper handling of those wastes can lead to expensive cleanups that can cost taxpayers billions of dollars. This NEI has been focused on the largest and highest risk mineral processing operations, to ensure that they properly manage their wastes and have sufficient financial assurance to properly close facilities. This NEI has resulted in a number of large, high impact cases to ensure proper handling of these hazardous wastes. By the end of FY16 many of the highest risk mineral processing facilities are expected to be under enforceable agreements or orders that will require them to properly address hazardous waste.

(5) Keeping raw sewage and contaminated stormwater out of our Nation's waters: Discharges of raw sewage and contaminated stormwater are a serious pollution problem in waters across the country. Under this initiative, EPA has tackled significant water pollution problems within communities that result from Clean Water Act noncompliance. Many communities with raw sewage discharges are now under enforceable commitments to reduce pollution, including numerous communities that have embraced green infrastructure as a solution. Green infrastructure can provide benefits beyond compliance with the Clean Water Act and can be more cost effective. EPA will need to continue to monitor implementation of these long-term agreements, and to adapt them to changing circumstances and new information, such as the increasing commitment of cities to implement green infrastructure, changes in financial capability, or technological advances. Municipal stormwater pollution also remains an important clean water challenge in communities around the country.

(6) Preventing animal waste from contaminating surface and ground water: Animal waste is a significant contributor to serious water quality issues and can result in environmental and human health risks such as water quality impairment, fish kills, algal blooms, contamination of drinking water sources, and transmission of disease-causing bacteria and parasites associated with food and waterborne diseases. The focus of this national enforcement initiative has been reduction of animal waste pollution that impairs our nation's waters, threatens drinking water sources, and adversely impacts communities. These impacts are often acutely felt in rural communities of environmental justice concern. EPA's enforcement strategy for this NEI has focused on animal agriculture operations that have a big impact or where action is necessary to ensure that all operations in the sector play by the same rules. For the future, EPA is considering an updated strategy

to explore the use of nutrient recovery technologies that show promise to reduce water pollution, implementation of instream monitoring to demonstrate impacts to water quality and identify violations, as well as new tools to identify the most significant violators.

IV. What are the FY 2017–2019 potential NEIs currently under consideration?

In addition to evaluating the current NEIs to determine which should continue and potentially be expanded and which can return to the standard enforcement program, EPA is also considering new initiatives for FY 2017–2019. We are very mindful that our resources have been declining over the past five years, so we need to keep resource constraints very much in mind as we consider taking on new work. A brief description and pertinent background information for each potential new FY 2017–2019 initiative is provided below.

(1) Protecting Communities from Exposure to Toxic Air Emissions. EPA is currently implementing an air toxics NEI and is considering expanding the initiative to include emissions from additional sources and industries. Emissions of toxic air pollutants continue to be a concern that threatens the health of communities. EPA seeks public comment on whether to significantly increase our commitment to addressing this national problem by expanding into one or both of the following two areas:

Organic Liquid Storage Tanks: In addition to the current areas of focus—flares and leaks—large storage tanks can be significant sources of excess air emissions at many sites, including terminals, refineries, and chemical plants. Using advanced monitoring, including optical remote sensing techniques, such as differential absorption light detection and ranging technology and optical gas imaging cameras, EPA has observed that volatile organic compound (VOC) and hazardous air pollutant (HAP) emissions from storage tanks can greatly exceed the permitted and/or estimated emissions. In many instances, EPA has observed that emissions are the result of violations, including inadequate maintenance of the tanks and associated emissions controls, design flaws, and expansion of production volumes without corresponding increases in emissions control. There are thousands of tanks operating in the United States at refineries, chemical plants, and other bulk storage facilities that are located in ozone nonattainment areas, communities of environmental justice concern, or other areas with sensitive populations.

Hazardous Waste Air Emissions: The handling of hazardous waste can also result in toxic air emissions, which present many of the same public health risks that led to the selection of air toxics as an NEI. In addition, these hazardous wastes, if improperly handled, can also present a potential for increased fire or explosion risk due to their high corrosivity and ignitability. Such catastrophic events not only create a safety risk for workers and the surrounding community, they also create the potential for significant associated releases of toxic air pollutants that have both acute and chronic health effects. Based on EPA's observations during field work, as well as the publicly available compliance information on Enforcement and Compliance History Online (ECHO), it appears that widespread violations of the air emission requirements under the Resource Conservation and Recovery Act (RCRA) are a significant contributing cause of these problems. Violations observed include the improper use of monitoring and control devices by facilities, resulting in releases of emissions from RCRA regulated units. Of particular concern are the toxic air emissions that result from the handling of hazardous waste at treatment, storage, and disposal facilities (TSDFs) and large quantity generators (LQGs) that are not properly controlling hazardous waste releases to the air as required by regulation.

One of the reasons to consider these areas for an expanded NEI is to support a level playing field, so that all industries with toxic air releases, which usually operate in multiple states across the country, are held to a common, consistent standard. EPA invites comment on whether to expand our work to reduce toxic air emissions to these two new focus areas.

(2) Keeping Industrial Pollutants out of the nation's Waters Many waters (including sediments) around the country are polluted by nutrients and metals. Certain industrial sectors contribute a disproportionate amount of the pollution over discharge limits. This potential NEI would focus on the top sectors that have many violations and are responsible for contributing to surface water pollution and putting our drinking water at risk: Mining, chemical manufacturing, food processing and primary metals manufacturing. A number of facilities in the top sectors discharge pollution in excess of their permit limits. In addition to being a focused attempt to significantly reduce serious water pollution across the nation, selecting this as an NEI would allow for a national approach for those companies that operate in more than one state and would support a consistent national strategy to achieve compliance across industry sectors.

(3) Reducing the Risks and Impacts of Industrial Accidents and Releases. It is an all too common occurrence for industrial facilities to have serious accidents and explosions that kill or injure employees and emergency responders, and release chemicals that threaten neighboring communities. Thousands of facilities across the country produce, process, store, and use extremely hazardous substances that are acutely toxic or can cause serious accidents. These facilities vary widely in nature, from municipal water treatment plants to the largest refineries in the United States and are often extremely large and complex. Across the country, approximately 150 catastrophic accidents occur per year among the universe of regulated facilities. These accidents pose a risk to neighboring communities and workers because they result in fatalities, injuries, significant property damage, evacuations, sheltering in place, or environmental damage. Approximately 2,000 facilities are currently considered ''high-risk'' because of their proximity to densely populated areas, the quantity and number of extremely hazardous substances they use, or their history of significant accidents.

Most of these serious accidents are preventable if the necessary precautions and actions are taken. Failure to adequately train personnel, maintain equipment, conduct routine inspections, or take other common sense precautions contribute to the dangers these facilities pose to their workers and to surrounding communities. This potential NEI would be a targeted focus on the facilities and the chemicals that pose the greatest risks, with a goal of increasing industry attention to preventing accidents, instead of addressing problems after accidents happen, thereby reducing the risk of harm to communities and workers.

For all of the NEIs that EPA ultimately selects for FY17–19, we intend to incorporate Next Generation Compliance approaches into our work. Our goal will be to use the most current monitoring technologies, data analytics and transparency, as well as the latest thinking on what drives better compliance, to get better results even in a time of serious resource constraints. We invite comment on what some of these Next Gen opportunities might be for the continuing and potential new NEIs.

EPA will consider all public comments in determining whether and to what extent to continue or expand an initiative or to select a new one, but will not respond to the comments received. Final selection will be incorporated into the EPA Office of Enforcement and Compliance Assurance FY 2017 National Program Manager Guidance Addendum that provides national program direction for all EPA regional offices.

Information in support of this Notice of Public Comment is available via the Internet at: *http://www2.epa.gov/enforcement/national-enforcement-initiatives.*

V. Can the deadline for comments be extended?

No. EPA will include the final selection of the national enforcement initiatives in the National Program Manager Guidance (NPM Guidance) to enable EPA, states, and federally-recognized Indian tribes (tribes) to effectively align their joint implementation of environmental laws to achieve mutual goals. The NPM guidance must be timely released for public comment in order to allow the EPA regions, as well as states and tribes with approved programs, to consider the NPM Guidance fully in their annual planning processes which direct the use of resources according to the fiscal calendar. As a result, EPA must receive public comments by October 14, 2015 in order to make selections in keeping with this schedule.

Dated: September 3, 2015.

Betsy Smidinger,

Acting Director, Office of Compliance.

[FR Doc. 2015–23056 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0086; FRL—9933–47–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Flexible Polyurethane Foam Fabrication (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Flexible Polyurethane Foam Fabrication (40 CFR part 63, subpart MMMMM) (Renewal)'' (EPA ICR No. 2027.06, OMB Control No. 2060–0516, to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2015. Public comments were previously requested via the **Federal Register** (79 FR 30117) on May 27, 2014 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 15, 2015.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0086, to (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA's public docket, visit: *www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP (40 CFR part 63, subpart A), and any changes, or additions to the Provisions specified at 40 CFR part 63, subpart MMMMM. Owners or operators of the affected facilities must submit initial notification reports, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative.

Form Numbers: None.

Respondents/affected entities: Flexible polyurethane foam fabrication facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart MMMMM).

Estimated number of respondents: 17 (total).

Frequency of response: Initially, occasionally, semiannually, and annually.

Total estimated burden: 18,900 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,930,000 (per year), including $29,500 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an increase in the total estimated respondent burden as currently identified in the OMB Inventory of Approved Burdens. This burden increase is due to adjustments EPA has made to account for industry growth that has occurred since the ICR was last approved. EPA has also updated corresponding labor costs to reflect current rates referenced from the Bureau of Labor Statistics. EPA has similarly adjusted the Agency labor burden to reflect industry growth over the past three years and has updated labor costs to reflect rates referenced from the Office of Personnel Management.

There is an increase in the total annual O&M cost as compared to the previous ICR. The previous ICR's estimate only reflected those costs associated with new sources. The resulting omission of O&M costs also incurred by existing sources resulted in a significant underestimation of the total cost; therefore, EPA has both reconciled the noted discrepancy and increased the total annual O&M cost accordingly.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015–23128 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0092; FRL–9932–69–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Printing, Coating and Dyeing of Fabrics and Other Textiles (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Printing, Coating and Dyeing of Fabrics and other Textiles (40 CFR part 63, subpart OOOO) (Renewal)'' (EPA ICR No. 2071.06, OMB Control No. 2060–0522) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2015. Public comments were requested previously via the **Federal Register** (79 FR 30117) on May 27, 2014, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 15, 2015.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0092, to (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP (40 CFR part 63, subpart A), and any changes, or additions, to the Provisions are specified at 40 CFR part 63, subpart OOOO. Owners or operators of the affected facilities must submit initial notification reports, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative.

Form Numbers: None.

Respondents/affected entities: Facilities involved in the printing, coating, slashing, dyeing or finishing of fabric and other textiles.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart OOOO).

Estimated number of respondents: 146 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 22,400 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,260,000 (per year), which includes a combined total of $6,750 in both annualized capital/startup and operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in both the respondent and Agency burden, including an increase in the O&M cost. This is not due to any program changes; rather, it is due to an increase in the estimated number of sources. We assume an additional coating and printing facility will become subject to the rule each year. In addition, we have updated all burden calculations using the latest labor rates, which contributes to an increase in cost.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015–23130 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0088; FRL—9934–09–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Refractory Products Manufacturing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Refractory Products Manufacturing (40 CFR part 63, subpart SSSSS) (Renewal)'' (EPA ICR No. 2040.06, OMB Control No. 2060–0515) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2015. Public comments were previously requested via the **Federal Register** (79 FR 30117) on May 27, 2014, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 15, 2015.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0088, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A, and any changes, or additions to the provisions specified at 40 CFR part 63, subpart SSSSS. Owners or operators of the affected facilities must submit initial notification, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative.

Form Numbers: None.

Respondents/affected entities: Refractory products manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart SSSSS).

Estimated number of respondents: 8 (total).

Frequency of response: Initially, occasionally and semiannually.

Total estimated burden: 343 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $37,000 (per year), includes $3,040 annualized capital or operation & maintenance costs.

Changes in the Estimates: The increase in burden from the most recently approved ICR is due to updates to assumptions in the burden estimates. The additional assumptions in the burden estimates included in this ICR are that all respondents will have to read and re-familiarize with the rule requirements annually, and total annual burdens and costs have been rounded to 3 significant values.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015–23129 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0081; FRL–9934–13–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Reinforced Plastic Composites Production (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Reinforced Plastic Composites Production (40 CFR part 63, subpart WWWW) (Renewal)'' (EPA ICR No. 1976.06, OMB Control No. 2060–0509) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2015. Public comments were previously requested via the **Federal Register** (79 FR 30117) on May 27, 2014 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 15, 2015.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0081, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Reinforced Plastic Composites Production apply to existing and new facilities with reinforced plastic composites (RPC) production operations and processes. New facilities include those that commenced construction or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart WWWW.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Any owner/operator subject to the provisions of this part shall maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintenance reports, and records. All

reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the United States Environmental Protection Agency (EPA) regional office.

Form Numbers: None.

Respondents/affected entities: Facilities with RPC production operations and processes.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart WWWW).

Estimated number of respondents: 600 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 20,900 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $2,580,000 (per year), includes $476,000 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in the burden and cost estimates occurred because the total number of respondents has increased, after accounting for anticipated industry growth over three years. The increase in O&M costs is due to the inclusion of the MACT compliance standard for SMC enclosure for one large facility, based on comment received from industry consultation.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015–23115 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0046; FRL—9933–87–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Benzene Waste Operations (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''NESHAP for Benzene Waste Operations (40 CFR part 61, subpart FF) (Renewal)'' (EPA ICR No. 1541.11, OMB Control No. 2060–0183), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through September 30, 2015. Public comments were previously requested via the **Federal Register** (79 FR 30117) on May 27, 2014, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before October 15, 2015.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0046, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The affected entities are subject to the General Provisions of the NESHAP (40 CFR part 61, subpart A), and any changes, or additions, to the Provisions are specified at 40 CFR part 61, subpart FF. Owners or operators of the affected facilities must submit an initial notification report, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative.

Form Numbers: None.

Respondents/affected entities: Owners and operators of facilities that generate or receive benzene waste.

Respondent's obligation to respond: Mandatory (40 CFR part 61, subpart FF).

Estimated number of respondents: 270 (total).

Frequency of response: Initially, occasionally, quarterly and annually.

Total estimated burden: 19,200 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,930,000 (per year), including $0 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the respondent burden from the most recently approved ICR. The increase is primarily attributed to correcting an entry error in the number of respondents that record monthly benzene waste concentration data under Table 1, labor item 4(c)(ii). In addition, we have rounded all total values to 3 significant figures.

There is also an adjustment increase in the number of responses due to a correction. The previous ICR did not account for quarterly emission reports and notifications of offsite facilities in calculating the number of responses.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015–23114 Filed 9–14–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; Open Commission Meeting Thursday, September 17, 2015

September 10, 2015.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, September 17, 2015, which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street SW., Washington, DC.

Item no.	Bureau	Subject
1	MEDIA	TITLE: Amendment of Section 73.1216 of the Commission's Rules Related to Broadcast Licensee-Conducted Contests (MB Docket No. 14–226). SUMMARY: The Commission will consider a Report and Order to provide broadcasters greater flexibility in their disclosure of contest terms.
2	PUBLIC SAFETY	TITLE: Improving Outage Reporting for Submarine Cables and Enhancing Submarine Cable Outage Data (GN Docket No. 15–206). SUMMARY: The Commission will consider a Notice of Proposed Rulemaking that proposes to require submarine cable licensees to report outages.

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Consent Agenda

The Commission will consider the following subjects listed below as a consent agenda and these items will not be presented individually:

Item no.	Bureau	Subject
1	MEDIA	TITLE: Radio Training Network, Application for a New Noncommercial FM Station at Dillon, South Carolina. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by several joint petitioners seeking review of a Media Bureau Order granting Radio Training Network a New Noncommercial FM Station.
2	MEDIA	TITLE: University of San Francisco (Assignor) and Classical Public Radio Network LLC (Assignee), Application for Consent to Assignment of License Station KOSC(FM), San Francisco, CA. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Applications for Review filed by Ted Hudacko and Friends of KUSF seeking review of a letter by the Media Bureau Order and Consent Decree approving an assignment application.
3	MEDIA	TITLE: Centennial Licensing, LLC, Assignor and Mel Wheeler, Inc., Assignee, Assignment of License WLNI(FM), Lynchburg, Virginia. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by 3 Daughters Media, Inc. seeking review of a Media Bureau Order granting an assignment application.
4	MEDIA	TITLE: Center for Emerging Media, Inc., *et al,* Application for a Construction Permit for a New LPFM Station at Baltimore, Maryland. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Loyola University of Maryland seeking review of a Commission Public Notice analyzing LPFM MX Group 198.
5	MEDIA	TITLE: Texas Grace Communications, Request to Toll the Period to Construct Unbuilt Station DKRZB(FM), Archer City, Texas. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Texas Grace Communications seeking review of a Media Bureau decision.
6	MEDIA	TITLE: Christian Charities Deliverance Church, Application for a Construction Permit for a New LPFM Station at Sayville, New York; By Faith Ministries Association, Application for a Construction Permit for a New LPFM Station at Sayville, New York; Rooftop Productions, Application for a Construction Permit for a New LPFM Station at Seattle, Washington; and Massasoit Community College, Application for a Construction Permit for a New LPFM Station at Brockton, Massachusetts. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning Applications for Review filed by Christian Charities Deliverance Church, By Faith Ministries Association, Rooftop Productions and Massasoit Community College seeking review of application dismissals by the Media Bureau.
7	MEDIA	TITLE: Royce International Broadcasting Company, Assignor, and Entercom Communications Corp., Assignee, Application for Consent to the Assignment of License of Station KWOD(FM), Sacramento, CA. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Royce International Broadcasting Company seeking review of a Media Bureau decision granting an assignment application.
8	MEDIA	TITLE: Hispanic Broadcasting Institute, Inc., Application for New LPFM Station at Lawrence, MA.

Item no.	Bureau	Subject
		SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Hispanic Broadcasting Institute, Inc. seeking review of a Media Bureau dismissal of its LPFM station application.
9	MEDIA	TITLE: Tango Radio, LLC, Applications for License to Cover Construction of DKNOS(FM), Albany Texas; DKANM(FM), Skyline-Ganipa, New Mexico; and DKKUL–FM, Trinity, Texas; and South Texas FM Investments, LLC, Applications for License to Cover Construction of DKAHA(FM), Olney, Texas, and DKXME(FM), Wellington, Texas. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning Applications for Review filed by Tango Radio, LLC and South Texas FM Investments, LLC seeking review of two Media Bureau decisions.
10	MEDIA	TITLE: Pandora Radio LLC, Petition for Declaratory Ruling Under Section 310(b)(4) of the Communications Act of 1934, as Amended; Application of Connoisseur Media Licenses, LLC for Consent to Assign Station KXMZ(FM), Box Elder, South Dakota, to Pandora Radio LLC (MB Docket No. 14–109). SUMMARY: The Commission will consider an Order on Reconsideration concerning two Petitions for Reconsideration filed by the American Society of Composers, Authors and Publishers seeking review of a Commission Declaratory Ruling and a Media Bureau grant of an assignment application.
11	MEDIA	TITLE: Hill Broadcasting Company, Inc., Request for Reinstatement of License and Application for Renewal of License for Station DKTVG–TV, Grand Island, NE. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Applications for Review Hill Broadcasting Company, Inc. seeking review of a Media Bureau renewal application dismissal.
12	CONSUMER AND GOVERNMENTAL AFFAIRS.	TITLE: San Fernando Cathedral of San Antonio, Texas, (SFC), Application for Review (CG Docket No. 06–181). SUMMARY: The Commission will consider a Memorandum Opinion and Order addressing an Application for Review filed by SFC seeking review of the Bureau's dismissal of SFC's petition for exemption from the Commission's closed captioning requirements.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015–23274 Filed 9–11–15; 4:15 pm]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act (PRA), to approve of and assign OMB numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

DATES: Comments must be submitted on or before November 16, 2015.

ADDRESSES: You may submit comments, identified by *Reg II or Reg K,* by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include OMB number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert deV. Frierson, Secretary, Board of Governors of the

Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW.) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposals

The following information collections, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collections, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Proposal to approve under OMB delegated authority the extension for three years, without revision, of the following reports:

1. *Report title:* Recordkeeping and Disclosure Requirements Associated with Regulation II (Debit Card Interchange Fees and Routing).

Agency form number: Reg II.

OMB control number: 7100–0349.

Frequency: On occasion.

Reporters: State member banks, national banks, insured nonmember banks, savings associations, and Federally-chartered credit unions.

Estimated annual reporting hours: Implement policies & procedures, 2,400 hours; Review and update policies and procedures, 5,240 hours; and Annual notification and change in status, 131 hours.

Estimated average hours per response: Implement policies & procedures, 160 hours; Review and update policies and procedures, 40 hours; and Annual notification and change in status, 1 hour.

Number of respondents: Implement policies & procedures, 15 respondents; Review and update policies and procedures, 131 respondents; and Annual notification and change in status, 131 respondents.

General description of report: This information collection is required to obtain or retain a benefit ((15 U.S.C. 1693o–2(a)(5)) and is not given confidential treatment.

Abstract: Regulation II implements, among other things, standards for assessing whether interchange transaction fees for electronic debit transactions are reasonable and proportional to the cost incurred by the issuer with respect to the transaction, as required by section 920 of the Electronic Fund Transfer Act. The regulation sets a cap of 21 cents plus 5 basis points of the transaction's value on interchange transaction fees of covered issuers.

Regulation II allows adjustments to debit card interchange transaction fees to make an allowance for fraud-prevention costs incurred by issuers. The regulation permits an issuer to receive or charge an amount of no more than 1 cent per transaction in addition to its interchange transaction fee if the issuer develops and implements policies and procedures that are reasonably designed to take effective steps to reduce the occurrence of, and costs to all parties from, fraudulent electronic debit transactions. An issuer must notify its payment card networks annually that it complies with the Board's standards for the fraud-prevention adjustment.

Regulation II requires issuers to retain evidence of compliance with the requirements imposed for a period of not less than five years after the end of the calendar year in which the electronic debit transaction occurred.

2. *Report title:* Recordkeeping Requirements of Regulation H and Regulation K Associated with Bank Secrecy Act Compliance Programs.

Agency form number: Reg K.

OMB control number: 7100–0310.

Frequency: Annually.

Reporters: State member banks; Edge and agreement corporations; and U.S. branches, agencies, and other offices of foreign banks supervised by the Federal Reserve.

Estimated annual reporting hours: Establish compliance program, 160 hours; and maintenance of compliance program, 4,872 hours.

Estimated average hours per response: Establish compliance program, 16 hours; and maintenance of compliance program, 4 hours.

Number of respondents: Establish compliance program, 10; and maintenance of compliance program, 1,218.

General description of report: The standards for Bank Secrecy Act (BSA) compliance programs associated with section 208.63 of Regulation H and with sections 211.5(m)(1) and 211.24(j)(1) of Regulation K are generally authorized pursuant to the BSA. In addition, sections 11, 21, 25, and 25A of the Federal Reserve Act authorize the Board to require the information collection and recordkeeping requirements set forth in Regulations H and K. Section 5 of the Bank Holding Company Act and section 13(a) of the International Banking Act provide further authority for sections 211.5(m) and 211.24(j)(1) of Regulation K. Since the Federal Reserve does not collect any information, no issue of confidentiality normally arises. However, if a BSA compliance program becomes a Federal Reserve record during an examination, the information may be protected from disclosure under

exemptions (b)(4) and (b)(8) of the Freedom of Information Act.

Abstract: Section 208.63 of Regulation H requires state member banks to establish and maintain the same procedures. Sections 211.5(m)(1) and 211.24(j)(1) of Regulation K require Edge and agreement corporations and U.S. branches, agencies, and other offices of foreign banks supervised by the Federal Reserve to establish and maintain procedures reasonably designed to ensure and monitor compliance with the BSA and related regulations. There are no required reporting forms associated with this information collection.

Board of Governors of the Federal Reserve System, September 10, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–23103 Filed 9–14–15; 8:45 am]

BILLING CODE 6210–01–P

GOVERNMENT PUBLISHING OFFICE

Depository Library Council to the Director; Meeting

The Depository Library Council (DLC) to the Director, Government Publishing Office (GPO) will meet on Monday, October 19, 2015 through Wednesday, October 21, 2015 in Arlington, Virginia. The sessions will take place from 8 a.m. to 5:30 p.m., Monday and Tuesday and 8 a.m. to 12:30 p.m., on Wednesday. The meeting will be held at the Doubletree Hotel, 300 Army Navy Drive, Arlington, Virginia. The purpose of this meeting is to discuss the Federal Depository Library Program. All sessions are open to the public. The United States Government Publishing Office is in compliance with the requirements of Title III of the Americans with Disabilities Act and meets all Fire Safety Act regulations.

Davita Vance-Cooks,

Director, Government Publishing Office.

[FR Doc. 2015–23089 Filed 9–14–15; 8:45 am]

BILLING CODE 1520–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15BEZ; Docket No. CDC–2015–0081]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a newly proposed information collection request entitled *Improving Fetal Alcohol Spectrum Disorders Prevention Practice through Practice and Implementation Centers and National Partnerships.*

DATES: Written comments must be received on or before November 16, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0081 by any of the following methods:

- Federal eRulemaking Portal: *Regulation.gov.* Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Improving Fetal Alcohol Spectrum Disorders Prevention and Practice through Practice and Implementation Centers and National Partnerships—New—National Center on Birth Defects and Developmental Disabilities

(NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center on Birth Defects and Developmental Disabilities seeks to collect training evaluation data from healthcare practitioners and staff in health systems where FASD-related practice and systems changes are implemented, and grantees of Practice and Implementation Centers and national partner organizations related to prevention, identification, and treatment of fetal alcohol spectrum disorders (FASDs).

Prenatal exposure to alcohol is a leading preventable cause of birth defects and developmental disabilities. The term ''fetal alcohol spectrum disorders'' describes the full continuum of effects that can occur in an individual exposed to alcohol in utero. These effects include physical, mental, behavioral, and learning disabilities. All of these have lifelong implications.

The purpose of this program is to expand previous efforts from FASD training programs and shift the perspective from individual training for practicing health care professionals to one that capitalizes on prevention opportunities and the ability to impact health care practice at the systems level.

Since 2002, CDC funded FASD Regional Training Centers (RTCs) to provide education and training to healthcare professionals and students about FASD prevention, identification, and treatment. In July 2013, CDC convened an expert review panel to evaluate the effectiveness of the RTC program overall and make recommendations about the program. The panel highlighted several accomplishments of the RTCs and proposed several changes for future programming: (1) The panel identified a need for more comprehensive coverage nationally with discipline-specific trainings, increased use of technology, greater collaboration with medical societies, and stronger linkages with national partner organizations to increase the reach of training opportunities, and (2) The panel suggested that the training centers focus on demonstrable practice change and sustainability and place a stronger emphasis on primary prevention of FASDs. In addition, it was recommended that future initiatives have stronger evaluation components.

Based on the recommendations of the expert review panel, CDC is placing increased focus on prevention, demonstrating practice change, achieving national coverage, and strengthening partnerships between FASD Practice and Implementation Centers, or PICs (the newly redesigned RTCs), and medical societies and national partner organizations. The National Organization on Fetal Alcohol Syndrome (NOFAS) also participates in this project as a resource to the PICS and national partners. The PICs and national partners are asked to closely collaborate in discipline-specific workgroups (DSWs) and identify strategies that will increase the reach of the program on a national level. While a major focus of the grantees' work will be national, regional approaches will be used to develop new content and ''test out'' feasibility and acceptability of materials, especially among health care providers and medical societies. In addition, CDC is placing a stronger emphasis on evaluation, with both individual DSW/NOFAS evaluations and a cross-site evaluation.

CDC requests OMB approval to collect program evaluation information from (1) healthcare practitioners from disciplines targeted by each DSW, including training participants, (2) health system staff, and (3) cooperative agreement grantees over a three-year period.

- Healthcare practitioners will complete surveys to provide information on whether project trainings impacted their knowledge and practice behavior regarding FASD identification, prevention, and treatment. The information will be used to improve future trainings and assess whether knowledge and practice changes occurred. Some participants will also complete qualitative key informant interviews to gain additional information on practice change.
- Health system employees will be interviewed as part of high impact evaluation studies. The high impact evaluation studies will be focused assessments of two to three specific grantee efforts that seem likely to result in achievement of program objectives.
- Grantees will complete program evaluation forms to track perceptions of DSW collaboration and perceptions of key successes and challenges encountered by the DSW.

It is estimated that 20,554 respondents will participate in the evaluation each year, for a total estimated burden of 4528.0 hours annually. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	DSW/ Organization	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
FASD Core Training Participants.	All	FASD Core Training Survey—Pre-Test.	4,013	1	15/60	1,003
FASD Core Training Participants.	All	FASD Core Training Survey—Post-Test.	4,013	1	15/60	1,003
FASD Core Training Participants.	All	FASD Core Training Survey—6 Month Follow-Up.	4,013	1	20/60	1,338
Project Grantee Staff	Westat (Cross-Site Evaluator).	DSW Report	90	2	10/60	30
Project Grantee Staff	Westat (Cross-Site Evaluator).	Key Informant Interview—DSW Project Director.	6	3	60/60	18
National Partner Staff	Westat (Cross-Site Evaluator).	Key Informant Interview—National Partner.	6	3	60/60	18
Health System Staff	Westat (Cross-Site Evaluator).	Key Informant Interview—Health System Staff.	60	3	30/60	90
Nurses	Nursing	Key Informant Interviews with Champions.	14	1	45/60	10
Nurses	Nursing	Online Survey with ''Friends''/Members of the Network.	34	2	15/60	17

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	DSW/ Organization	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Healthcare Organization Representatives.	Nursing	Online Survey with Healthcare Organization Representatives.	67	1	30/60	33
Nurses and Nursing Students.	Nursing	Brief Online Questionnaire for Nursing Organization Memberships.	2,934	1	10/60	489
Physicians and students in allied health professions.	Obstetrics & Gynecology	Avatar Training Satisfaction Survey.	1,200	1	6/60	120
Students in allied health professions.	Obstetrics & Gynecology	Proficiency Ratings Scale—Standardized Patient Version.	600	1	6/60	60
Physicians	Obstetrics & Gynecology	Proficiency Ratings Scale—Provider—Baseline.	600	1	6/60	60
Physicians	Obstetrics & Gynecology	Proficiency Rating Scale—Provider—1 Month Follow-Up.	600	1	2/60	20
Physicians	Obstetrics & Gynecology	FASD Training Event Evaluation.	124	1	2/60	4
Residency Directors, Training Coordinators, Clinic Directors.	Obstetrics & Gynecology	Pre- Assessment of Training Implementation.	14	1	30/60	7
Residency Directors, Training Coordinators, Clinical Directors, Physicians.	Obstetrics & Gynecology	Post-Assessment of Training Implementation.	14	1	30/60	7
Physicians	Pediatrics	FASD Core Training Survey—Pediatrics 3 Month Follow-Up.	120	1	15/60	30
Physicians	Pediatrics	Pediatrics DSW Baseline Survey.	535	1	4/60	36
Physicians	Pediatrics	Pediatrics DSW Year 4 Survey.	535	1	4/60	36
Physicians	Pediatrics	FASD Toolkit User Survey	50	1	15/60	13
Physicians	Social Work & Family Physicians.	Family Medicine Comprehensive Practice Evaluation.	62	1	8/60	8
Medical and allied health professionals.	National Organization on Fetal Alcohol Syndrome.	NOFAS Webinar Survey—Post-Test.	400	1	5/60	33
Medical and allied health professionals.	National Organization on Fetal Alcohol Syndrome.	NOFAS Webinar Survey—3 Month Follow-Up.	400	1	5/60	33
General public	National Organization on Fetal Alcohol Syndrome.	NOFAS Outcomes Vignette.	50	1	10/60	8
TOTAL						4,524

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–23088 Filed 9–14–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by October 15, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the

OMB Control number 0910–NEW and title ''Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (OMB Control Number 0910—NEW)

In the **Federal Register** of June 11, 2014 (79 FR 33564), FDA announced the availability of a draft guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' The draft guidance addressed new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Section 202 of the DSCSA adds section 582(h)(2) (21 U.S.C. 360eee–1(h)(2)) to the FD&C Act, which requires FDA to issue guidance to aid certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product and terminating notifications. The draft of this guidance identified specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain and provided recommendations on how trading partners can identify the product and determine whether the product is a suspect product as soon as practicable.

Beginning January 1, 2015, section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify (1) FDA and (2) all immediate trading partners that they have reason to believe may have received the illegitimate product, not later than 24 hours after making the determination. Manufacturers are additionally required under section 582(b)(4)(B)(ii)(II) of the FD&C Act to notify FDA, and any immediate trading partners that the manufacturer has reason to believe may possess a product manufactured by or purported to be manufactured by the manufacturer, not later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that a product is illegitimate. The draft guidance addressed how trading partners should notify FDA using Form FDA 3911. In addition, in accordance with section 582(h)(2) of the FD&C Act, the draft guidance sets forth the process by which trading partners must terminate the notifications using Form FDA 3911, in consultation with FDA, regarding illegitimate product and, for a manufacturer, a product with a high risk of illegitimacy, under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B).

Burden Estimates: Under section 202 of the DSCSA, manufacturers, repackagers, wholesale distributors, and dispensers (*e.g.,* pharmacies) must: (1) Notify FDA when they have determined that a product in their possession or control is illegitimate (and, for manufacturers, when they have determined or been notified by FDA or a trading partner that a product has a high risk of illegitimacy); (2) notify immediate trading partners about an illegitimate product that they may have received (and, for manufacturers, a product with a high risk of illegitimacy); (3) terminate notifications regarding illegitimate products (and, for manufacturers, products with a high risk of illegitimacy), in consultation with FDA when the notifications are no longer necessary; and (4) notify immediate trading partners when the notifications are terminated.

1. Notifications to FDA

Under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, and beginning not later than January 1, 2015, a manufacturer, repackager, wholesale distributor, or dispenser who determines that a product in its possession or control is illegitimate, must notify FDA of that determination not later than 24 hours after the determination is made. In addition, section 582(b)(4)(B)(ii)(II) of the FD&C Act requires manufacturers to notify FDA when a manufacturer determines that a product poses a high risk of illegitimacy.

FDA originally estimated that a total of approximately 5,000 notifications per year would be made by all manufacturers, repackagers, wholesale distributors, and dispensers. This estimate included the notifications by trading partners who have determined that illegitimate product is in their possession or control, as well as notifications by manufacturers that have determined a product poses a high risk of illegitimacy. As discussed in the June 11, 2014, **Federal Register** notice, this estimate was based on FDA's experience with FARs (Form FDA 3331) required to be submitted by holders of approved drug applications for certain drug quality issues (§ 314.81(b)(1) (21 CFR 314.81(b)(1))), and with reports of the falsification of drug sample records, diversion, loss, and known theft of prescription drug samples as currently required under § 203.37 (21 CFR 203.37). In response to the **Federal Register** notice, FDA received a comment from a trade association representing a primary stakeholder stating that the estimate of 5,000 notifications was too high based on experience of its members. In response to the comment, FDA reexamined the estimate of 5,000 notifications. We determined that the 5,000 FARs and 5,000 sample reports under § 203.37 received each year included initial, followup and final reports. While FDA does not know the exact number of notifications that will be submitted, we lowered the estimate to 1,000 notifications in response to the comment and our reexamination of the data, and adjusted the PRA accordingly.

FDA is combining the estimates for manufacturers and repackagers because FDA's establishment and drug product listing database indicates that many companies perform activities of both manufacturers and repackagers. While the DSCSA specifically defines dispensers, for estimation purposes, FDA is using estimates for pharmacies in general terms based on those that must comply with the new requirements under section 582(d) of the FD&C Act.

Because, collectively, manufacturers, repackagers, and wholesale distributors are responsible for prescription drugs from the point of manufacturing through distribution in the drug supply chain, in the June 11, 2014, **Federal Register** notice, FDA assumed that most notifications of illegitimate products would be made by these three trading partners. FDA received a comment from a major stakeholder group stating that they believed that the number of notifications estimated for wholesale distributors was too high based on their past experience. The commenter speculated that most notifications would be made by manufacturers. In addition, manufacturers are the only stakeholder group required to submit notifications of high risk of illegitimacy. FDA originally estimated that approximately 50 percent of the notifications will be made by manufacturers and repackagers, 45

percent by wholesaler distributors, and 5 percent by pharmacies. In response to the comment and the fact that only manufacturers submit notifications of high risk of illegitimacy, FDA is changing the proportion that will be made by manufacturers and repackagers to 80 percent (800), 16 percent by wholesale distributors (160), and 4 percent by pharmacies (40).

FDA estimates that the number of annual notifications will vary from 0–2 for manufacturers/repackagers, wholesale distributors, and pharmacies, with the vast majority of companies making no notifications. While the FDA establishment and drug product listing database currently contains registrations for approximately 6,500 manufacturers and repackagers, we estimate that approximately 800 manufacturers/repackagers will notify FDA of illegitimate product or a product with a high risk of illegitimacy an average of one time per year. While FDA estimates approximately 69,000 pharmacy sites in the United States, based on data from the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the American Hospital Association, we estimate that approximately 40 pharmacies will notify FDA of illegitimate product an average of one time per year. Because, according to Healthcare Distribution Management Association, approximately 30 wholesale distributors are responsible for over 90 percent of drug distributions, based on sales, and because FDA is estimating that over 2,200 small wholesale distributors might be responsible for the remaining 10 percent of drug sales, we estimate that distributors will be responsible for making an estimated 160 notifications FDA will receive regarding illegitimate product.

FDA intends to make Form FDA 3911 available on its Web page for trading partners to use to notify FDA. Each notification should include information about the person or entity initiating the notification, the product determined to be illegitimate, or to have a high risk of illegitimacy, and a description of the circumstances surrounding the event that prompted the notification. FDA estimates that each notification will take about 1 hour. The estimated total annual burden hours for making notifications to FDA is approximately 1,000 hours annually (table 1).

2. Notifications to Trading Partners of an Illegitimate Product or Product With a High Risk of Illegitimacy

Under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, a trading partner who determines that a product in its possession is illegitimate must also notify all immediate trading partners that the trading partner has reason to believe may have received such illegitimate product of that determination not later than 24 hours after the determination is made. In addition, a manufacturer is required, under section 582(b)(4)(B)(ii)(II) of the FD&C Act, to notify all immediate trading partners that the manufacturer has reason to believe may possess a product manufactured by or purported to be manufactured by the manufacturer not later than 24 hours after the manufacturer has determined or been notified by FDA or a trading partner that the product has a high risk of illegitimacy.

Because the extent of distribution of any illegitimate product is likely to vary from one situation to another, FDA assumed a wide distribution of each illegitimate product. FDA estimates that for each notification made by a manufacturer or repackager to FDA, approximately 30 trading partners (based on the number of distributors) will also be notified. This results in approximately 24,000 notifications annually to trading partners of manufacturers/repackagers. This estimate includes the notifications by manufacturers and repackagers who have determined that illegitimate product is in their possession or control, as well as notifications by manufacturers that have determined that a product poses a high risk of illegitimacy.

FDA estimates that a large wholesale distributor may have up to 4,500 trading partners, but a small wholesale distributor may have 200 trading partners, for an average of approximately 2,350. FDA originally estimated that a wholesale distributor would notify all 2,350 trading partners for each of the illegitimate products identified. However, comments received from a trade association indicated that they believed this number was too high based on past experience. FDA has reduced the number of trading partners that a wholesale distributor would notify to 50 percent resulting in the notification of 1,175 trading partners for each of the 160 notifications resulting in a total of 188,000 notifications to trading partners.

FDA estimates that a pharmacy purchases prescription drugs from an average of two wholesale distributors. Therefore, a pharmacy would notify 2 trading partners for each of the 40 illegitimate products identified, resulting in approximately 80 notifications annually to pharmacy trading partners.

Manufacturers/repackagers, wholesale distributors, and pharmacies may notify their trading partners using existing systems and processes used for similar types of communications, which might include, but is not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a letter or notification. The information contained in the notification to the immediate trading partner should be the same as or based on the notification that was already submitted to FDA. FDA estimates that for all trading partners, each notification of immediate trading partners will take approximately 0.2 hours. The estimated total burden hours of making notifications to trading partners is approximately 42,416 hours annually (table 2).

3. Consultation With FDA and Termination of Notification

Section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act require that a trading partner, who determines in consultation with FDA that a notification made under section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), or (e)(4)(B)(ii) is no longer necessary, must terminate the notification. The guidance sets forth the process by which trading partners must consult with FDA to terminate notifications that are no longer necessary.

FDA is making Form FDA 3911 available to trading partners on its Web page to request a termination of notification. Each request for termination of notification must include information about the person or entity initiating the request for termination, the illegitimate product or product with a high risk of illegitimacy, the notification that was issued, and an explanation about what actions have taken place or what information has become available that make the notification no longer necessary. Trading partners should also include the FDA-assigned incident number associated with the initial notification on the request for termination. The request for a termination will be viewed as a request for consultation with FDA. FDA estimates that the same amount of time will be required to provide the information necessary to request termination as is required to make the notification. The time required to investigate and resolve an illegitimate product notification will vary, but FDA assumes that each notification will eventually be terminated at some point. FDA assumes that the number of

requests for termination of a notification per year will be the same as the original number of notifications for a given year. The estimated total burden hours of making requests for termination of notifications to FDA is approximately 1,000 hours annually (table 3).

4. Notifications to Trading Partners That a Notification Has Been Terminated

Section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act require that a trading partner who, in consultation with FDA, terminates a notification made under section 582(b)(4)(B)(ii)(I) or (II), (c)(4)(B)(ii), (d)(4)(B)(ii), or (e)(4)(B)(ii) must also promptly inform previously-notified immediate trading partners that the notification has been terminated. FDA estimates that the burden for notifying trading partners of an illegitimate product and the number of trading partners notified will be the same as the estimates for notification of termination. The estimated total burden of notifying trading partners that the notification is terminated is approximately 42,416 hours annually (table 4).

The total burden of drug notifications for all stakeholders is 86,832 hours.

In the **Federal Register** of June 11, 2014 (79 FR 33564), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments on the draft guidance from 20 different organizations, companies, and individuals. The draft guidance provided scenarios that could increase the risk of a suspect product entering the supply chain and recommendations on how trading partners may identify products that may be suspect. The draft guidance also provided the process for notifying FDA and immediate trading partners when a trading partner has determined that a product is an illegitimate product or a manufacturer has determined that a product has a high risk of illegitimacy and the process for terminating those notifications in consultation with FDA. Many of the comments requested information about parts of the DSCSA that were not specifically covered by, nor intended to be covered by, the draft guidance, such as cleared product notifications, suspect product investigation, illegitimate product determinations, quarantine, and verifications, which FDA intends to address in other guidance or by other public means.

Several commenters raised issues pertaining to the information collection provisions in the draft guidance and Form FDA 3911. FDA has clarified the process for making notifications and requests for termination to FDA in the final guidance. FDA also clarified several fields on Form FDA 3911 and the instructions for using Form FDA 3911 in response to comments received to the draft guidance. The issues raised by the commenters are addressed further in this document.

Scope-Related Issues

Issue 1: Several comments were received requesting clarification about the scope of what is considered to be an illegitimate product or what constitutes a high risk of illegitimacy. For example, commenters requested clarification that a product may be determined to be illegitimate only as a result of fraud and not due solely to quality issues. Commenters also asked for a definition of high risk of illegitimacy.

FDA Response to Issue 1: The purpose of this guidance is to provide a process for trading partners to submit notifications to FDA and immediate trading partners after the determination of illegitimacy or high risk of illegitimacy has been made and to submit requests for consultation to FDA to terminate a notification. To determine the scope of illegitimate products, trading partners should refer to the definition of illegitimate product in section 581(8) of the FD&C Act (21 U.S.C. 360eee(8)), which does not exempt quality issues. The current guidance has been amended to add scenarios to help manufacturers determine if a product has a high risk of illegitimacy. Please refer to *Issue 14* for more information on ''high risk of illegitimacy.''

Issue 2: Is it necessary to send a notification to FDA when an illegitimate product or product with high risk of illegitimacy can be dispositioned or contained quickly?

FDA Response to Issue 2: Yes. Provisions of the DSCSA require trading partners to notify FDA when a determination has been made that a product is illegitimate, or for manufacturers, that a product has a high risk of illegitimacy. The amount of time it takes for a firm to control the product or manage the situation is not a factor in determining when a notification to FDA and other trading partners is required, *i.e.* not later than 24 hours after the determination is made that a product is illegitimate or has a high risk of illegitimacy.

Issue 3: Many commenters asked if FDA was going to make either Form FDA 3911 or information about the notifications public.

FDA Response to Issue 3: The notifications and requests for termination will be handled according to Agency regulations, the Freedom of Information Act, and other applicable disclosure law. In some cases, FDA may coordinate with the notifying person or entity and issue Agency public health alerts to protect the public health based on information received through drug notifications received under section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act.

Form FDA 3911 and Instruction-Related Issues

Several commenters requested clarification of the instructions for filling out existing fields on Form FDA 3911 or requested additional information be added to Form FDA 3911 including additional fields.

Issue 4: Commenters requested clarification about the fields on Form FDA 3911 to describe the product that is the subject of the notification. Specifically, commenters wanted clarification about the terms ''generic'' and ''trade'' names.

FDA Response to Issue 4: FDA has clarified the names of these fields on Form FDA 3911 and the associated instructions. The field called ''Generic Name'' was changed to ''Name of Product as it appears on the label''. The field called ''Trade Name (if applicable)'' was changed to ''Primary Ingredients'' and the instructions were amended to request that the notifying person or entity list the active pharmaceutical or biological ingredients, if known, and if the information is not already listed in the ''Name of Product as it appears on the label'' field. These changes will clarify how the notifying person or entity should describe the product that is the subject of the notification.

Issue 5: Several commenters wanted clarification about the fields on Form FDA 3911 for identification of company versus the reporter.

FDA Response to Issue 5: FDA modified Form FDA 3911 to make it clearer that we want information about the company who is responsible for making the notification. The ''reporter'' is the person whom the FDA may contact for additional information about the notification. FDA considers the company with the illegitimate product in its possession or control, or a manufacturer that has made a determination that a product has a high risk of illegitimacy, to be the company that is responsible for making and terminating the notification, even if that company contracts with another person or entity to submit the notification on its behalf.

Issue 6: Commenters asked about the term ''unique facility identifier'' since the D-U-N-S number is a corporate identifier not a facility identifier. The commenter requested that FDA clarify that it is asking for the unique ''Corporate'' and not ''Facility'' identifier.

FDA Response to Issue 6: FDA uses a site specific identifier called the unique facility identifier (UFI) as a useful resource in identifying and confirming certain business information for the company responsible for making the notification. FDA currently prefers the D-U-N-S number as the UFI. Since the commenters were confused about the term ''facility'', we clarified in the instructions to Form FDA 3911 that the UFI for the company making the notification is the number being requested.

Issue 7: Several commenters requested a notification reference number for identification purposes.

FDA Response to Issue 7: FDA agrees with the commenters and has added a field for an incident number. FDA plans to assign an incident number when the initial notification is received. FDA will send the incident number in the response that confirms the receipt of the initial notification to the notifying person or entity. This incident number should be used in all future correspondence about the specific incident/event that is the subject of the initial notification, including any request for termination. The form, instructions, and process in the guidance have been amended to include the incident number. There is no additional burden to the company making the notification to include this number on any additional correspondence with FDA including the request for termination.

Issue 8: Commenters requested the addition of an FDA contact be added to Form FDA 3911 for questions about the form.

FDA Response to Issue 8: FDA has added a contact telephone number in addition to the email address previously provided on the Drug Notification Web page referenced in the guidance.

Issue 9: Commenters requested a field to indicate that the company making the notification (wholesale distributor, repackager, or dispenser) has consulted with the manufacturer when determining whether a product is illegitimate.

FDA Response to Issue 9: The DSCSA, section 582(c)(4)(B), (d)(4)(B), and (e)(4)(B), requires that wholesale drug distributors, dispensers, and repackagers coordinate with the manufacturer when determining whether a product is illegitimate. Form FDA 3911 should be used to submit a notification after the determination that a product is illegitimate is made. A separate field was not designated for this topic because the company making the notification may identify the manufacturer they coordinated within the ''For Notification, Description of Event/Issue'' Field. This option has been added to the instructions.

Issue 10: Commenters requested a field on Form FDA 3911 to list all trading partners that they believe may possess the illegitimate product.

FDA Response to Issue 10: FDA did not add a specific field to Form FDA 3911 for companies to list the names of trading partners that may have illegitimate product. While not required, a company may identify all trading partners that they believe may possess the illegitimate product in the ''Description of Event/Issue'' Field. Under the DSCSA, trading partners are responsible for making notifications to all immediate trading partners that they have reason to believe may have received such product.

Issue 11: Commenters requested a space or field to list a case or report number associated with a Medwatch report or other report submitted to FDA.

FDA Response to Issue 11: FDA agrees with commenters that it may be useful to know the report or case number for other required or voluntary submissions made to FDA about the same issue. This information may be included in the ''For Notification: Description of Event/Issue'' or ''For Request for Termination of Notification: Description of Why Notification is No Longer Necessary'' fields. FDA amended the instructions on Form FDA 3911 for notifying parties to provide this information if known.

Issue 12: Commenters requested a check box to indicate that testing of the drug product was completed.

FDA Response to Issue 12: FDA did not add a check box to indicate if testing was completed. However, the company making the notification or request for termination should provide this type of information in the fields, ''For Notification, Description of Event/Issue'' or ''For Request for Termination of Notification: Description of Why Notification is No Longer Necessary.''

Issue 13: Commenters asked for clarification about the purpose of the ''drug use'' and ''drug description'' fields.

FDA Response to Issue 13: The DSCSA applies to prescription drugs for human use. Including these fields helps FDA confirm that the DSCSA requirement applies to the product(s) subject to the notification. The fields also provide flexibility for future use of this form in other contexts. FDA included an ''other'' option under the ''drug use'' field to choose if a drug has multiple approvals for use. An instruction to explain ''other'' when selected by a notifying person or entity was added. We have also included more choices under the ''drug description'' field to help FDA distinguish between products regulated by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.

High Risk of Illegitimacy-Related Issues

Issue 14: Several manufacturers requested clarification and specific information about how to document that a notification is for a product with ''a high risk of illegitimacy.'' Commenters also requested clarification on FDA's interpretation of ''high risk of illegitimacy.''

FDA Response to Issue 14: In the draft guidance, FDA did not distinguish between illegitimate product notifications and high risk of illegitimacy notifications because the timing and process for these submissions is the same. However, because we received several comments, FDA has revised the guidance to specify the process for notifications for products with a ''high risk of illegitimacy'' that are required by the DSCSA to be submitted by manufacturers. The guidance provides direction for manufacturers on how to submit notifications for products with a high risk of illegitimacy. It also clarifies when products may have a high risk of illegitimacy. These clarifications do not affect our expected numbers of notifications or terminations, since the PRA estimates in the draft guidance already included products with a high risk of illegitimacy. FDA also amended the instructions for Form FDA 3911 to indicate that manufacturers document a notification for product with a ''high risk of Illegitimacy'' in the ''For Notification, Description of Event/Issue'' field. FDA clarified the instructions for several other fields on Form FDA 3911 to indicate more clearly that they apply to both notifications for illegitimate products and for products with a high risk of illegitimacy.

Timing-Related Issues

Issue 15: Commenters asked for clarification regarding the requirement to submit a notification within 24 hours of making the determination that a product is illegitimate or has a high risk of illegitimacy.

FDA Response to Issue 15: The DSCSA specifies that notifications are to

be submitted no later than 24 hours after making the determination that a product in the possession or control of the trading partner is illegitimate. This same timeframe also applies to manufacturers notifying FDA and other trading partners when they determine that a product has a high risk of illegitimacy. This timeframe will help prevent or limit illegitimate product or product with a high risk of illegitimacy from entering or being further distributed in the U.S. supply chain.

Issue 16: Several commenters indicated that a 10-day timeframe for FDA to provide a consultation in response to a request for termination is too long and could result in drug shortages. Commenters stated that the process for requesting expedited consultation was unclear.

FDA Response to Issue 16: FDA will review and consult with notifying parties regarding requests for termination as soon as possible. The timing of FDA's review and consultation will depend on the number of requests and the circumstances surrounding the requests for termination that are received. Since notifications under the DSCSA are submitted to FDA when it has been determined by trading partners that a product is illegitimate or by manufacturers that a product has a high risk of illegitimacy, in many cases, these products would be counterfeit, intentionally adulterated, diverted, stolen, or otherwise unfit for further distribution and would likely not be further distributed. As FDA indicated in the draft guidance, FDA will consider requests for expedited review when included with a request for termination. We have clarified the process for requesting expedited review by adding an instruction to Form FDA 3911 directing the company that is requesting termination to also request and justify the need for expedited review when explaining why the notification is no longer necessary.

Duplication of Submission-Related Issues

Issue 17: Comments were received requesting an explanation of why the development of Form FDA 3911 was necessary instead of using the standard FAR for notifications under the DSCSA.

FDA Response to Issue 17: The FAR is a required postmarketing report made by an application holder (new drug or generic drug) when there is a problem, generally a quality problem, associated with a drug as outlined in § 314.81(b)(1). FDA developed Form FDA 3911 because the FAR form was inadequate for making notifications required under the DSCSA for a product that is illegitimate or has a high risk of illegitimacy for a reason not necessarily related to product quality or otherwise described in § 314.81(b)(1) (*e.g.,* diverted, stolen, etc.). In addition, only applicant holders are required to submit the FAR to FDA. Illegitimate product notifications are required to be sent to FDA by manufacturers, repackagers, distributors, and dispensers. Notifications of products with a high risk of illegitimacy are also required to be submitted by manufacturers. It is not known how frequently the same incident will generate submission of a FAR and Form FDA 3911 notifications. FDA is collecting information on FDA Form 3911 that will enable us to quantify duplication of submissions.

Issue 18: Commenters requested clarification about whether every trading partner should submit a separate notification to FDA about the same illegitimate product.

FDA Response to Issue 18: The DSCSA (section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii)) requires that certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) with illegitimate product in their possession or control submit a notification. Trading partners should submit notifications as required by the relevant statutory provisions.

Issue 19: Commenters requested clarification about whether they are required to submit a notification to FDA if they are notified of a suspect or illegitimate product by FDA and determine that they have it in their possession or control.

FDA Response to Issue 19: The DSCSA (section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii)) requires certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) to submit an illegitimate product notification to FDA if a trading partner determines that it has illegitimate product in its possession or control.

Notifying Trading Partners-Related Issues

Issue 20: Several comments asked for clarification about the process for notifying trading partners of an illegitimate product. Commenters stated that FDA should clarify that existing systems and processes can be used to make notifications to trading partners as well as informing them of terminations of such notifications.

FDA Response to Issue 20: In the draft guidance, FDA specified that existing processes and systems can be used to inform trading partners that a notification has been terminated. FDA agrees with the comments received and has added to the final guidance that trading partners can use existing systems and processes to provide notification to trading partners that they believe may have received the illegitimate product or a product with high risk of illegitimacy.

Issue 21: A commenter requested that FDA develop a system that would allow for notification of FDA and other trading partners at the same time.

FDA Response to Issue 21: Manufacturers, repackagers, wholesale distributors, and dispensers with illegitimate product or manufacturers that determine that a product has a high risk of illegitimacy are responsible for notifying their trading partners in addition to FDA. FDA developed a process for trading partners to use to notify FDA using Form FDA 3911. As clarified in the guidance and *Issue 20,* the notifying person or entity can use its existing systems and processes to provide the necessary notification to trading partners. If preferred, the notifying person or entity may provide a copy of Form FDA 3911 to other trading partners in addition to FDA to meet that requirement.

Issue 22: A commenter asked for clarification if dispensers' immediate trading partners include other pharmacies in the same group of chain pharmacies as well as the wholesale distributor or manufacturer from whom the dispenser purchased drug.

FDA Response to Issue 22: The intent of the notification provisions in the DSCSA is to prevent illegitimate product entering or being further distributed into the supply chain to protect public health. FDA expects that a dispenser that has illegitimate product in its possession or control would let the other trading partners know about such illegitimate product if the dispenser has reason to believe that they might have possession or control of the same product. This analysis will be situation-specific. FDA refers the commenter to the definition of ''trading partner'' in section 581(23) of the FD&C Act and the definition of ''dispenser'' in section 581(3) of the FD&C Act.

Termination Process-Related Issues

Issue 23: One commenter stated that FDA should publish guidance on criteria to terminate a notification so that the FDA does not have to play ''gatekeeper'' for the termination of a notification.

FDA Response to Issue 23: The DSCSA (section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of FD&C Act) requires that a notification be terminated in

consultation with FDA. This guidance addresses the process by which trading partners should use Form FDA 3911 to make requests for termination, and the form will serve as a request to consult with FDA.

Issue 24: Comments were received asking for clarification about which entities could request to terminate a notification. Several commenters thought that FDA should be able to self-initiate a termination. Other commenters suggested that the request for termination could be made by any involved trading partner and not limited to the trading partner making the initial notification.

FDA Response to Issue 24: FDA believes that the trading partner making the notification should be responsible for making the request for termination because it knows if the illegitimate product in its possession or control has been satisfactorily dispositioned and if the notification is no longer necessary. The process in the guidance has been amended to clarify this point. The guidance does not specify a process for trading partners to terminate notifications submitted by other trading partners.

PRA Analysis Related Issues

Issue 25: One commenter stated that the estimates in the PRA analysis did not take into account the time it takes to investigate and make the determination that a product is illegitimate. It only included the time to fill out the form and notify trading partners.

FDA Response to Issue 25: While the commenter's assessment is correct, the PRA analysis in this guidance was calculated for the process for making and terminating notifications to FDA and notifying immediate trading partners who are believed to have the drug. This guidance assumes that the determination has already been made that the drug is illegitimate or has a high risk of illegitimacy. FDA intends to publish additional guidance that will address the investigation of suspect product to determine whether the product is illegitimate. The PRA analysis for those activities will be covered at that time.

Issue 26: One commenter stated that, based on its experience, FDA estimates for notifications are high.

FDA Response to Issue 26: FDA reexamined the estimate of notifications in response to this comment. FDA originally estimated that a total of approximately 5,000 notifications per year would be made by all manufacturers, repackagers, wholesale distributors, and dispensers based on FDA's experience with FARs (Form FDA 3331) required to be submitted by holders of approved drug applications for certain issues specified by § 314.81(b)(1), and with reports of the falsification of drug sample records, diversion, loss, and known theft of prescription drug samples as currently required under § 203.37. We determined that the 5,000 FARs and 5,000 sample reporting under § 203.37 received each year included initial, followup, and final reports. While FDA does not know the exact number of notifications that will be submitted, we lowered the estimate to 1,000 notifications in response to the comment and our reexamination of the data and adjusted the PRA analysis accordingly.

Issue 27: Commenters stated that the FDA estimated number of trading partners that would likely have the illegitimate product and have to be notified was high.

FDA Response to Issue 27: FDA recognizes that not every trading partner will possess illegitimate product. However, until serialization is required and implemented, the initial notifying person or entity may not be able to identify which specific immediate trading partners may possess or control illegitimate product. FDA assumed that the initial notifying person or entity would notify all trading partners and we have chosen not to amend the number of trading partners that are notified at this time.

Issue 28: A major stakeholder association stated that it did not believe, based on past experience, that wholesale distributors would be making as many notifications as FDA estimated both to FDA and to trading partners.

FDA Response to Issue 28: In the original estimates, FDA assumed that most notifications will be made by three trading partners, manufacturers, repackagers, and wholesale distributors. FDA reexamined the proportion of notification expected from each of the regulated groups. The commenter had speculated that it believed that manufacturers would be making most notifications. In addition, manufacturers are required to submit notifications of high risk of illegitimacy. In response to the comment and the fact that only manufacturers submit notifications of high risk of illegitimacy, FDA is changing the proportion of notifications that will be made by manufacturers and repackagers from 50 percent to 80 percent (800), from 45 percent to 16 percent by wholesale distributors (160), and 5 percent to 4 percent by pharmacies (40). FDA had also originally assumed that wholesale distributors would have to notify an average of 2,350 trading partners for each notification. We agree with the commenters that this was an overestimation and have lowered the number of trading partners to be notified by wholesale distributors to 1,175 (50 percent) for each notification.

Description of Respondents: Respondents are drug manufacturers, repackagers, wholesale distributors, and dispensers and might include small businesses in these categories.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Notifications to FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	800	1	800	1	800
Wholesale Distributors	160	1	160	1	160
Dispensers	40	1	40	1	40
Total					1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Notifications to trading partners of an illegitimate product	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	800	30	24,000	0.20 (12 minutes)	4800
Wholesale Distributors	160	1,175	188,000	0.20 (12 minutes)	37,600
Dispensers	40	2	80	0.20 (12 minutes)	16
Total	.....	.....	.....	.....	42,416

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Consultation with FDA and termination of notification	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	800	1	800	1	800
Wholesale Distributors	160	1	160	1	160
Dispensers	40	1	40	1	40
Total	.....	.....	.....	.....	1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Notifications to trading partners of an illegitimate product termination	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	800	30	24,000	0.20 (12 minutes)	4800
Wholesale Distributors	160	1,175	188,000	0.20 (12 minutes)	37,600
Dispensers	40	2	80	0.20 (12 minutes)	16
Total	.....	.....	.....	.....	42,416

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23203 Filed 9–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 15, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 594–4306.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Childhood Home Visiting (Home Visiting) Program Fiscal Year (FY) 2015, FY2016, FY2017 Non-Competing Continuation Progress Report for Formula Grant OMB No. 0915–0355—Extension.

A 30-day notice was previously published on July 8, 2015, for this information collection request but it contained incorrect burden figures.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) Program, administered by the Health Resources and Services Administration (HRSA) in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. The purpose of this formula grant program is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices. All fifty states, the District of Columbia, and five territories and nonprofit organizations that would provide services in jurisdictions that have not directly applied for or been approved for a grant are eligible for formula grants and submit non-competing continuation progress reports annually. There are 56 jurisdictions eligible for formula awards and 56 formula awards are issued annually.

Need and Proposed Use of the Information: This information collection

is needed for eligible entities to report progress under the Home Visiting Program annually. On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA), Section 2951 of the ACA amending Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Home Visiting Program (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf,* pages 216–225). A portion of funding under this program is awarded to participating states and eligible jurisdictions by formula. The purpose of formula funding is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices.

The information collected will be used to review grantee progress on proposed project plans sufficient to permit project officers to assess whether the project is performing adequately to achieve the goals and objectives that were previously approved. This report will also provide implementation plans for the upcoming year, which project officers can assess to determine whether the plan is consistent with the grant as approved, and will result in implementation of a high-quality project that will complement the home visiting program as a whole. Progress Reports are submitted to project officers through the Electronic HandBooks (EHB). Failure to collect this information would result in the inability of the project officers to exercise due diligence in monitoring and overseeing the use of grant funds in keeping with legislative, policy, and programmatic requirements. Grantees are required to provide a performance narrative with the following sections: Project identifier information, accomplishments and barriers, home visiting program goals and objectives, update on the home visiting program promising approach, implementation of the home visiting program in targeted at-risk communities, progress toward meeting legislatively-mandated reporting on benchmark areas, home visiting quality improvement efforts, and updates on the administration of the home visiting program.

In the event a new Funding Opportunity Announcement is issued annually for the formula grant program, the application for new grant funds may take the place of completion of a non-competing continuation progress report.

Likely Respondents: Grantees with Home Visiting Formula Awards Awarded in Federal FYs 2013–2017.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden—Hours: The burden estimates presented in the table below are based on consultations with a few states on the guidance. Grantees receive a new formula grant annually and are expected to report on progress annually, so the expectation is that grantees would submit non-competing continuation progress reports four times between Federal Fiscal Years 2015 and 2018. Only seven grantees are currently implementing a promising approach and require an annual update on the promising approach.

Form name	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total burden hours
Formula Grant Award	56	1	56	42	2,352
Total	56	1	56	42	2,352

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–23097 Filed 9–14–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Planning Grants

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of class deviation from competition requirement for one-time extension for the State Planning Grants for Improving Services for Children and Youth with Autism Spectrum Disorder (ASD) and Other Developmental Disabilities (DD) Grant Program.

SUMMARY: HRSA announces the award of a one-time extension in the amount of $54,244 each to four State Planning Grants for Improving Services for Children and Youth with Autism Spectrum Disorder (ASD) and Other Developmental Disabilities (DD) grants. The purpose of the program is to support states in the planning and development of activities that are designed to improve state systems of care for children and youth with ASD and related DDs and increase access to comprehensive coordinated health care. Grantees develop comprehensive, measurable state plans in collaboration with a diverse group of stakeholders that outline an approach to improve access to comprehensive, coordinated health care and related services for children and youth with ASD and other DDs. The purpose of this notice is to award a one-time, 12-month extension to ensure the completion of activities and an orderly phase out of HRSA support.

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Awards: University of Arkansas System, University of Massachusetts, New Hampshire Department of Health and Human Services, and the University of Texas Health Science Center at Houston.

Amount of Each Non-Competitive Award: $54,244.

Period of Low-Cost Extension Funding: 9/1/2015–8/31/2016.

CFDA Number: 93.110.

Authority: Public Health Service Act, § 399BB (42 U.S.C. 280i–1) and the Combating Autism Act of 2006 (Pub. L. 109–416), as amended by the Combating Autism Reauthorization Act of 2011 (Pub. L. 112–32) and the Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2014 (H.R. 4631; Pub. L. 113–157).

Justification: The State Planning Grants for Improving Services for Children and Youth with Autism Spectrum Disorder (ASD) and Other Developmental Disabilities (DDs) grant program (hereafter referred to as State Planning Grants) is authorized by the Public Health Service Act, § 399BB (42 U.S.C. 280i–1) and the Combating Autism Act of 2006 (Pub. L. 109–416), as amended by the Combating Autism Reauthorization Act of 2011 (Pub. L. 112–32) and the Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2014 (*H.R. 4631; Pub. L. 113–157*). The purpose of the program is to support states in the planning and development of activities that are designed to improve state systems of care for children and youth with ASD and related DDs and increase access to comprehensive coordinated health care. Grantees develop comprehensive, measurable state plans in collaboration with a diverse group of stakeholders that outline an approach to improve access to comprehensive, coordinated health care and related services for children and youth with ASD and other DDs.

State Planning Grants support state efforts to improve infrastructure that results in community and state systems that are integrated across service sectors and are collectively responsible for achieving appropriate individual, family, and community outcomes. To ensure that the capacity and infrastructure continue in these important areas, the Maternal and Child Health Bureau is requesting a one-time extension for completion of activities and an orderly phase-out of HRSA support. The additional funds and time will allow the grantees to complete their planning and strengthen their partnerships with the stakeholders who will be critical in implementing a comprehensive, coordinated system of health care for children and youth with ASD and DD. The current State Planning Grant awardees continue to achieve the original goals required by HRSA; however, the additional funding and time will allow awardees to complete their project activities. The impact of not granting this one-time extension would be to interrupt the activities of the State Planning Grant awardees and not allow them to complete their state planning.

FOR FURTHER INFORMATION CONTACT: CDR Deidre Washington-Jones, MPH, CHES, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 13–103, Rockville, Maryland 20857; *dwashington-jones@hrsa.gov.*

Grantee/organization name	Grant No.	State	Current project end date	Revised project end date	FY 2014 Authorized funding level	FY 2015 Estimated funding level
UNIVERSITY OF ARKANSAS SYSTEM	H6MMC26243	AR	8/31/2015	8/31/2016	$75,000	$54,244
UNIVERSITY OF MASSACHUSETTS	H6MMC26244	MA	8/31/2015	8/31/2016	75,000	54,244
HEALTH AND HUMAN SERVICES, NEW HAMPSHIRE DEPT OF.	H6MMC26245	NH	8/31/2015	8/31/2016	75,000	54,244
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON.	H6MMC26246	TX	5/31/2016	8/31/2016	75,000	54,244

Dated: September 4, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015–23125 Filed 9–14–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, October 01, 2015, 03:00 p.m. to October 01, 2015, 03:30 p.m., Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on September 09, 2015, 80 FR 54302.

The meeting notice is amended to change the meeting title to National Institute on Aging Special Emphasis Panel—MIND Diet. The meeting is closed to the public.

Dated: September 10, 2015.

Melanie J. Gray-Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–23112 Filed 9–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for the NIEHS Climate Change and Environmental Exposures Challenge

Authority: 15 U.S.C. 3719.

SUMMARY: To assist the country in preparing for the potential health risks from climate change, the National Institutes of Health (NIH) through the National Institute on Environmental Health Sciences (NIEHS) is sponsoring the NIEHS *Climate Change and Environmental Exposures Challenge* (the ''Challenge'') under the America COMPETES Reauthorization Act of 2010. This Challenge calls on talented software developers, data scientists, and other innovators from around the country to create data visualizations, tools, and applications that use the best available science on environmental exposures and the relationship of these exposures to increased temperature, precipitation, flooding, and sea level rise. The Challenge has two goals: To raise awareness of how environmental health risks may be exacerbated by climate change in communities, and to enable protective decision-making from local to national levels.

DATES: The Challenge begins September 15, 2015.

(1) Submission period begins 9 a.m. EDT September 28, 2015.

(2) Submission period ends 12 p.m. EDT December 4, 2015.

(3) Judging Period: December 7, 2015 to January 6, 2016.

(4) Winners Announced: January 12, 2016.

ADDRESSES: To register for this Challenge, participants can access either the *http://www.challenge.gov* Web site (search for the Challenge's title) or the Climate and Health Innovation Challenge Series Web site at *http://www.challenge.gov/agency/health-and-human-services/climate-and-health-innovation-challenge-series/*.

FOR FURTHER INFORMATION CONTACT: John Balbus, M.D., M.P.H., Senior Advisor for Public Health, National Institute of Environmental Health Sciences, Phone 301.496.3511. [*john.balbus@nih.gov*]

SUPPLEMENTARY INFORMATION:

Communities currently face risks from hazardous wastes and deposits of industrial chemicals, air pollution, harmful algal blooms and toxic contaminants in food, and exposures to pesticides. While the impacts of climate change on many of these environmental health risks are not well understood or addressed at present, newly released data and tools, in combination with other publicly available datasets, allow for innovative approaches to identifying, demonstrating and assessing those risks. Protective decisions at the local level may include siting of schools, day care centers, new housing, or critical infrastructure such as new water intakes for drinking water systems; design or siting of urban waste water drainage or green infrastructure; placement of monitoring equipment or other sensors; or other permits or regulations. Nationally, protective decisions about prioritizing remediation efforts or other interventions, or setting national standards or policies may be informed by greater understanding of the influence of climate change on the magnitude and spatial distribution of potential environmental exposures.

Statutory Authority: Pursuant to Section 402 of the Public Health Service Act, 42 U.S.C. 285, the general purpose of the National Institute of Environmental Health Sciences (NIEHS) is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly. Supported by the NIEHS, the Challenge furthers the Institute's statutory authority by advancing research to understand the potential health risks from climate change. This Challenge aligns with both the mission of NIEHS to ''discover how the environment affects people in order to promote more healthier lives'' as well as elements of the Institute's 2012–2017 Strategic plan, including:

Goal 5: Identify and respond to emerging environmental threats to human health, on both a local and global scale (*https://www.niehs.nih.gov/about/strategicplan/*).

Subject of the Challenge: The Challenge calls on talented software developers, data and exposure scientists, public health students and professionals, and other innovators to produce a data visualization or visualization tool or application (each a ''submission'') to help convey potential risks of environmental exposures in the United States that may be exacerbated by climate change. Submissions may be produced using existing tools and platforms or created with newly developed applications. The geographic scale can be as small as the neighborhood or community level or as large as the regional or national level. Prizes will be made available in two categories according to the scale of the submission; one for state level or smaller, one for multi-state or national.

Submissions should help identify potential areas or zones of increased exposure and/or the degree of changes in exposure or health risk resulting from climate change. Participants may consider a short-term time scale (*e.g.,* 0 to 20 years) for impacts associated with extreme events, or a longer time scale (*e.g.,* 2050 or beyond) for impacts associated with sea level rise or other phenomena whose greatest impact will clearly be decades from now. These exposures may include:

(1) Toxic chemicals released from hazardous waste, mining or other industrial sites by rising sea level, increased temperatures and permafrost melting, changes in wind patterns, or other climate-related ecological processes;

(2) air pollutants, including ozone and particulate matter, that may increase or decrease in concentration in certain regions because of increased temperatures and changing weather patterns;

(3) toxins created by molds or waterborne bacteria or algae;

(4) pesticides, whose usage or dispersion patterns may be influenced by changes in climate.

Participants in the Challenge may also propose environmental exposures not listed here. If a participant wishes to explore a different environmental exposure, the submission should include a statement explaining the importance of the exposure to human health and the relationship between climate change and changes in that exposure in the future.

This Challenge is most interested in submissions that show the interaction between these three data layers:

(1) Locations and concentrations of harmful agents (*i.e.,* exposures);

(2) locations of potentially exposed populations; and

(3) geographic and climatologic parameters conveying changing risks of exposure.

At a minimum, all submissions should include a data layer related to location of potential harmful agents and a data layer related to changes in levels of exposure to those potential agents cause by factors related to climate change.

Potentially useful datasets can be found at *climate.data.gov* and on the Climate and Health Innovation Challenge Series Web site (*http://www.challenge.gov/agency/health-and-human-services/climate-and-health-innovation-challenge-series/*). Participants are also encouraged to seek out additional scientifically valid datasets for their submissions.

Participants in the Challenge should specify the target audience for their submission. Potential target audiences include local public health and environmental officials, clinical health professionals, urban planners, emergency preparedness and response officials, and the general public.

Rules for Participating in the Challenge

(1) To be eligible to win a prize under this Challenge, an individual or entity—

a. Shall have registered to participate in the Challenge under the rules promulgated by the NIEHS as published in this Notice;

b. Shall have complied with all the requirements set forth in this Notice;

c. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States 18 years of age or older;

d. May not be a Federal entity;

e. May not be a Federal employee acting within the scope of the employee's employment and further, in the case of HHS employees, may not work on their submission(s) during assigned duty hours;

f. May not be an employee of the NIH, a judge of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (*i.e.,* spouse, parent, step-parent, child, or step-child).

(2) Federal grantees may not use Federal grant funds to develop their Challenge submissions unless use of such funds is consistent with the purpose of their grant award and specifically requested to do so due to the Challenge design, and as announced in the **Federal Register**.

(3) Federal contractors may not use Federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.

(4) Submissions must not infringe upon any copyright or any other rights of any third party.

(5) By participating in this Challenge, each individual (whether competing singly or in a group) and entity agrees to assume any and all risks and waive claims against the Federal government and its related entities (as defined in the America COMPETES Act), except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

(6) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no individual (whether competing singly or in a group) or entity participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

(7) By participating in this Challenge, each individual (whether competing singly or in a group) and entity agrees to indemnify the Federal government against third party claims for damages arising from or related to Challenge activities.

(8) An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during the Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

(9) By participating in this Challenge, each individual (whether participating singly or in a group) and entity grants to the NIH an irrevocable, paid-up, royalty-free nonexclusive worldwide license to post, link to, share, and display publicly on the Web the submission. Each participant will retain all other intellectual property rights in their submissions, as applicable.

(10) NIH reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, and/or (b) not award any prizes if no submissions are deemed worthy.

(11) Each individual (whether participating singly or in a group) or entity agrees to follow all applicable federal, state, and local laws, regulations, and policies.

(12) Each individual (whether participating singly or in a group) and entity participating in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

Registration Process for Participants: To register for this Challenge, participants can access either the *http://www.challenge.gov* Web site (search for the Challenge's title) or the Climate and Health Innovation Challenge Series Web site at *http://www.challenge.gov/agency/health-and-human-services/climate-and-health-innovation-challenge-series/*

Amount of the Prize: There will be two prize categories, one for data visualizations, tools or applications at the regional (multi-state) or national level, and one for data visualizations, tools or applications at the local or municipal level, with a grand prize, second prize, and third prize available for each category. Each category may award up to $17,500 in prizes (total prize amount available is $35,000) to the best overall projects in that category, based on the established judging criteria. For each category:

Grand Prize—$10,000
Second Prize—$5,000
Third Prize—$2,500

The Award Approving Official will be Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S, Director, National Institute of Environmental Health Sciences.

Payment of the Prizes: Prizes awarded under this Challenge will be paid by NIEHS by electronic funds transfer and may be subject to Federal income taxes. HHS/NIH/NIEHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis upon Which Winners Will Be Selected: The judges will evaluate submissions based upon the following criteria: scientific validity, innovative use of data and visualization tools or applications, and clarity of presentation. In order for submissions to be evaluated, they must include clear, detailed processes on how they were produced, including any code if applicable. The processes can be submitted in a text document. More details on the specific judging criteria and the judging panel can be found on the Challenge Web site.

- 34% Scientific validity—associations between exposures and climate change phenomena must be scientifically credible.
- 33% Innovative use of data and visualization tools or applications—creative selection of datasets and ways to display data overlays; inclusion of new ideas and types of data.
- 33% Clarity—depiction of vulnerability and risk easily understood to a general public audience.

In order for a submission to be eligible to win this Challenge, it must meet the following requirements:

1. *Submission:* The following items constitute a complete submission for this Challenge: A short (less than 250 words) description of the visualization and its value in improving our understanding of the relationship between environmental exposures and climate change; a detailed description of the visualization, tool, or application, including the technical basis for combining data layers and references to the scientific literature supporting the relationships between climate change, altered exposures, and human health outcomes where relevant (limited to 1000 words, not including figures or references); the visualization tool and any application or code needed to run the tool; instructions on how to install and operate any application behind a visualization tool; system requirements required to run the application; and a description of, rationale for selecting, and complete copy of the data set. For data sets contained within *climate.data.gov* or otherwise easily obtainable from federal sources, the URLs for the datasets are sufficient. Alternatively, instead of providing the tool or application itself, participants may provide either a link to a visualization generated by the tool or application; a video demonstrating the tool or application; or one or more pdfs of example visualizations.

2. Participants must provide continuous access to any submissions that include web postings through the Challenge period until January 12, 2016.

3. Challenge submissions must be submitted via the Challenge's homepage on challenge.gov.

4. Submissions must be in English.

5. The tool or application must not use HHS's or NIH's logos or official seals in the submission, and must not claim or imply endorsement by the Federal government.

6. The data visualization tool or application must be designed for use with existing web, mobile, voice, or other platform for supporting interactions of the content provided with other capabilities.

7. A submission may be disqualified if the visualization tool or application fails to function as expressed in the description provided by the participant, or if the tool or application provides inaccurate or incomplete information.

8. Submissions must be free of malware. Participant agrees that NIH may conduct testing on the visualization tool or application to determine whether malware or other security threats may be present. NIEHS may disqualify the submission if, in NIEHS' judgment, the visualization tool or application or any other part of the submission may damage government or others' equipment or operating environment.

Additional Information: To help the public understand the health implications of climate change and improve the nation's ability to be resilient to negative impacts, HHS has organized the *Climate and Health Innovation Challenge Series*. This Challenge Series spotlights the over 150 climate and health data sets that have become available via the Climate Data Initiative, while also identifying and promoting additional relevant data sets. The Challenge Series will include challenges aimed at one or more of the following goals:

1. Create appealing applications that empower the public to take action by providing information about climate change's impacts on health or about the potential health benefits of personal actions to reduce greenhouse gas emissions.

2. Create climate change and health decision support tools for health professionals and, potentially, other professionals (*e.g.* urban planners).

3. Empower the academic and technology communities to analyze data in innovative ways, moving research forward in key areas (products may range from data visualizations to useful indices/metrics to adopt).

4. Challenge the private sector to combine government data with their own data to develop innovative decision support tools or address research questions.

Dated: September 4, 2015.

Linda S. Birnbaum,

Director, National Institute of Environmental Health Sciences.

[FR Doc. 2015–23126 Filed 9–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, October 01, 2015, 03:30 p.m. to October 01, 2015, 04:00 p.m., Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on September 09, 2015, 80 FR 54302.

The meeting notice is amended to change the meeting title to National Institute on Aging Special Emphasis Panel—Agitation in Alzheimer's. The meeting is closed to the public.

Dated: September 10, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–23113 Filed 9–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Advisory Committee to the Director, National Institutes of Health, September 17, 2015, 3:00 p.m. to 5:00 p.m., that was published in the **Federal Register** on Monday, August 20, 2015, 80 FR 50642.

The time of the meeting is changed from 3:00 p.m. to 5:00 p.m. to 1:00 to 3:00 p.m. The agenda will also include an update from the HeLa Working Group.

This meeting is open to the public but is being held by teleconference only. No physical meeting location is provided for any interested individuals to listen to committee discussions. Any individual interested in listening to the meeting discussions must call: 877–917–9486 and use Passcode: 8027865, for access to the meeting.

Dated: September 9, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–23084 Filed 9–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2015–0043]

Meeting: Homeland Security Advisory Council

AGENCY: The Office of Intergovernmental Affairs, DHS.

ACTION: Notice of partially closed Federal Advisory Committee meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will meet in person on September 29, 2015. Members of the public may participate in person. The meeting will be partially closed to the public.

DATES: The HSAC will meet Tuesday, September 29, 2015 from 10:05 a.m. to 5:00 p.m. EDT. The meeting will be open to the public from 11:15 a.m. to 2:05 p.m. EDT and 4:00 p.m. to 5:00 p.m. Please note the meeting may close early if the Council has completed its business. The meeting will be closed to the public from 10:05 a.m. to 11:05 a.m. EDT and 2:15 p.m. to 3:55 p.m. EDT.

ADDRESSES: The meeting will be held at the Woodrow Wilson International Center for Scholars (''Wilson Center''), located at 1300 Pennsylvania Avenue NW., Washington, DC 20004. All visitors will be processed through the lobby of the Wilson Center. Written public comments prior to the meeting must be received by 5:00 p.m. EDT on September 23, 2015, and must by identified by Docket No. DHS–2015–0043. Written public comments after the meeting must be identified by Docket No. DHS–2015–0043 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: HSAC@hq.dhs.gov.* Include Docket No. DHS–2015–0043 in the subject line of the message.
- *Fax:* (202) 282–9207.
- *Mail:* Homeland Security Advisory Council, Department of Homeland Security, Mailstop 0445, 245 Murray Lane SW., Washington, DC 20528.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and ''DHS–2015–0043,'' the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read comments received by the DHS Homeland Security Advisory Council, go to *http://www.regulations.gov,* search ''DHS–2015–0043,'' ''Open Docket Folder'' and provide your comments.

FOR FURTHER INFORMATION CONTACT: Mike Miron at *HSAC@hq.dhs.gov* or at (202) 447–3135.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under Section 10(a) of the Federal Advisory Committee Act (FACA), Public Law 92–463 (5 U.S.C. Appendix) requires each FACA committee meeting to be open to the public.

The HSAC provides organizationally independent, strategic, timely, specific, and actionable advice and

recommendations for the consideration of the Secretary of the Department of Homeland Security (DHS) on matters related to homeland security. The Council is comprised of leaders of local law enforcement, first responders, state and local government, the private sector, and academia.

The HSAC will meet in an open session between 11:15 a.m. and 2:05 p.m. EDT and from 4:00 p.m. to 5:00 p.m. EDT. The HSAC will receive observations and remarks from DHS senior leadership. Members will receive verbal progress reports from the subcommittees and Departmental leadership on: The DHS Grant Review Task Force, the CBP Integrity Advisory Panel, the DHS Employee Task Force, the Foreign Fighter Task Force, and the Cybersecurity Subcommittee.

The HSAC will meet in a closed session from 10:05 a.m. to 11:05 a.m. and 2:15 p.m. to 3:55 p.m. EDT to receive sensitive operational information from senior DHS leadership. This information regards threats to our homeland, specifically operational updates to the National Terrorism Advisory System, cybersecurity, aviation, and the current threat environment.

Basis for Partial Closure: In accordance with Section 10(d) of the Federal Advisory Committee Act (FACA), this meeting has been determined to require partial-closure. The disclosure of the information relayed would be detrimental to the public interest for the following reasons:

The HSAC will receive closed session briefings from DHS officials on operational updates to the National Terrorism Advisory System, aviation security, cybersecurity, and the current threat environment. These briefings will concern matters sensitive to homeland security within the meaning of 5 U.S.C. 552b(c)(7)(E)and 552b(c)(9)(B), disclosure of these techniques and procedures could frustrate the successful implementation of protective measures designed to keep our country safe. In addition, 5 U.S.C. 552b(c)(7)(E), disclosure of that information could reveal investigative techniques and procedures not generally available to the public, allowing terrorist and those with interests against the United States to circumvent the law.

Participation: Members of the public will have until 5 p.m. EDT on Wednesday, September 23, 2015 to register to attend the HSAC meeting on September 29, 2015. Due to limited availability of seating, admittance will be on a first-come first-served basis. Participants interested in attending the meeting can contact Mike Miron at *HSAC@hq.dhs.gov* or via phone (202) 447–3135. Please indicate which public session you would like to attend: first session (11:15 a.m. to 2:05 p.m. EDT) or second session (4:00 p.m. to 5:00 p.m. EDT) or both sessions. You are required to provide your full legal name, date of birth, and company/agency affiliation. The public may access the facility via public transportation or use the public parking garages located near the Wilson Center. Wilson Center directions can be found at: *http://wilsoncenter.org/directions*. Members of the public will meet at 10:45 a.m. EDT at the Wilson Center's main entrance for sign in and escorting to the public meeting room for the first public session. Late arrivals after 11:30 a.m. EDT will not be permitted access to the facility. Members of the public will meet at 3:45 p.m. EDT at the Wilson Center's main entrance for sign in and escorting to the public meeting room for the second public session. Late arrivals after 4:15 p.m. EDT will not be permitted access to the facility.

Facility Access: You are required to present a valid original government issued ID; State Driver's License or Non-Driver's Identification Card, U.S. Government Common Access Card (CAC), Military Identification Card or Person Identification Verification Card; U.S. Passport, U.S. Border Crossing Card, Permanent Resident Card or Alien Registration Card; or Native American Tribal Document.

Information of Services for Individuals with Disabilities: For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact Mike Miron at *HSAC@hq.dhs.gov* or at (202) 447–3135 as soon as possible.

Dated: September 9, 2015.

Sarah E. Morgenthau,

Executive Director, Homeland Security Advisory Council, DHS.

[FR Doc. 2015–23116 Filed 9–14–15; 8:45 am]

BILLING CODE 9110–9M–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCA942000 L57000000.BX0000 13X L5017AR]

Filing of Plats of Survey: California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of lands described below are scheduled to be officially filed in the Bureau of Land Management, California State Office, Sacramento, California.

DATES: October 15, 2015.

ADDRESSES: A copy of the plats may be obtained from the California State Office, Bureau of Land Management, 2800 Cottage Way, Sacramento, California 95825, upon required payment.

FOR FURTHER INFORMATION CONTACT: Chief, Branch of Geographic Services, Bureau of Land Management, California State Office, 2800 Cottage Way W–1623, Sacramento, California 95825, 1–916–978–4310. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: A person or party who wishes to protest a survey must file a notice that they wish to protest with the Chief, Branch of Geographic Services. A statement of reasons for a protest may be filed with the notice of protest and must be filed with the Chief, Branch of Geographic Services within thirty days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Mount Diablo Meridian, California

T. 36 N., R. 14 E., dependent resurvey and subdivision of sections, accepted August 5, 2015.

T. 36 N., R. 13 E., dependent resurvey and subdivision of sections, accepted August 11, 2015.

T. 11 N., R. 11 E., supplemental plat of section 25, accepted August 13, 2015.

T. 17 N., R. 6 W., dependent resurvey and metes-and-bounds survey, accepted August 24, 2015.

San Bernardino Meridian, California

T. 11 S., R. 1 E., dependent resurvey, mineral

survey and subdivision of sections, accepted August 5, 2015.
T. 15 S., R. 3 E., dependent resurvey and metes-and-bounds survey, accepted August 5, 2015.
T. 10 S., R. 14 E., supplemental plat of the SW 1/4 of the SW 1/4 of section 4, accepted August 20, 2015.
T. 10 S., R. 14 E., supplemental plat of the SE 1/4 of section 15 and the NW 1/4 of the NW 1/4 of section 23, accepted August 20, 2015.

Authority: 43 U.S.C., Chapter 3.

Dated: August 28, 2015.

Lance J. Bishop,

Chief Cadastral Surveyor, California.

[FR Doc. 2015–23134 Filed 9–14–15; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWR–PWRO–18359;PX.P0206452B.00.1]

Record of Decision for Wilderness Stewardship Plan, Sequoia and Kings Canyon National Parks, Fresno and Tulare Counties, California

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability.

SUMMARY: The National Park Service (NPS) has prepared and approved a Record of Decision for the Final Environmental Impact Statement (EIS) and Wilderness Stewardship Plan (WSP) for Sequoia and Kings Canyon National Parks. Approval of the WSP culminates an extensive public engagement and environmental impact analysis effort that began in 2009. The legally required thirty-day no-action ''wait period'' was initiated on April 3, 2015, with the Environmental Protection Agency's **Federal Register** publication of the filing of the Final EIS.

ADDRESSES: Those wishing to review the Record of Decision may obtain a copy by submitting their request to the Superintendent, Sequoia and Kings Canyon National Parks, 47050 Generals Highway, Three Rivers, CA 93271.

FOR FURTHER INFORMATION CONTACT: Woody Smeck, Superintendent, (559) 565–3100.

SUPPLEMENTARY INFORMATION: On April 26, 2011, a Notice of Intent to prepare an EIS for the WSP was published in the **Federal Register**. The NPS developed the WSP/EIS with substantial input and participation from the public. The park hosted 16 public meetings and presentations (including one webinar) and received over 1,300 written public comments throughout the public scoping period and public review of the Draft WSP/EIS (released for sixty-day review period on July 1, 2014). The NPS consulted with park partners; traditionally associated American Indian tribes and groups; the State Historic Preservation Officer; and other federal and state agencies. The U.S. Forest Service was a cooperating agency in the planning process.

The Final WSP/EIS (released on April 3, 2015) evaluated the environmental consequences of four action alternatives and a no-action alternative. These alternatives described five different ways to provide appropriate types and levels of access for visitors and authorized users, preserve wilderness character, protect cultural and natural resources, and adhere to legally required management and preservation objectives.

Alternative 2, the management-preferred alternative, has been selected for implementation. It provides a targeted approach to preserving wilderness character by focusing on those areas where conditions warrant management actions. Alternative 2 allows for current types and levels of use, and builds on existing management practices to protect wilderness character and the natural and cultural resources in the parks. The goal of Alternative 2 is to encourage wilderness use and minimize restrictions while preserving wilderness character. Alternative 2 recommends a 691-mile designated trail system (mirrors current conditions), of which 650 miles (95 percent) are open to stock. Approximately 41 miles of trails are closed to stock for visitor safety and protection of natural and cultural resources. Meadows in areas open to stock are available for grazing under a meadow management program with limited exceptions. Seven meadows are closed to grazing along the Pacific Crest Trail and High Sierra Trail to protect scenery for public enjoyment.

Dated: September 1, 2015.

Martha J. Lee,

Acting Regional Director, Pacific West Region.

[FR Doc. 2015–23170 Filed 9–14–15; 8:45 am]

BILLING CODE 4312–FF–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[15XR5173F7, RR02142500, RX.12056050.0000004]

Notice of Availability for the Final Environmental Impact Statement for the North Valley Regional Recycled Water Program

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation has made available the North Valley Regional Recycled Water Program Final Environmental Impact Statement (EIS). The North Valley Regional Recycled Water Program would provide recycled water from the Cities of Turlock and Modesto via the Central Valley Project's Delta-Mendota Canal to Del Puerto Water District for irrigation purposes, and would further provide annual supplemental water to south of the Sacramento-San Joaquin River Delta Central Valley Project Improvement Act-designated wildlife refuges.

DATES: The Bureau of Reclamation will not make a decision on the proposed action until at least 30 days after release of the Final EIS. After the 30-day waiting period, Reclamation will complete a Record of Decision (ROD). The ROD will state the action that will be implemented and will discuss all factors leading to the decision.

ADDRESSES: To request a compact disc of the Final EIS, please contact Ms. Rain Emerson, Bureau of Reclamation, 1243 N Street, Fresno, California 93721; telephone at (559) 487–5196; or via email at *remerson@usbr.gov.*

The Final EIS may be viewed at the Bureau of Reclamation's Web site at *http://www.usbr.gov/mp/nepa/nepa_projdetails.cfm?Project_ID=17241,* or at the following locations:

1. Bureau of Reclamation, South-Central California Area Office, 1243 N Street, Fresno, CA 93721.

2. Natural Resources Library, U.S. Department of the Interior, 1849 C Street NW., Main Interior Building, Washington, DC 20240–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Rain Emerson, Supervisory Natural Resources Specialist, Bureau of Reclamation, via email at *remerson@usbr.gov,* or at (559) 487–5196; or Mr. Scott Taylor, Repayment Specialist, Bureau of Reclamation, via email at *staylor@usbr.gov,* or at (559) 487–5504.

SUPPLEMENTARY INFORMATION: The Del Puerto Water District (Del Puerto WD) and the Cities of Turlock and Modesto

propose to implement a regional solution to address water supply shortages within Del Puerto WD's service area on the west side of the San Joaquin River in San Joaquin, Stanislaus and Merced Counties. Specifically, the project proposes to deliver up to 59,000 acre-feet per year by 2045 of recycled water produced by the cities to the Delta Mendota Canal (DMC). After introduction to the DMC, the recycled water would be conveyed to Del Puerto WD customers, to the Central Valley Project Improvement Act-designated refuges or to San Luis Reservoir for storage, depending on time of year and water demand. The Final EIS assesses the environmental effects of four alternatives being considered, which are described below. In each case (except for the No Action Alternative), operational exchanges with the Bureau of Reclamation may be necessary in order to balance seasonal supply and demand.

Under Alternative 1, the Combined Alignment Alternative, a new pipe would be constructed to deliver treated water from Turlock's facilities to the city of Modesto's pumping plant. From there, a pipeline would be constructed to deliver the combined water from both cities west, underneath the San Joaquin River. The pipeline would end at a new discharge structure on the DMC. The DMC would then be used to convey water to downstream users.

Alternative 2, the Separate Alignment Alternative, is similar to Alternative 1, except that separate pipelines would be constructed from the Modesto and Turlock water treatment facilities. There would be two crossings underneath the San Joaquin River, and two new discharge structures on the DMC.

Under Alternative 3, the Patterson Irrigation District (PID) Conveyance Alternative, Modesto and Turlock would continue to discharge their treated water to the San Joaquin River. The water would be diverted by PID at their existing intake on the river, which would need to be expanded, delivered to the DMC by way of an expanded PID conveyance system, and discharged to the DMC by way of a new outfall structure. From there, the water would be conveyed to downstream users. This alternative would require an expansion of PID's fish screen facility and a pipeline parallel to PID's main canal to accommodate increased water volume, but no new river crossings.

Alternative 4, the No Action Alternative, represents the state of the environment without implementation of any action alternatives. Modesto and Turlock would continue to discharge their treated municipal water to the San Joaquin River, and no additional water would be supplied to Del Puerto WD or the Central Valley Project Improvement Act refuges.

A Notice of Availability of the Draft EIS/EIR was published in the **Federal Register** on January 9, 2015 (80 FR 1432). The comment period on the Draft EIS/EIR ended on March 10, 2015. The Final EIS contains responses to all comments received and reflects comments and any additional information received during the review period.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in any communication, you should be aware that your entire communication—including your personal identifying information—may be made publicly available at any time. While you can ask us in your communication to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 18,2015.

Pablo R. Arroyave,

Deputy Regional Director, Mid-Pacific Region.

Editorial Note: This document was received for publication by the Office of **Federal Register** on September 10, 2015.

[FR Doc. 2015–23138 Filed 9–14–15; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On September 10, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Middle District of North Carolina in the lawsuit entitled *United States, et al.* v. *Duke Energy Corporation,* Civil Case No. 1:00–cv–1262 (M.D.N.C). Environmental Defense, the North Carolina Sierra Club, and Environment North Carolina (formerly the North Carolina Public Interest Research Group) are co-plaintiffs in the case.

In this civil enforcement action under the federal Clean Air Act (''Act''), the United States and its co-plaintiffs allege that Duke Energy Corporation (''Defendant''), failed to comply with certain requirements of the Act intended to protect air quality at power plants in North Carolina. The complaint seeks injunctive relief and civil penalties for violations of the Clean Air Act's Prevention of Significant Deterioration (''PSD'') provisions, 42 U.S.C. 7470–92, and various Clean Air Act implementing regulations. Specifically, the complaint alleges that Defendant failed to obtain appropriate permits and failed to install and operate required pollution control devices to reduce emissions of sulfur dioxide (''SO_2'') nitrogen oxides (''NO_X''), and/or particulate matter (''PM'') at electricity generating units at the following North Carolina plants: the Allen and Riverbend plants in Gaston County, the Buck plant in Rowan County, the Cliffside plant in Cleveland and Rutherford Counties, and the Dan River plant in Rockingham County.

The proposed Consent Decree would resolve violations for certain provisions of the Act at Allen Units 1 and 2, Riverbend Units 4, 6, and 7, Buck Units 3, 4, and 5, Cliffside Units 1, 2, 3, and 4, and Dan River Unit 3. Eleven of these thirteen units have been recently shut down, and the proposed settlement would render those retirements a permanent obligation under the Consent Decree. At the remaining units (Allen Units 1 and 2), the proposed Consent Decree requires Defendant to operate pollution controls and meet interim emission limitations prior to permanently retiring the units in 2024. In addition, Duke will retire an additional unit at the Allen plant, and spend $4,400,000 to fund environmental mitigation projects that will further reduce emissions and benefit communities adversely affected by the pollution from the plants, and pay a civil penalty of $975,000.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, et al.* v. *Duke Energy Corporation,* Civil Case No. 1:00–cv-1262 (M.D.N.C), D.J. Ref. No. 90–5–2–1–07155. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General U.S. DOJ—ENRD P.O. Box 7611 Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees.*

We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $18.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–23142 Filed 9–14–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Abandoned Individual Account Plan Termination

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, ''Abandoned Individual Account Plan Termination,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq*. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 15, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201508-1210-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov*. Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov*.

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Abandoned Individual Account Plan Termination information collection requirements codified in regulations 29 CFR 2520.103–11, 2550.404a–3, and 2578 and in Prohibited Transaction Exemption (PTE) 2006–06 as amended. More specifically the ICR supports the following information collections:

Qualified Termination Administrator (QTA) Regulation (29 CFR 2578.1): The QTA regulation creates an orderly and efficient process by which a financial institution holding assets of a plan deemed to have been abandoned may undertake to terminate the plan and distribute its assets to participants and beneficiaries holding accounts under the plan, with protections and DOL approval under the regulatory standards. The regulation requires the QTA to provide certain notices to the DOL, to participants and beneficiaries, and to the plan sponsor (or service providers to the plan, if necessary), and to keep certain records pertaining to the termination.

Abandoned Plan Terminal Report Regulation (29 CFR 2520.103–11): The terminal report regulation provides an alternative method for a QTA to satisfy the annual report requirement otherwise applicable to a terminating plan. The QTA files a simplified terminal report with the DOL after terminating an abandoned plan and distributing its accounts to participants and beneficiaries.

Terminated Plan Distribution Regulation (29 CFR 2550.404a–3): The terminated plan distribution regulation establishes a safe harbor method by which a fiduciary terminating an individual account pension plan (whether abandoned or not) may select an investment vehicle to receive account balances distributed from the terminated plan when the participant has failed to provide investment instructions. The regulation requires the fiduciary to provide advance notice to participants and beneficiaries of how such distributions will be invested, if no other investment instructions are provided.

Abandoned Plan Class Exemption (PTE 2006–06): The exemption permits a QTA terminating an abandoned plan under the QTA regulation to receive payment for its services from the abandoned plan and to distribute the account balance of a participant who has failed to provide investment direction into an individual retirement account maintained by the QTA or an affiliate. Without the exemption, financial institutions could be unable to receive payment for services rendered out of plan assets without violating Employee Retirement Income Security Act (ERISA) prohibited transaction provisions and being subject to taxes imposed by Internal Revenue Code of 1986 section 4975; consequently, without the exemption, the institutions would be highly unlikely to terminate abandoned plans. One exemption condition requires the QTA to record the distributions, retain the records for six (6) years, and make these records available on request to interested persons (including the DOL, participants, and beneficiaries). If a QTA wishes to be paid out of plan assets for services provided prior to becoming a QTA, the exemption requires the QTA to enter into a written agreement with a plan fiduciary or the plan sponsor prior to receiving payment and provide the DOL with a copy of the agreement.

The regulations and PTE encourage the orderly termination of an abandoned plan and the timely distribution of plan assets to participants and beneficiaries. Participants and beneficiaries would likely be denied access to the money in their individual account plans in the absence of these regulations and exemption, because financial institutions holding assets of abandoned plans usually do not have the authority to take any of these steps.

Because these regulations and the PTE relate to either or both abandoned plan termination and benefit distribution and rollover when no participant investment election has been made, the DOL has combined the paperwork burden for all of these actions into one ICR. This combination allows the public to have a better understanding of the aggregate burden imposed on the public for these related regulatory actions. ERISA sections 101, 404, 408, and 505

authorize this information collection. *See* 29 U.S.C. 29 U.S.C. 1021, 1104, 1108, and 1135.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0127.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on September 30, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 17, 2015 (80 FR 34696).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0127. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: Abandoned Individual Account Plan Termination.

OMB Control Number: 1210–0127.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 26,700.

Total Estimated Number of Responses: 1,308,000.

Total Estimated Annual Time Burden: 47,700 hours.

Total Estimated Annual Other Costs Burden: $689,000.

Dated: September 9, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–23153 Filed 9–14–15; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's *ad* hoc Task Force on NEON Performance and Plans, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of a meeting for the transaction of National Science Board business, as follows:

DATE AND TIME: Thursday, September 17, 2015 at 2:30–3:30 p.m. EDT.

SUBJECT MATTER: Task Force Chair's opening remarks; approval of minutes; discussion of upcoming Congressional hearing on NEON, and related background documents.

STATUS: Closed.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201Wilson Blvd., Arlington, VA 22230.

Please refer to the National Science Board Web site (*www.nsf.gov/nsb*) for information or schedule updates, or contact: John Veysey (*jveysey@nsf.gov*), National Science Foundation, 4201Wilson Blvd., Arlington, VA 22230.

Kyscha Slater-Williams,

Program Specialist.

[FR Doc. 2015–23207 Filed 9–11–15; 11:15 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's *ad* hoc Task Force on NEON Performance and Plans, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of a meeting for the transaction of National Science Board business, as follows:

DATE AND TIME: Friday, September 11, 2015 at 10–11:30 a.m. EDT.

SUBJECT MATTER: Task Force Chair's opening remarks; discussion of background documents, including a table that summarizes near-term deliverables and metrics for NEON, Inc.

STATUS: Closed.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201Wilson Blvd., Arlington, VA 22230.

Please refer to the National Science Board Web site (*www.nsf.gov/nsb*) for information or schedule updates, or contact: John Veysey (*jveysey@nsf.gov*), National Science Foundation, 4201Wilson Blvd., Arlington, VA 22230.

Kyscha Slater-Williams,

Program Specialist.

[FR Doc. 2015–23208 Filed 9–11–15; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–027 and 52–028; NRC–2008–0441]

Virgil C. Summer Nuclear Station, Units 2 and 3; South Carolina Electric & Gas Company

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and issuing License Amendment No. 29 to Combined Licenses (COL), NPF–93 and NPF–94. The COLs were issued to South Carolina Electric & Gas Company (SCE&G), and South Carolina Public Service Authority (the licensee), for construction and operation of the Virgil C. Summer Nuclear Station (VCSNS),

Units 2 and 3 located in Fairfield County, South Carolina.

The granting of the exemption allows the changes to Tier 1 information requested in the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: September 15, 2015.

ADDRESSES: Please refer to Docket ID NRC–2008–0441 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0441. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that a document is referenced. The request for the amendment and exemption was submitted by the letter dated September 25, 2014 (ADAMS Accession No. ML14268A388). The licensee supplemented this request by letter dated March 13, 2015 (ADAMS Accession No. ML15072A306).

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Ruth Reyes, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3249; email: *Ruth.Reyes@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting an exemption from Tier 1 information in the certified DCD incorporated by reference in part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR), appendix D, ''Design Certification Rule for the AP1000 Design,'' and issuing License Amendment No. 29 to COLs, NPF–93 and NPF–94, to the licensee. The exemption is required by Paragraph A.4 of Section VIII, ''Processes for Changes and Departures,'' appendix D to 10 CFR part 52 to allow the licensee to depart from Tier 1 information. With the requested amendment, the licensee sought proposed changes related to the design details of the containment internal structural wall modules (CA04, CA01, and CB65). The proposed changes to Tier 2 information in the VCSNS Units 2 and 3 Updated Final Safety Analysis Report (UFSAR), plant-specific Tier 1 information, and corresponding COL appendix C information would allow an increase of the concrete wall thickness tolerances. The proposed changes would allow:

(1) A change to Tier 2 information in UFSAR Subsection 3.8.3.6.1, ''Fabrication, Erection, and Construction of Structural Modules,'' to allow an increase in wall thickness tolerance beyond the American Concrete Institute (ACI) 117, ''Standard Specifications for Tolerance for Concrete Construction and Material,'' specified tolerance for some ContainmentInternal Structure (CIS) walls;

(2) the addition of Notes 10 and 11 to Tier 1 Table 3.3–1, which provides the wall thickness tolerance deviations.

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in 10 CFR 50.12, 10 CFR 52.7, and 10 CFR 52.63(b)(1). The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML15216A264.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to the licensee for VCSNS Units 2 and 3 (COLs NPF–93 and NPF–94). These documents can be found in ADAMS under Accession Nos. ML15216A245 and ML15216A249, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–93 and NPF–94 are available in ADAMS under Accession Nos. ML15216A075 and ML15216A183, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption document issued to VCSNS, Units 2 and 3. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In a letter dated September 25, 2014, and supplemented by letter dated March 13, 2015, South Carolina Electric & Gas Company (licensee) requested from the Nuclear Regulatory Commission (Commission) an exemption to allow departures from Tier 1 information in the certified Design Control Document (DCD) incorporated by reference in 10 CFR part 52, appendix D, ''Design Certification Rule for the AP1000 Design,'' as part of license amendment request (LAR) 14–07, ''CA04 Structural Module Inspection, Test, Analysis, and Acceptance Criteria Dimensions Change.''

For the reasons set forth in Section 3.1 of the NRC staff's Safety Evaluation, which can be found at ADAMS Accession No. ML15216A264, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption, and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, the licensee is granted an exemption from the certified DCD Tier 1 Table: 3.3–1, as described in the licensee's request dated September 25, 2014, and supplemented by letter dated March 13, 2015. This exemption is related to, and necessary for the granting of License Amendment No. 29, which is being issued concurrently with this exemption.

3. As explained in Section 5.0 of the NRC staff's Safety Evaluation (ADAMS Accession No. ML15216A264), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

The request for the amendment and exemption was submitted by the letter dated September 25, 2014. The licensee supplemented this request by the letter dated March 13, 2015. The proposed amendment is described in Section I, above.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on April 14, 2015 (80 FR 20020). No comments were received during the 30-day comment period.

The NRC staff has found that the amendment involves no significant hazards consideration. The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that the licensee requested on September 25, 2014, and supplemented by the letter dated March 13, 2015. The exemption and amendment were issued on August 24, 2015, as part of a combined package to the licensee (ADAMS Accession No. ML15216A071).

Dated at Rockville, Maryland, this 4th day of September 2015.

For the Nuclear Regulatory Commission.

Lawrence Burkhart,

Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2015–23086 Filed 9–14–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–390; NRC–2015–0170]

Watts Bar Nuclear Plant, Unit No. 1; Application and Amendment to Facility Operating License Involving Proposed No Significant Hazards Consideration Determination

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. NFP–90, issued to the Tennessee Valley Authority (the licensee), for operation of the Watts Bar Nuclear Plant (WBN), Unit No. 1. The proposed amendment would modify the technical specifications (TSs) to define support systems needed in the first 48 hours after a unit shutdown when steam generators are not available for heat removal. The proposed amendment would also make changes consistent with Technical Specification Task Force (TSTF) Traveler TSTF–273–A, Revision 2, to provide clarifications related to the requirements of the Safety Function Determination Program (SFDP). The proposed license amendment was submitted by letter dated June 17, 2015, and was supplemented by letters dated July 14, August 28, and September 3, 2015. The NRC staff previously made a proposed determination that the amendment involves no significant hazards consideration. By letter dated September 3, 2015, the licensee provided additional information that expanded the scope of the amendment request as originally noticed. The September 3, 2015, supplement proposed new modifications to TS 3.3.2 and TS 3.4.6. This notice supersedes the previous notice in its entirety to update the description of the amendment request and the no significant hazards determination.

DATES: Submit comments by October 15, 2015. A request for a hearing or petition for leave to intervene must be filed by November 16, 2015.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0170. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jeanne A. Dion, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1349; email: *Jeanne.Dion@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0170 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- Federal rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0170.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select *''ADAMS Public Documents''* and then select *''Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The application for amendment, dated June 17, 2015, and supplemented by letters dated July 14, August 28, and September 3, 2015, are available in ADAMS under ADAMS Accession Nos. ML15170A474, ML15197A357, ML15243A044, and ML15246A638.

• NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0170 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering issuance of an amendment to Facility Operating License No. NFP–90, issued to the Tennessee Valley Authority, for operation of the WBN, Unit No. 1, located in Spring City, Tennessee.

The proposed amendment, initially submitted by letter dated June 17, 2015, would modify the TSs to define support systems needed in the first 48 hours after a unit shutdown when steam generators are not available for heat removal. The proposed change is required to support dual unit operation of WBN (a licensing decision for WBN, Unit No. 2, is currently expected to be made in the fall of 2015). The proposed amendment would also make changes consistent with TSTF–273–A, Revision 2, to provide clarifications related to the requirements of the SFDP. The proposed license amendment was supplemented by letters dated July 14, August 28, and September 3, 2015. The supplement dated September 3, 2015, proposed changes to TSs 3.3.2 and 3.4.6), beyond those that had been included in the June 17, 2015, letter. The NRC staff previously made a proposed determination that the amendment request dated June 17, 2015, involves no significant hazards consideration (80 FR 42554; July 17, 2015). This notice supersedes the previous notice in its entirety to update the description of the amendment request and the no significant hazards consideration.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The NRC has made a proposed determination that the amendment request involves no significant hazards consideration. Under the NRC's regulations in § 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The likelihood of a malfunction of any systems, structures or components (SSCs) supported by containment cooling system (CCS) and essential raw cooling water (ERCW) is not significantly increased by adding new technical specification (TS) for ERCW and CCS that require alternate CCS and ERCW system alignments during the first 48 hours after shut down of a unit when the steam generators are not available for heat removal. CCS and ERCW provide the means for transferring residual and decay heat to the Residual Heat Removal (RHR) System for process and operating heat from safety related components during a transient or accident, as well as during normal operation. Although the proposed change includes a design change to allow two ERCW pumps to be powered from one diesel generator (DG), the additional ERCW pump is only aligned to the DG on a non-accident unit during a design basis event on the other unit, and does not result in overloading the DG due to the reduced loading on the non-accident DG. The CCS and ERCW are not initiators of any analyzed accident. All equipment supported by CCS and ERCW has been evaluated to demonstrate that their performance and operation remains as described in the FSAR [Final Safety Analysis Report] with no increase in probability of failure or malfunction.

The SSCs credited to mitigate the consequences of postulated design basis accidents remain capable of performing their design basis function. The change in CCS and ERCW system alignments has been evaluated to ensure the RHR System remains capable of removing normal operating and post-accident heat. Additionally, all the CCS and ERCW supported equipment, credited in the accident analysis to mitigate an accident, has been shown to continue to perform their design function as described in the FSAR.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed TS changes add explanatory text to the programmatic description of the Safety Function Determination Program (SFDP) in TS 5.7.2.18 to clarify the requirements that consideration does not have to be made for a loss of power in determining loss of function. The Bases for LCO [Limiting Condition for Operation] 3.0.6 is revised to provide clarification of the ''appropriate LCO for loss of function,'' and that consideration does not have to be made for a loss of power in determining loss of function. The changes are editorial and administrative in nature, and therefore do not increase the probability of any accident previously evaluated. No physical or operational changes are made to the plant. The proposed changes do not change how the plant would mitigate an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change to require the Reactor Coolant System (RCS) loops to be operable for the initial seven hours after shutdown and for the automatic switching of the auxiliary feedwater (AFW) pumps suction from the condensate storage tank (CST) to the and essential raw cooling water (ERCW) System to be operable in Mode 4 when relying on steam generators for heat removal does not increase the probability or consequences of an accident that has been previously evaluated at WBN. The RCS loops are currently required to be operable to remove decay heat until plant conditions allow the Residual Heat Removal (RHR) System to be placed in service. Specifying that the RCS loops are required to be operable for the initial seven hours after shutdown is consistent with the heat load assumptions at the specified time after shutdown described in the Updated Final Safety Analysis Report (UFSAR). The suction piping to the AFW pumps from either the CST or ERCW is not an initiator of any analyzed accident. The equipment supported by AFW and ERCW as described in the UFSAR has not been changed.

The systems, structures or components (SSCs) credited to mitigate the consequences of postulated design basis accidents remain capable of performing their design basis function. The change requiring the RCS loops to be operable for the initial seven hours after shutdown does not affect heat removal capability. It ensures the RHR System is not solely relied on for decay heat removal before the decay heat load is within the capability of the RHR System. The change requiring the pressure switches in the AFW pump suction piping to remain in service in Mode 4 when steam generators are relied on to remove heat from the RCS does not affect heat removal capability. It retains the same automatic

action required by the instruments in Modes 1, 2, and 3, consistent with the TS Applicability requirements for the AFW System.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change does not introduce any new modes of plant operation, change the design function of any SSC, or change the mode of operation of any SSC. There are no new equipment failure modes or malfunctions created as the affected SSCs continue to operate in the same manner as previously evaluated and have been evaluated to perform their safety functions when in the alternate alignments as assumed in the accident analysis. Additionally, accident initiators remain as described in the FSAR and no new accident initiators are postulated as a result of the alternate CCS and ERCW alignments.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes [to TS 5.7.2.18] are editorial and administrative in nature and do not result in a change in the manner in which the plant operates. The loss of function of any specific component will continue to be addressed in its specific TS LCO, and plant configuration will be governed by the required actions of those LCOs. The proposed changes are clarifications that do not degrade the availability or capability of safety related equipment, and therefore do not create the possibility of a new or different kind of accident from any accident previously evaluated. There are no design changes associated with the proposed changes, and the changes do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed). The changes do not alter assumptions made in the safety analysis, and are consistent with the safety analysis assumptions and current plant operating practice. Due to the administrative nature of the changes, they cannot be an accident initiator.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change does not introduce any new modes of plant operation, change the design function of any SSC, or change the mode of operation of any SSC. There are no new equipment failure modes or malfunctions created as the affected SSCs continue to operate in the same manner as previously evaluated. Additionally, accident initiators remain as described in the UFSAR and no new accident initiators are postulated as a result of requiring the RCS loops to be operable for a specified duration after plant shutdown or by extending the Mode of Applicability of the AFW pump suction swap over from the CST to ERCW.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change continues to ensure that the cooling capability of RHR during normal operation and during the mitigation of a design basis event remains within the evaluated equipment limits and capabilities assumed in the accident analysis. The proposed change does not result in any changes to plant equipment functions, including setpoints and actuations. The proposed change does not alter existing limiting conditions for operation, limiting safety system settings, or safety limits specified in the Technical Specifications. The proposed change to add a new TS for ERCW and CCS assures the ability of these systems to support post-accident residual heat removal.

Therefore, since there is no adverse impact of this change on the Watts Bar Nuclear Plant safety analysis, there is no significant reduction in the margin of safety of the plant.

The proposed changes to TS 5.7.2.18 are clarifications and are editorial and administrative in nature. No changes are made to the LCOs for plant equipment, the time required for the TS Required Actions to be completed, or the out of service time for the components involved. The proposed changes do not affect the safety analysis acceptance criteria for any analyzed event, nor is there a change to any safety analysis limit. The proposed changes do not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined, nor is there any adverse effect on those plant systems necessary to assure the accomplishment of protection functions. The proposed changes will not result in plant operation in a configuration outside the design basis.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The proposed change does not result in any changes to plant equipment functions, including setpoints and actuations. The proposed change does not alter limiting safety system settings or safety limits specified in the TS for these instruments. The proposed change ensures the decay heat load of the plant is within the capability of the RHR System prior to allowing sole use of the RHR loops for decay heat removal. In addition, the proposed change ensures the same automatic action to align ERCW as a supply source to AFW that occurs in Modes 1, 2, and 3 will remain available in Mode 4 when relying on the steam generators for decay heat removal. Thus, the proposed change does not reduce the margin of safety.

Therefore, since there is no adverse impact of this change on the safety analysis, there is no significant reduction in the margin of safety of the plant.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The NRC is seeking public comments on this proposed determination that the license amendment request involves no significant hazards consideration. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this **Federal Register** notice, any person whose interest may be affected by this proceeding and who desires to participate as a party in the proceeding must file a written request for hearing or a petition for leave to intervene specifying the contentions which the person seeks to have litigated in the hearing with respect to the license amendment request. Requests for hearing and petitions for leave to intervene shall be filed in accordance with the NRC's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

As required by 10 CFR 2.309, a request for hearing or petition for leave to intervene must set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The hearing request or petition must specifically explain the reasons why intervention should be permitted, with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The hearing request or petition must also include the specific contentions that the requestor/petitioner seeks to have litigated at the proceeding. For each contention, the requestor/petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the requestor/petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings that the NRC must make to support the granting of a license amendment in response to the application. The hearing request or petition must also include a concise statement of the alleged facts or expert opinion that support the contention and on which the requestor/petitioner intends to rely at the hearing, together with references to those specific sources and documents. The hearing request or petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for amendment that the petitioner disputes and the supporting reasons for each dispute. If the requestor/petitioner believes that the application for amendment fails to contain information on a relevant matter as required by law, the requestor/petitioner must identify each failure and the supporting reasons for the requestor's/petitioner's belief. Each contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who does not satisfy these requirements for at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Hearing requests or petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call to 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

For further details with respect to this action, see the application for amendment, dated June 17, 2015, and supplemented by letters dated July 14, August 28, and September 3, 2015, in ADAMS under ADAMS Accession Nos. ML15170A474, ML15197A357, ML15243A044, and ML15246A638.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, Tennessee 37902.

NRC Branch Chief: Jessie F. Quichocho.

Dated at Rockville, Maryland, this 8th day of September 2015.

For the Nuclear Regulatory Commission.

Jeanne A. Dion,

Project Manager, Watts Bar Special Projects Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–23085 Filed 9–14–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0219]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from August 18 to August 31, 2015. The last biweekly notice was published on September 1, 2015.

DATES: Comments must be filed by October 15, 2015. A request for a hearing must be filed by November 16, 2015.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0219. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Mable Henderson, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–3760, email: *Mable.Henderson@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0219 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0219.

• NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

• NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0219, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific

contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and

Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Florida Power & Light Company, et al., Docket No. 50–335, St. Lucie Plant, Unit No. 1, St. Lucie County, Florida

Date of amendment request: July 15, 2015. A publicly-available version is in ADAMS under Accession No. ML15198A029.

Description of amendment request: The amendment would revise Technical Specification (TS) Surveillance Requirements for snubbers to conform to revisions to the Snubber Testing Program.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes would revise SR [Surveillance Requirement] 4.7.10 to conform the TS to the revised surveillance program for snubbers. Snubber examination, testing and service life monitoring will continue to meet the requirements of 10 CFR 50.55a(g).

Snubber examination, testing and service life monitoring is not an initiator of any accident previously evaluated. Therefore, the probability of an accident previously evaluated is not significantly increased.

Snubbers will continue to be demonstrated OPERABLE by performance of a program for examination, testing and service life monitoring in compliance with 10 CFR 50.55a or authorized alternatives. The proposed change does not adversely affect plant operations, design functions or analyses that verify the capability of systems, structures, and components to perform their design functions therefore, the consequences of accidents previously evaluated are not significantly increased.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not involve any physical alteration of plant equipment. The proposed changes do not alter the method by which any safety-related system performs its function. As such, no new or different types of equipment will be installed, and the basic operation of installed equipment is unchanged. The methods governing plant operation and testing remain consistent with current safety analysis assumptions.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes ensure snubber examination, testing and service life monitoring will continue to meet the requirements of 10 CFR 50.55a(g). Snubbers will continue to be demonstrated OPERABLE by performance of a program for examination, testing and service life monitoring in compliance with 10 CFR 50.55a or authorized alternatives.

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William S. Blair, Managing Attorney—Nuclear, Florida Power & Light, 700 Universe Blvd., MS LAW/JB, Juno Beach, Florida 33408–0420.

NRC Branch Chief: Shana R. Helton.

III. Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and

page cited. This notice does not extend the notice period of the original notice.

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg Counties, North Carolina

Date of amendment request: June 30, 2015. A publicly-available version is in ADAMS under Accession No. ML15191A025.

Brief description of amendment request: The proposed amendment would allow a temporary extension of selected Technical Specification required Completion Times to support repair activities associated with the Nuclear Service Water System.

Date of publication of individual notice in ***Federal Register****:* August 20, 2015 (80 FR 50663).

Expiration date of individual notice: September 19, 2015 (public comments) and October 19, 2015 (hearing requests).

IV. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Dominion Nuclear Connecticut, Inc., Docket No. 50–336, Millstone Power Station, Unit No. 2 (MPS2), New London County, Connecticut

Date of amendment request: October 31, 2014.

Brief description of amendment: The amendment revised the MPS2 Final Safety Analysis Report (FSAR) to allow for the use of the encoded ultrasonic examination technique in lieu of the FSAR committed additional radiography examination for certain piping welds fabricated to American National Standards Institute B31.1.0. Specifically, the legend notes of MPS2 FSAR Figure 9.0.3, ''General Piping and Instrumentation Diagram'' were revised to replace the references to ''radiography'' with ''volumetric examination.''

Date of issuance: August 26, 2015.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment No.: 322. A publicly-available version is in ADAMS under Accession No. ML15225A008; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–65: Amendment revised the Renewed Operating License.

Date of initial notice in ***Federal Register****:* June 9, 2015 (80 FR 32626).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 26, 2015.

No significant hazards consideration comments received: No.

Dominion Nuclear Connecticut, Inc., Docket No. 50–423, Millstone Power Station, Unit No. 3 (MPS3), New London County, Connecticut

Date of amendment request: October 14, 2014, as supplemented by letter dated August 27, 2015.

Brief description of amendment: The amendment revised the MPS3 Technical Specification (TS) surveillance requirement (SR) 4.4.4.2 to remove the requirement to perform the surveillance for a pressurizer power-operated relief valve block valve that is being maintained closed in accordance with TS 3.4.4 Action a.

Date of issuance: August 28, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 264. A publicly-available version is in ADAMS under Accession No. ML15225A010; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–49: Amendment revised the Renewed Operating License and TSs.

Date of initial notice in ***Federal Register****:* April 28, 2015 (80 FR 23601). The supplemental letter dated August 27, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 28, 2015.

No significant hazards consideration comments received: No.

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: March 23, 2015.

Brief description of amendments: The amendments modify the definition of RATED THERMAL POWER and delete a footnote that allowed for staggered implementation of the previously approved Measurement Uncertainty Recapture Power Uprate.

Date of issuance: August 24, 2015.

Effective date: This license amendment is effective as of its date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: 280 and 260. A publicly-available version is in ADAMS under Accession No. ML15174A173; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. NPF–9 and NPF–17: Amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register****:* June 9, 2015 (80 FR 32627).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 24, 2015.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., System Energy Resources, Inc., South Mississippi Electric Power Association, and Entergy Mississippi, Inc., Docket No. 50–416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of application for amendment: November 21, 2014, as supplemented by letter dated April 14, 2015.

Brief description of amendment: The amendment revised Technical Specification (TS) 2.1.1.2 of TS Section 2.1.1, ''Reactor Core SLs [Safety Limits].'' Specifically, the cycle-specific safety limit minimum critical power ratio values for Cycle 20 were revised in support of the Maximum Extended Load Line Limit Analysis Plus license amendment request.

Date of issuance: August 18, 2015.

Effective date: As of the date of issuance and shall be implemented within 180 days of issuance.

Amendment No: 203. A publicly-available version is in ADAMS under Accession No. ML15229A213; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–29: The amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register****:* March 31, 2015 (80 FR 17087). The supplemental letter dated April 14, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 18, 2015.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., System Energy Resources, Inc., South Mississippi Electric Power Association, and Entergy Mississippi, Inc., Docket No. 50–416, Grand Gulf Nuclear Station, Unit 1 (GGNS), Claiborne County, Mississippi

Date of application for amendment: November 21, 2014, as supplemented by letters dated February 18, March 30, May 8, June 11, 2015 and August 10, 2015.

Brief description of amendment: The amendment revised the GGNS Updated Final Safety Analysis Report from the use of two different fluence calculational methods to the use of a single 3D fluence methodology for 0 effective full power years through the end of extended operations.

Date of issuance: August 18, 2015.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment No: 204. A publicly-available version is in ADAMS under Accession No. ML15229A218; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–29: The amendment revised the Updated Final Safety Analysis Report.

Date of initial notice in ***Federal Register****:* March 31, 2015 (80 FR 17087). The supplemental letters dated March 30, May 8, June 11, 2015 and August 10, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 18, 2015.

No significant hazards consideration comments received: Yes. The comments received on Amendment No. 204 are addressed in the Safety Evaluation dated August 18, 2015.

Entergy Operations, Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit 3 (WF3), St. Charles Parish, Louisiana

Date of amendment request: August 28, 2014, as supplemented by letters dated April 15, May 4, and June 18, 2015.

Brief description of amendment: The amendment revised Technical Specification 6.15, ''Containment Leakage Rate Testing Program,'' to allow for the extension of the 10-year frequency of the WF3 Type A or Integrated Leak Rate Test to 15 years on a permanent basis.

Date of issuance: August 24, 2015.

Effective date: As of the date of issuance and shall be implemented 30 days from the date of issuance.

Amendment No.: 244. A publicly-available version is in ADAMS under Accession No. ML15217A143; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–38: The amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register****:* December 9, 2014 (79 FR 73109). The supplements dated April 15, May 4, and June 18, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 24, 2015.

No significant hazards consideration comments received: No.

Florida Power and Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: August 26, 2014, as supplemented by letters dated January 14, February 6, and May 14, 2015.

Brief description of amendments: The amendments revised Technical Specification 6.8.4.h, ''Containment Leakage Rate Testing Program,'' to allow extension of the Type A test (*i.e.,* Integrated Leak Rate Test) to a 15-year frequency.

Date of issuance: August 27, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 226 and 176. A publicly available version is in ADAMS under Accession No. ML15195A655; documents related to these amendments are listed in the safety evaluation (SE) enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–67 and NPF–16: Amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register****:* January 20, 2015 (80 FR 2750). The supplemental letters dated January 14, February 6, and May 14, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in an SE dated August 27, 2015.

No significant hazards consideration comments received: No. A comment was received but it was not related to the amendment or to the proposed no significant hazards consideration determination.

Florida Power and Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: August 7, 2014, as supplemented by letters dated February 20 and May 21, 2015.

Brief description of amendments: The amendments revised the Technical Specifications (TSs) by adopting Technical Specification Task Force (TSTF) traveler TSTF–426, Revision 5, ''Revise or Add Actions to Preclude Entry into Limiting Condition for Operation 3.0.3—RITSTF [Risk-Informed TSTF] Initiatives 6b and 6c,'' which is an NRC-approved change to the Standard TSs. The amendments provide an additional allowed outage time to restore an inoperable system for conditions under which existing TSs require a plant shutdown.

Date of Issuance: August 31, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 227 and 177. A publicly-available version is in ADAMS under Accession No. ML15191A403; documents related to these amendments are listed in the Safety Evaluation (SE) enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–67 and NPF–16: Amendments revised the TSs.

Date of initial notice in ***Federal Register****:* March 17, 2015 (80 FR 13908). The supplemental letters dated February 20 and May 21, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in an SE dated August 30, 2015.

No significant hazards consideration comments received: No.

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: August 26, 2014, as supplemented by letters dated February 25 and July 13, 2015.

Brief description of amendment: The proposed amendment revised the CNS Technical Specifications (TSs) by deleting Option b from TS Surveillance Requirement 3.5.2.1. Option b allows use of Condensate Storage Tank (CST) A as an alternative source of makeup water to the reactor pressure vessel during MODE 4 and MODE 5, but CST A is not qualified to Seismic Category I.

Date of issuance: August 27, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 252. A publicly-available version is in ADAMS under Accession No. ML15216A259; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–46: Amendment revised the Facility Operating License and TSs.

Date of initial notice in ***Federal Register****:* December 23, 2014 (79 FR 77047). The supplemental letters dated February 25 and July 13, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 27, 2015.

No significant hazards consideration comments received: No.

NextEra Energy Duane Arnold, LLC, Docket No. 50–331, Duane Arnold Energy Center (DAEC), Linn County, Iowa

Date of amendment request: August 28, 2014.

Brief description of amendment: The amendment revised the DAEC Renewed Facility Operating License (FOL) to change the scheduled completion date for Milestone 8 of the Cyber Security Plan (CSP) Implementation Schedule. The amendment modified paragraph 2.C.(5) of the Renewed FOL No. DPR–49, which provides a license condition to require the licensee, to fully implement and maintain in effect all provisions of the NRC-approved CSP.

Date of issuance: August 18, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No.: 291. A publicly-available version is in ADAMS under Accession No. ML15169A261; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–49: The amendment revised the renewed FOL.

Date of initial notice in ***Federal Register****:* January 6, 2015 (80 FR 535).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 18, 2015.

No significant hazards consideration comments received: No.

Northern States Power Company—Minnesota, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Units 1 and 2, Goodhue County, Minnesota

Date of amendment requests: August 21, 2014, as supplemented by letters dated February 9, 2015, and July 31, 2015.

Brief description of amendments: The amendments revised the licensing basis analysis for a waste gas decay tank rupture at the Prairie Island Nuclear Generating Plant, Units 1 and 2.

Date of issuance: August 26, 2015.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: Unit 1—215; Unit 2—203. A publicly-available version is in ADAMS under Accession No. ML15229A176; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Date of initial notice in ***Federal Register****:* October 28, 2014 (79 FR 64227). The supplements dated February 9, 2015, and July 31, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 26, 2015.

No significant hazards consideration comments received: No.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of application for amendments: July 28, 2014, as supplemented by letters dated May 7, 2015 and August 6, 2015.

Brief description of amendments: The amendments modified the technical specifications to risk-inform requirements regarding selected Required Action End States. The proposed changes to the Required Action End States are described in Table 1 of the Enclosure to the licensee's letter dated July 28, 2014. The changes are consistent with Technical Specification Task Force (TSTF) Traveler TSTF–432, Revision 1, ''Change in Technical Specifications End States (WCAP–16294)'' (ADAMS Accession No. ML103430249).

Date of issuance: August 27, 2015.

Effective date: As of its date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: Unit 1—219; Unit 2—221. A publicly-available version is in ADAMS under Accession No. ML15204A222; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. DPR–80 and DPR–82: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register****:* September 30, 2014 (79 FR 58823). The supplemental letters dated May 7 and August 6, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 27, 2015.

No significant hazards consideration comments received: No.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit 1, Fairfield County, South Carolina

Date of amendment request: December 19, 2014.

Date of issuance: August 18, 2015.

Brief description of amendment: The amendment approves expansion of the Emergency Planning Zone (EPZ) boundary, a revision to the Evacuation Time Estimates analysis, and a revision to the Alert and Notification System design reports to encompass the expanded EPZ boundary.

Effective date: As of the date of its issuance and shall be implemented within 90 days of issuance.

Amendment No.: 201. A publicly-available version is in ADAMS under Accession No. ML15170A087; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–12: Amendment revised the Renewed Facility Operating License.

Date of initial notice in ***Federal Register****:* February 3, 2015 (80 FR 5803).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 18, 2015.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket No. 50–424, Vogtle Electric Generating Plant, Unit 1, Burke County, Georgia

Date of application for amendments: June 4, 2015, as supplemented July 22 and July 31, 2015.

Brief description of amendment: The amendment revises the Vogtle Electric Generating Plant (VEGP) Unit 1, Technical Specification (TS) Limiting Condition for Operation (LCO) 3.5.2, ''ECCS Operating'', such that with the '1A' Residual Heat Removal (RHR) pump inoperable for a motor replacement, the Completion Time of Condition 3.5.2.A changes from 72 hours to 7 days. This TS change would be in effect only for the '1A' RHR pump for the remainder of Cycle 19.

Date of issuance: August 19, 2015.

Effective date: As of the date of issuance and shall be implemented within 30 days from the date of issuance.

Amendment No.: 176. A publicly-available version is in ADAMS under Accession No. ML15209A874. Documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License Nos NPF–68: Amendment revised the Renewed Facility Operating License.

Date of initial notice in ***Federal Register****:* June 23, 2015 (80 FR 35983). The supplemental letters dated July 22 and July 31, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposal no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 19, 2015. The Commission has made a final determination that no significant hazards consideration is involved for the proposed amendment, as discussed in the aforementioned Safety Evaluation.

No significant hazards consideration comments received: No.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: May 15, 2014, as supplemented by letters dated July 10, 2014, February 11 and 26, and July 1, 2015.

Brief description of amendments: The amendments support a conversion from the current emergency action level scheme to a scheme based on Nuclear Energy Institute (NEI) 99–01, Revision 6, ''Development of Emergency Action Levels for Non-Passive Reactors,'' dated November 2012.

Date of issuance: August 20, 2015.

Effective date: As of the date of issuance and shall be implemented within 180 days of issuance.

Amendment Nos.: Unit 1—206; Unit 2—194. A publicly-available version is in ADAMS under Accession No. ML15201A195; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–76 and NPF–80: The amendments authorize revisions to the Emergency Action Level Technical Bases Document.

Date of initial notice in ***Federal Register****:* October 28, 2014 (79 FR 64229). The supplemental letters dated February 11 and 26, and July 1, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 20, 2015.

No significant hazards consideration comments received: No.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: February 26, 2014, as supplemented by letters dated December 8, 2014, and January 21 and July 15, 2015.

Brief description of amendment: The amendment revised Technical Specification 5.6.5, ''CORE OPERATING LIMITS REPORT (COLR),'' to incorporate Westinghouse Electric Company LLC's topical report WCAP–16009–P–A, ''Realistic Large-Break LOCA [Loss-of-Coolant Accident] Evaluation Methodology Using the Automated Statistical Treatment of Uncertainty Method (ASTRUM),'' January 2005, to the list of analytical methods used to determine the core operating limits.

Date of issuance: August 28, 2015.

Effective date: Upon issuance and shall be implemented within 90 days of the date of issuance.

Amendment No.: 213. A publicly-available version is in ADAMS under Accession No. ML15203A005; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–42. The amendment revised the Operating License and Technical Specifications.

Date of initial notice in ***Federal Register****:* September 9, 2014 (79 FR 53462). The supplemental letters dated December 8, 2014, January 21, and July 15, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 28, 2015.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 8th day of September 2015.

For the Nuclear Regulatory Commission.

Anne Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–23083 Filed 9–14–15; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75867]

ISE Mercury, LLC; Order Granting Application for a Conditional Exemption Pursuant to Section 36(a) of the Exchange Act From Certain Requirements of Rules 6a–1 and 6a–2 Under the Exchange Act

September 9, 2015.

I. Introduction

On September 29, 2014, ISE Mercury, LLC (''Applicant'') submitted to the Securities and Exchange Commission (''Commission'') an application on Form 1 under the Securities Exchange Act of 1934 (''Exchange Act'') to register as a national securities exchange. In connection with this application, the Applicant, pursuant to Exchange Act Rule 0–12,[1] has requested an exemption under Section 36(a)(1) of the Exchange Act[2] from certain requirements of Exchange Act Rules 6a–1(a) and 6a–2 (''Exemption Request'').[3] This order grants the Applicant's request for exemptive relief, subject to the satisfaction of certain conditions, which are outlined below.

II. Application for Conditional Exemption from Certain Requirements of Exchange Act Rules 6a–1 and 6a–2

A. Filing Requirements Under Exchange Act Rule 6a–1(a)

Exchange Act Rule 6a–1(a) requires an applicant for registration as a national securities exchange to file an application with the Commission on Form 1. Exhibit C to Form 1 requires the applicant to provide certain information with respect to each of its subsidiaries and affiliates.[4] For purposes of Form 1, an ''affiliate'' is ''[a]ny person that, directly or indirectly, controls, is under common control with, or is controlled by, the national securities exchange . . . including any employees.'' [5] Form 1 defines ''control'' as ''[t]he power, directly or indirectly, to direct the management or policies of a company, whether through ownership of securities, by contract, or otherwise . . . .'' [6] Form 1 provides, further, that any person that directly or indirectly has the right to vote 25% or more of a class of voting securities, or has the power to sell or direct the sale of 25% or more of a class of voting securities, is presumed to control the entity.[7]

Exhibit D to Form 1 requires an applicant for registration as a national securities exchange to provide unconsolidated financial statements for the latest fiscal year for each subsidiary or affiliate. Exhibit D requires the financial statements to include, at a minimum, a balance sheet and an income statement with such footnotes and other disclosures as are necessary to avoid rendering the financial statements misleading. Exhibit D provides, in addition, that if any affiliate or subsidiary of the applicant is required by another Commission rule to submit annual financial statements, a statement to that effect, with a citation to the other Commission rule, may be provided in lieu of the financial statements required in Exhibit D.

A Form 1 application is not considered filed until all necessary information, including financial statements and other required documents, have been furnished in the proper form.[8]

B. Filing Requirements under Exchange Act Rule 6a–2

Exchange Act Rule 6a–2(a)(2) requires a national securities exchange to update the information provided in Exhibit C within 10 days of any action that causes the information provided in Exhibit C to become inaccurate or incomplete. In addition, Exchange Act Rule 6a–2(b)(1) requires a national securities exchange to file Exhibit D on or before June 30 of each year, and Exchange Act Rule 6a–2(c) requires a national securities exchange to file Exhibit C every three years.

C. Exemption Request

On June 26, 2015, the Applicant requested that the Commission grant an exemption under Section 36 of the Exchange Act from the requirement under Exchange Act Rule 6a–1 to file the information requested of the Applicant in Exhibits C and D to Form 1 for the ''Foreign Indirect Affiliates,'' as defined below.[9] In addition, the Applicant requested an exemption, subject to certain conditions, with respect to the Foreign Indirect Affiliates from the requirements under: (1) Exchange Act Rule 6a–2(a)(2) to amend Exhibit C within 10 days if the information in Exhibit C becomes inaccurate or incomplete; and (2) Exchange Act Rules 6a–2(b)(1) and (c) to

[1] 17 CFR 240.0–12.

[2] 15 U.S.C. 78mm(a)(1).

[3] 17 CFR 240.6a–1(a) and 6a–2. *See* letter from Michael Simon, Secretary and General Counsel, ISE Mercury, LLC, to Brent J. Fields, Secretary, Commission, dated June 26, 2015.

[4] Specifically, Exhibit C requires the applicant to provide, for each subsidiary or affiliate, and for any entity with whom the applicant has a contractual or other agreement relating to the operation of an electronic trading system used to effect transactions on the exchange: (1) The name and address of the organization; (2) the form of organization; (3) the name of the state and statute citation under which it is organized, and the date of its incorporation in its present form; (4) a brief description of the nature and extent of the affiliation; (5) a brief description of the organization's business or functions; (6) a copy of the organization's constitution; (7) a copy of the organization's articles of incorporation or association, including all amendments; (8) a copy of the organization's by-laws or corresponding rules or instruments; (9) the name and title of the organization's present officers, governors, members of all standing committees, or persons performing similar functions; and (10) an indication of whether the business or organization ceased to be associated with the applicant during the previous year, and a brief statement of the reasons for termination of the association.

[5] Form 1 Instructions, Explanation of Terms, 17 CFR 249.1.

[6] *Id.*

[7] *Id.*

[8] 17 CFR 202.3(b)(2). *See also* 17 CFR 240.0–3(a). Defective Form 1 applications ''may be returned with a request for correction or held until corrected before being accepted as a filing.'' *See* 17 CFR 202.3(b)(2). *See also* Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844, 70881 (December 22, 1998) (''Regulation ATS Adopting Release'') at note 329 and accompanying text.

[9] *See* Exemption Request, *supra* note 3.

file periodic updates to Exhibits C and D.

The Applicant is a wholly-owned subsidiary of International Securities Exchange Holdings, Inc. (''ISE Holdings'').[10] ISE Holdings is a wholly-owned subsidiary of U.S. Exchange Holdings, Inc., which is 15% owned by Deutsche Börse AG (''Deutsche Börse'') and 85% owned by a German stock corporation, Eurex Frankfurt AG (''Eurex Frankfurt''). Eurex Frankfurt is wholly-owned by Deutsche Börse. According to the Applicant, the parent ownership structure of U.S. Exchange Holdings, Inc. is comprised entirely of foreign entities, Eurex Frankfurt and Deutsche Börse (collectively, the ''Foreign Direct Affiliates''), which in turn hold ownership interests, either directly or indirectly, in excess of 25% in a large number of other foreign entities, some of which also own interests in other entities in excess of 25% as well (such Foreign Direct Affiliate-owned entities are referred to, collectively, as the ''Foreign Indirect Affiliates'').[11]

Because of the limited and indirect nature of its connection to the Foreign Indirect Affiliates, the Applicant believes that the corporate and financial information of the Foreign Indirect Affiliates required by Exhibits C and D of Form 1 would have little relevance to the Commission's review of the Applicant's Form 1 application or, if the Commission were to approve the Applicant's Form 1 application, as amended, to the Commission's ongoing oversight of the Applicant as a national securities exchange.[12] In this regard, the Exemption Request states that the Foreign Indirect Affiliates have no ability to influence the management, policies, or finances of the Applicant and no obligation to provide funding to, or ability to materially affect the funding of, the Applicant.[13] The Exemption Request also states that: (1) The Foreign Indirect Affiliates have no ownership interest in the Applicant or in any of the controlling shareholders of the Applicant; and (2) there are no commercial dealings between the Applicant and the Foreign Indirect Affiliates.[14] Further, the Exemption Request states that obtaining detailed corporate and financial information with respect to the Foreign Indirect Affiliates (1) is unnecessary for the protection of investors and the public interest and (2) would be unduly burdensome and inefficient because these affiliates are located in foreign jurisdictions and the disclosure of such information could implicate foreign information sharing restrictions in such jurisdictions.[15]

As a condition to the granting of exemptive relief, the Applicant has agreed to provide: (i) A listing of the names of the Foreign Indirect Affiliates; (ii) an organizational chart setting forth the affiliation of the Foreign Indirect Affiliates and the Foreign Direct Affiliates and the Applicant; and (iii) in Exhibit C of the Applicant's Form 1 application, a description of the nature of the Foreign Indirect Affiliates' affiliation with the Foreign Direct Affiliates and the Applicant. In addition, as a condition to the granting of exemptive relief from the requirements of Exchange Act Rule 6a–2(a)(2), 6a–2(b)(1), and 6a–2(c), as described above, the Applicant has agreed to provide amendments to the information required under conditions (i) through (iii) above on or before June 30th of each year. Further, the Applicant notes that it will provide the information required by Exhibits C and D for all of its affiliates other than the Foreign Indirect Affiliates, including the Foreign Direct Affiliates.[16]

III. Order Granting Conditional Section 36 Exemption

Section 6 of the Exchange Act[17] sets forth a procedure for an exchange to register as a national securities exchange.[18] Exchange Act Rule 6a–1(a)[19] requires an application for registration as a national securities exchange to be filed on Form 1 in accordance with the instructions in Form 1. A Form 1 application is not considered filed until all necessary information, including financial statements and other required documents, has been furnished in the proper form.[20] Exchange Act Rule 6a–2 establishes ongoing requirements to file certain amendments to Form 1.

Section 36(a)(1) of the Exchange Act provides that ''the Commission, by rule, regulation, or order, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of [the Exchange Act] or of any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.'' [21] For the reasons discussed below, the Commission believes that it is appropriate in the public interest and consistent with the protection of investors to exempt the Applicant from the requirement under Exchange Act Rule 6a–1 to provide the information required in Exhibits C and D to Form 1 with respect to the Foreign Indirect Affiliates, subject to the following conditions:

(1) The Applicant must provide a list of the names of the Foreign Indirect Affiliates;

(2) the Applicant must provide an organizational chart setting forth the affiliation of the Foreign Indirect Affiliates and the Foreign Direct Affiliates and the Applicant; and

(3) as part of Exhibit C to the Applicant's Form 1 Application, the Applicant must provide a description of the nature of the affiliation between the Foreign Indirect Affiliates and the Foreign Direct Affiliates and the Applicant.

The Commission believes, further, that it is appropriate in the public interest and consistent with the protection of investors to exempt the Applicant, with respect to the Foreign Indirect Affiliates, from the requirements under: (a) Exchange Act Rule 6a–2(a)(2) to amend Exhibit C within 10 days of any action that renders the information in Exhibit C inaccurate or incomplete; (b) Exchange Act Rules 6a–2(c) to provide periodic updates of Exhibit C; and (c) Exchange Act Rules 6a–2(b)(1) to provide periodic updates of Exhibit D, subject to the condition that the Applicant provide amendments to the information required under conditions (1) through (3) above on or before June 30th of each year.

As part of an application for exchange registration, the information included in

[10] *See* Exemption Request, *supra* note 3, at 2.

[11] *See id.*

[12] *See id.* at 2–3.

[13] *See* Exemption Request, *supra* note 3, at 3.

[14] *See id.* The Applicant states that ''commercial dealings'' means any direct or indirect arrangement, agreement, or understanding or any other relationship including, but not limited to, the providing of hardware, software, technology services or any other goods or services that support the operation of ISE Mercury or any facility of ISE Mercury. *See id., supra* note 3, at 3 n. 5.

[15] *See id.* The Applicant also believes that providing the information required by Exhibits C and D with respect to the Foreign Indirect Affiliates could raise confidentiality concerns because many of the Foreign Indirect Affiliates are not public companies. *Id.*

[16] *See* Exemption Request, *supra* note 3, at 3.

[17] 15 U.S.C. 78f.

[18] Specifically, Section 6(a) of the Exchange Act states that ''[a]n exchange may be registered as a national securities exchange . . . by filing with the Commission an application for registration in such form as the Commission, by rule, may prescribe containing the rules of the exchange and such other information and documents as the Commission, by rule, may prescribe as necessary or appropriate in the public interest or for the protection of investors.'' Section 6 of the Exchange Act also sets forth various requirements to which a national securities exchange is subject.

[19] 17 CFR 240.6a–1(a).

[20] 17 CFR 202.3(b)(2). *See also supra* note 8.

[21] 15 U.S.C. 78mm(a)(1).

Exhibits C and D is designed to help the Commission make the determinations required under Sections 6(b) and 19(a) of the Exchange Act [22] with respect to the application. The updated Exhibit C and D information required under Exchange Act Rule 6a–2 is designed to help the Commission exercise its oversight responsibilities with respect to national securities exchanges. Specifically, Exhibit D is designed to provide the Commission with information concerning the financial status of an exchange and its affiliates and subsidiaries,[23] and Exhibit C is designed to provide the Commission with the names and organizational documents of these affiliates and subsidiaries.[24] Such information is designed to help the Commission determine whether an applicant for exchange registration would have, and a national securities exchange continues to have, the ability to carry out its obligations under the Exchange Act.

Since the most recent amendments to Form 1 in 1998,[25] many national securities exchanges that previously were member-owned organizations with few affiliated entities have demutualized. Some of these demutualized exchanges have consolidated under holding companies with numerous affiliates that, in some cases, have only a limited and indirect connection to the national securities exchange, with no ability to influence the management or policies of the registered exchange, and no obligation to fund, or to materially affect the funding of, the registered exchange. The Commission believes that, for these affiliated entities, the information required under Exhibits C and D would have limited relevance to the Commission's review of an application for exchange registration or to its oversight of a registered exchange.

Based on the Applicant's representations, the indirect nature of the relationship between the Applicant and the Foreign Indirect Affiliates, and the information that the Applicant will provide with respect to the Foreign Direct Affiliates and the Foreign Indirect Affiliates, the Commission believes that it will have sufficient information to review the Applicant's Form 1 application and to make the determinations required under Sections 6(b) and 19(a) of the Exchange Act with respect to its application for registration as a national securities exchange.[26] The Commission believes, further, that if the Commission were to approve the Applicant's Form 1 application, it will have the information necessary to oversee the Applicant's activities as a national securities exchange. In particular, the Commission notes that the Applicant has represented that it would have no direct connection to the Foreign Indirect Affiliates, that the Foreign Indirect Affiliates would have no ability to influence the management or policies of the Applicant, and that the Foreign Indirect Affiliates would have no obligation to fund, or ability to materially affect the funding of, the Applicant. In addition, the Commission notes that the Applicant has represented that: (1) The Foreign Indirect Affiliates have no ownership interest in the Applicant or in any of the controlling equity holders of the Applicant; and (2) there are no commercial dealings between the Applicant and the Foreign Indirect Affiliates.[27]

Given the limited and indirect relationship between the Applicant and the Foreign Indirect Affiliates, as described above, the Commission believes that the detailed corporate and financial information required in Exhibits C and D with respect to the Foreign Indirect Affiliates is unnecessary for the Commission's review of the Applicant's Form 1 application and would be unnecessary for the Commission's oversight of the Applicant as a registered national securities exchange following any Commission approval of its Form 1 application.

For the reasons discussed above, the Commission finds that the conditional exemptive relief requested by the Applicant is appropriate in the public interest and is consistent with the protection of investors.

The Commission may modify by order the terms, scope or conditions of this exemption if it determines that such modification is necessary or appropriate in the public interest, or is consistent with the protection of investors. Furthermore, the Commission may limit, suspend, or revoke this exemption if it finds that the Applicant has failed to comply with, or is unable to comply with, any of the conditions set forth in this order, if such action is necessary or appropriate in the public interest, or is consistent with the protection of investors.

It is ordered, pursuant to Section 36 of the Exchange Act,[28] that the Applicant is exempt from the requirements to: (1) Include in its Form 1 application the information required in Exhibits C and D to Form 1 with respect to the Foreign Indirect Affiliates; and (2) with respect to the Foreign Indirect Affiliates, update the information in Exhibits C and D to Form 1 as required by Exchange Act Rules 6a–2(a)(2), 6a–2(b)(1), and 6a–2(c) subject to the following conditions:

(i) The Applicant must provide a list of the names of the Foreign Indirect Affiliates;

(ii) the Applicant must provide an organizational chart setting forth the affiliation of the Foreign Indirect Affiliates and the Foreign Direct Affiliates and the Applicant; and

(iii) as part of Exhibit C to the Applicant's Form 1 Application, the Applicant must provide a description of the nature of the affiliation between the Foreign Indirect Affiliates and the Foreign Direct Affiliates and the Applicant.

In addition, the Applicant must provide amendments to the information required under conditions (i) through (iii) above on or before June 30th of each year.

By the Commission.

Robert W. Errett,

Deputy Secretary.

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[22] 15 U.S.C. 78f(b) and 78s(a).

[23] *See* Securities Exchange Act Release No. 18843 (June 25, 1982), 47 FR 29259 (July 6, 1982) (proposing amendments to Form 1); *see also* Form 1, 17 CFR 249.1, and *supra* Section II.A.

[24] Form 1, 17 CFR 249.1. *See also supra* note 4.

[25] *See* Regulation ATS Adopting Release, *supra* note 8, at Section IV.C.

[26] 15 U.S.C. 78f(b) and 78s(a). Section 6(b) of the Exchange Act enumerates certain determinations that the Commission must make with respect to an exchange before granting the registration of the exchange as a national securities exchange. The Commission will not grant an exchange registration as a national securities exchange unless the Commission determines that the exchange meets these requirements. *See* Regulation ATS Adopting Release, *supra* note 8, at Section IV.B.

[27] *See* Exemption Request, *supra* note 3, at 3; *supra* note 15.

[28] 15 U.S.C. 78mm.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75866; File No. SR–Phlx–2015–75]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the Phlx Pricing Schedule

September 9, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 27, 2015, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the Phlx Pricing Schedule (''Pricing Schedule''). Specifically, the Exchange proposes to amend Section I, entitled ''Rebates and Fees for Adding and Removing Liquidity in SPY'' by assessing all market participants other than Customers [3] a fee of $0.15 per contract for executions against an order for which the Exchange broadcasts an order exposure alert in SPY.[4]

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify the Pricing Schedule by amending Section I, entitled ''Rebates and Fees for Adding and Removing Liquidity in SPY.'' Currently, Section 1 provides that no fees will be assessed and no rebates will be paid on transactions which execute against an order for which the Exchange broadcast (sic) [5] an order exposure alert in SPY.[6]

The Exchange now proposes to assess all market participants other than Customers a fee of $0.15 per contract for such executions. Thus, the fee for such executions will apply to transactions for the accounts of Specialists,[7] Market Makers,[8] Firms,[9] Professionals,[10] Broker-Dealers [11] and JBOs [12] (collectively, ''Non-Customers''). The Exchange is adopting this fee at this time because it believes that the associated revenue will allow the Exchange to enhance its services and that offering this service for free is no longer a required incentive to remain competitive with other options exchanges.

2. Statutory Basis

The Exchange believes that its proposal to amend the Pricing Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) and (b)(5) of the Act [14] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which Phlx operates or controls, and is not designed to permit unfair discrimination between market participants to whom the Exchange's fees and rebates are applicable.

The Exchange's proposal is reasonable because the proposed $0.15 fee is lower than the standard fee for removing liquidity in SPY and lower than fees assessed for similar activities at other options exchanges. For example, the Chicago Board Options Exchange (''CBOE'') assesses fees ranging from $0.05 to $0.45 for executions in Equity and ETF Options, including SPY, and offers market makers a $0.05 rebate if they meet certain quoting obligations for executions in Hybrid Agency Liaison (''HAL''). The Exchange's order exposure alert is similar to HAL and the proposed rate is within the range of fees CBOE assesses for executions in HAL. It is also reasonable not to extend the new fee to Customer transactions because Customer orders bring valuable liquidity to the market which benefits other market participants. Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Specialists and Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

The Exchange's proposal is equitable and not unfairly discriminatory because the Exchange will be assessing the same new $0.15 fee on transactions by all market participants (except Customers) in the same manner. As stated above, Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Specialists and Market Makers. It is therefore equitable and not unfairly discriminatory to not apply the new fee to Customer transactions.

[3] The term ''Customer'' applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of broker or dealer or for the account of a ''professional'' (as that term is defined in Rule 1000(b)(14)). The term ''Non-Customer'' applies to transactions for the accounts of Specialists, Market Makers, Firms, Professionals, Broker-Dealers and JBOs.

[4] Options overlying Standard and Poor's Depositary Receipts/SPDRs (''SPY'') are based on the SPDR exchange-traded fund (''ETF''), which is designed to track the performance of the S&P 500 Index.

[5] The Exchange is correcting the word ''broadcast'' to read ''broadcasts''.

[6] Exchange Rule 1080(m) provides for the broadcast of certain orders that are on the Phlx Book. The Exchange broadcasts orders on the Phlx Book by issuing order exposure alerts to all Phlx market participants that subscribe to certain data feeds. *See* Securities Exchange Act Release No. 68517 (December 21, 2012), 77 FR 77134 (December 31, 2012) (SR-Phlx-2012–136). When it adopted the current pricing schedule provision which now is proposed to be amended, the Exchange stated its belief that not assessing fees (or paying a rebate) when removing orders from the order book in SPY where an order exposure alert was issued would incentivize market participants to remove liquidity from the Phlx Book. *See* Securities Exchange Act Release No. 69768 (June 14, 2013), 78 FR 37250 (June 20, 2013) (SR–Phlx–2013–61).

[7] A Specialist is an Exchange member who is registered as an options specialist pursuant to Rule 1020(a).

[8] A ''Market Maker'' includes Registered Options Traders (Rule 1014(b)(i) and (ii)), which includes Streaming Quote Traders (see Rule 1014(b)(ii)(A)) and Remote Streaming Quote Traders (see Rule 1014(b)(ii)(B)). Directed Participants are also market makers.

[9] The term ''Firm'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC.

[10] The term ''professional'' means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). See Rule 1000(b)(14).

[11] The term ''Broker-Dealer'' applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

[12] The term ''Joint Back Office'' or ''JBO'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC and is identified with an origin code as a JBO. A JBO will be priced the same as a Broker-Dealer. A JBO participant is a member, member organization or non-member organization that maintains a JBO arrangement with a clearing broker-dealer (''JBO Broker'') subject to the requirements of Regulation T Section 220.7 of the Federal Reserve System as further discussed at Exchange Rule 703.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4), (5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposal to impose the new $0.15 fee on executions other than Customer executions does not misalign the fees related to Customer as compared to Non-Customer orders. Today, Customers have lower fees because Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Specialists and Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The new fee does not impose any undue burden on competition as all market participants, except Customers will be assessed the same fee.

The Exchange operates in a highly competitive market, comprised of twelve options exchanges, in which market participants can easily and readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or rebates to be inadequate. Accordingly, the fees that are assessed and the rebates paid by the Exchange, as described in the proposal, are influenced by these robust market forces and therefore must remain competitive with fees charged and rebates paid by other venues and therefore must continue to be reasonable and equitably allocated to those members that opt to direct orders to the Exchange rather than competing venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2015–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2015–75. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–Phlx–2015–75 and should be submitted on or before October 6, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–23094 Filed 9–14–15; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31807; 812–13995]

TIAA–CREF Funds, et al.; Notice of Application

September 8, 2015.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under sections 6(c) and 17(b) of the Investment Company Act of 1940 (''Act'') for exemptions from section 17(a) of the Act, and under section 17(d) of the Act and rule 17d–1 thereunder to permit certain joint transactions.

SUMMARY OF APPLICATION: Applicants requests an order that would permit certain registered management investment companies or series thereof that are advised by Teachers Advisors, Inc. (''Advisors'') to invest in a private investment vehicle established by Advisors to invest directly in real estate.

APPLICANTS: TIAA–CREF Funds (the ''Trust''), Advisors, TIAA–CREF Real Property Fund LP (''TCLP''), TIAA–CREF Real Property Fund GP LLC (''TCGP''), and TIAA–CREF Real Property Fund REIT LLC (''TC REIT'').

FILING DATES: The application was filed on January 4, 2012, and amended on June 25, 2012, December 3, 2012, October 16, 2013, June 26, 2014, May 8, 2015, and September 4, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 5, 2015, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 of the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish

to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549. Applicants: TIAA–CREF, Attn: Rachael Zufall, 8500 Andrew Carnegie Boulevard, Charlotte, NC, 28262.

FOR FURTHER INFORMATION CONTACT: Mark N. Zaruba, Senior Counsel, at (202) 551–6878, or David Bartels, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is organized as a Delaware statutory trust and is an open-end management investment company registered under the Act. The Trust currently consists of multiple Funds (as defined below).

2. TCLP is organized as a limited partnership, and applicants state that it will rely on an exception from the definition of ''investment company'' such as Section 3(c)(1) or Section 3(c)(7) of the Act (or any other applicable exclusion). TCGP, the sole general partner of TCLP, is organized as a limited liability company and will be a direct or indirect wholly owned subsidiary of Teachers Insurance and Annuity Association of America (''TIAA''). As general partner of TCLP, TCGP will be responsible for the operational and administrative maintenance of TCLP, but it will not exercise any responsibilities for the management of TCLP's assets.

3. TC REIT is organized as a limited liability company, and Applicants anticipate that it will be excluded from the definition of ''investment company'' under Section 3(a)(1) of the Act by reason of its real estate investments. Applicants state that TC REIT will elect to be taxed as a real estate investment trust (''REIT'') under the Internal Revenue Code of 1986, as amended (the ''Code'') and will not incur separate, entity level tax under the current provisions of the Code.

4. Advisors, a Delaware corporation, is an investment adviser that is registered with the Commission under the Investment Advisers Act of 1940, as amended (the ''Advisers Act''). Advisors is an indirect, wholly owned subsidiary of TIAA. Advisors will be the investment adviser to each of the Funds (as defined below), TCLP and TC REIT.[1]

5. TIAA and Advisors believe that exposure to direct real estate investments is an important element of diversified retirement investing. Advisors seeks to provide shareholders who invest for retirement and other long-term purposes through the Funds (as defined below) with exposure to direct real estate. Applicants argue that direct exposure to real estate offers advantages over investment in conventional real estate mutual funds that invest primarily in publicly traded REITs. In addition, Applicants note that, while the Act does not preclude a registered management investment company from investing directly in real estate (provided that the fund is not subject to a fundamental policy precluding such investment and, in the case of an open-end fund, has sufficient liquidity to comply with applicable Commission and Commission staff positions), direct investment in real estate would be impractical due to the typical size of such investments and for tax reasons. Accordingly, applicants propose to allow each Fund (solely to the extent consistent with its investment policies, objectives, strategies and restrictions) to obtain exposure to real estate through TCLP, which will be dedicated to investing indirectly in real estate through TC REIT.

6. For this reason, Applicants request an order under sections 6(c) and 17(b) of the Act for exemptions from section 17(a) of the Act, and under section 17(d) of the Act and rule 17d-1 thereunder, to permit: (i) One or more Funds (as defined below) to purchase, hold and redeem units of limited partnership interests of TCLP (''Units''); (ii) TCLP to sell Units to one or more Funds and redeem such Units following demand of such Funds; (iii) to the extent it could be deemed an element of a ''joint transaction,'' as defined below, TCLP to purchase, hold and redeem interests in TC REIT; and (iv) the Funds and Other Accounts (as defined below) to engage in certain purchase or sale cross transactions in securities, all as described and subject to the conditions set forth in the application.[2]

7. Applicants request that the relief extend to each existing or future registered management investment company or series thereof that is advised by Advisors or any successor entity or any entity controlling, controlled by, or under common control with Advisors (each, a ''Fund'').[3] Applicants further request that the relief extend to any future limited partnership (''Future LP''), general partner thereof (''Future GP''), and underlying real estate investment vehicle (''Future Real Estate Fund'') in which such Future LP invests that has elected to be taxed as a REIT pursuant to the Code that operate in a manner that is identical to TCLP, TCGP and TC REIT except for the types of real estate investments held by a Future Real Estate Fund.[4]

8. Applicants state that TC REIT will invest in direct real estate holdings and, to maintain some liquidity, may invest a portion of its assets in liquid investments. To finance its investments in real estate holdings, TC REIT plans to borrow from banks, as well as from insurance companies, pension/retirement systems, state and federal government related entities (*e.g.,* Freddie Mac), investment banks, and other commercial lenders (*e.g.,* GE Capital Corporation (or its successor), Ally Financial) (lenders other than banks are referred to as ''Non-bank Commercial Lenders''). Applicants represent that TC REIT plans to incur loans from Non-bank Commercial Lenders because such lenders have been longstanding capital resources to the commercial real estate market and often are able to offer more favorable lending terms to borrowers.[5] TC REIT will not incur any loans that are callable at the option of the lender.

9. Applicants state that TCLP will invest a substantial portion of its assets in TC REIT and, if deemed appropriate by Advisors, may, for purposes of maintaining some liquidity, invest a portion of its assets in liquid investments. TCLP will incur expenses relating to the management of any liquid investments held by TCLP, as well as for

[1] Only Advisors or a successor entity will serve as investment adviser to TCLP or TC REIT, and any other investment adviser to TCLP or TC REIT will serve only as investment sub-adviser.

[2] Applicants acknowledge that they are not seeking, and the Commission is not granting, relief from any disclosure requirements that are applicable to Applicants.

[3] Each entity that currently intends to rely on the requested relief has been named as an applicant. For purposes of the requested order, ''successor'' is limited to an entity that results from reorganization into another jurisdiction or a change in the type of business organization.

[4] Any entity that relies in the future on the requested relief will comply with the terms and conditions of the Application as they apply to the corresponding current party.

[5] Applicants submit that, in light of the presence of a bona fide business purpose for TCLP and TC REIT and the difficulty a Fund would have in directly investing in real estate, the structure proposed by this Application can be distinguished from a structure intended primarily to evade leverage restrictions applicable to open-end funds.

the general operation and administration of the entity.[6]

10. TCLP will conduct a non-public offering of its Units, and will not be publicly traded. Applicants state that TCLP is currently expected to be made available solely to the Funds, although it is possible that it will be made available in the future to: (i) Unaffiliated registered investment companies, pension plans, other institutional investors or high-net-worth individuals (''Outside Investors''); as well as to (ii) pension plans, or other institutional investors or high-net-worth individuals for which Advisors or an affiliate of Advisors serves as investment adviser (''Other Accounts'').[7]

11. Applicants state that the Funds (as well as any Other Accounts or Outside Investors) that invest in TCLP will be able to purchase and redeem Units on a daily basis at the next determined net asset value (''NAV'') per Unit. In the event that TCLP is unable to accommodate investment demand from the Funds, Other Accounts and/or Outside Investors, opportunities for investment will be allocated in accordance with allocation policies and procedures drafted and maintained by Advisors.[8] Applicants represent that, while such allocation policies and procedures may be subject to revision over time, the allocation policies and procedures generally will allocate opportunities on a *pro rata* basis based on orders received, with normal exceptions for rounding and *de minimis* amounts, although applicants state that other allocation methodologies may be employed as appropriate. Any such methodology will be applied in a manner that is objective and verifiable and will be consistent with Advisors' fiduciary obligation to treat client accounts in a manner that is fair and provides for equality of opportunity over time. However, TCLP will reserve the right to give the Funds preferential access to opportunities to invest in TCLP as compared to Outside Investors and (to the extent permitted under the allocation policies and procedures) Other Accounts, and the Funds will always have opportunities to invest in TCLP that are at least as favorable as the opportunities to invest in TCLP made available to Other Accounts or Outside Investors. The policies and procedures will require the documentation of the basis of allocation, as well as the basis for any exception to the general principles set forth in the policies and procedures, which exception will be subject to review by legal or compliance personnel.

12. Applicants anticipate that TCLP will be managed to maintain sufficient liquidity to satisfy the daily liquidity needs of its limited partners under ordinary market conditions. However, any investment in TCLP will be subject to terms permitting TCLP, under circumstances described in the application, to (a) cease offering new Units; (b) limit or postpone redemptions in the event that TC REIT has insufficient liquidity to satisfy redemption requests; or (c) utilize a ''gate'' pursuant to which the amount of redemptions from TCLP by any limited partner on any business day may be limited to a percentage of the limited partner's investment in TCLP.[9] Accordingly, each Fund that is an open-end investment company will treat its investments in TCLP and any Future LPs as investments that are not liquid for purposes of any applicable rules or guidance of the Commission or its staff regarding the management of liquidity. Similarly, each Fund that is a closed-end investment company will, at all times, limit its holdings in TCLP (together with any Future LPs) to no more than 15% of its net assets.[10]

13. Redemption requests will be considered on a first in basis based upon the business day of receipt, unless a limited partner (other than a registered investment company or Other Account) has agreed to a lower priority of redemption. Except as a limited partner (other than a registered investment company or Other Account) has otherwise agreed, redemption requests of all investors will be treated equally, and TCLP will allocate redemption proceeds on a *pro rata* basis in the event that there are insufficient liquid assets to satisfy fully all redemption requests. The rules on redemption and TCLP's policy regarding the allocation of redemption proceeds, and any changes to either of these, will be disclosed to all prospective investors in TCLP. TCLP will have a written policy regarding the allocation of redemption proceeds that will be applied in a manner that is objective and verifiable and will be consistent with Advisors' fiduciary obligation to treat client accounts in a manner that is fair.

14. Each Fund and Other Account limited partner of TCLP will have identical rights, duties and obligations under the limited partnership agreement as each other Fund and Other Account limited partner. If Outside Investors are permitted to invest in TCLP, the Funds and Other Accounts will be entitled to purchase, hold and redeem Units on terms that are at least as favorable, including (without limitation) the expenses associated with an investment in TCLP, as the terms on which any Outside Investor purchases, holds or redeems Units. Limited partners other than the Funds and Other Accounts will have substantially similar rights, duties and obligations as the Funds and Other Accounts, but Applicants currently contemplate that they may distinguish among Outside Investors with respect to rights, duties and obligations pursuant to the terms of the limited partnership agreement, or otherwise, with respect to the following issues (without limitation): (a) Utilization of redemption gates; (b) limitation of rights of redemption; or (c) the level of expenses charged to limited partners other than the Funds and Other Accounts in connection with an investment in TCLP, which may be higher than the level of expenses borne by the Funds and Other Accounts.

15. TCLP will be able to purchase and redeem limited liability company interests in TC REIT on a daily basis at the next determined NAV. Applicants represent that TCLP will be the sole investor in TC REIT, other than the ninety-nine or more additional investors necessary or appropriate to allow TC REIT to qualify as a REIT under section 856(a)(5) of the Code (the ''Tax Holders''). The Tax Holders' interests in TC REIT will be preferred to TCLP's interests in TC REIT. However, (a) the Tax Holders will have only limited

[6] Applicants anticipate that TCLP will be able to efficiently deploy assets invested by the Funds in light of the ability of TCLP to invest in liquid investments in addition to interests in TC REIT, so that any Fund assets invested in TCLP that are not currently invested in real estate will be effectively deployed pending completion of real estate investments. The performance of TCLP, the costs of investing in TCLP, and the related expenses, will be considered by the Funds' Board during the course of its oversight of the Funds' investments in TCLP, including its annual determinations as required by condition 1 below.

[7] No Applicant, or an affiliated person thereof, will have a proprietary interest in any Outside Investor or Other Account, except that an Applicant or an affiliated person thereof may be a shareholder of an Outside Investor that is a registered investment company.

[8] Applicants are not seeking any comfort and acknowledge that the Commission is providing no opinion on whether these allocation policies and procedures meet the standards applicable under either the Act or the Advisers Act.

[9] TCLP expects that the ability to limit or postpone redemption will help to minimize transaction costs and any dilutive effects on non-redeeming limited partners. TCLP's ability to limit or postpone redemption and the circumstances under which TCLP may waive an established redemption gate, in whole or in part, are discussed in greater detail in the application.

[10] Applicants submit that, although closed-end Funds do not present the same concerns with respect to liquidity as open-end Funds, it is nonetheless appropriate to limit the investments of these Funds in TCLP (and Future LPs) to address concerns that may arise regarding complex structures and the use of leverage, among other things.

voting rights, (b) the Tax Holders' aggregate interests in TC REIT will be *de minimis* in relation to that of TCLP,[11] and (c) TC REIT will not issue additional interests to the Tax Holders after the initial organization of TC REIT (clause (a), (b), and (c), collectively, the ''Tax Holder Limitations'').[12] Accordingly, it is anticipated that TCLP will own substantially all of the total outstanding securities of TC REIT at all times during the operation of TC REIT.

16. Applicants represent that TC REIT will not participate in any joint enterprise or other joint arrangement, within the meaning of rule 17d–1 under the Act, with the Future Real Estate Funds or other TIAA related accounts, and the Applicants are not asking for an order pursuant to rule 17d–1 with respect to any such transaction. Further, Applicants state that TIAA has adopted policies and procedures applicable to any purchasing conflicts between TC REIT and any other TIAA related accounts, which are designed to allocate opportunities consistent with Advisors' fiduciary obligations to its clients and will be applied in a manner that is objective and verifiable.

Applicants' Legal Analysis

Section 17(a)—Purchase and Sale of Units

1. Section 17(a) of the Act generally prohibits an ''affiliated person'' as defined by section 2(a)(3) of the Act, or an affiliated person of an affiliated person, of a registered investment company, acting as principal, from purchasing securities or other property from the registered investment company or selling securities or other property to the registered investment company. Section 2(a)(3) of the Act defines an ''affiliated person'' of another person to include, among others, (a) any person directly or indirectly owning, controlling, or holding with power to vote, 5% or more of the outstanding voting securities of the other person; (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with the power to vote by the other person; and (c) any person directly or indirectly controlling, controlled by, or under common control with the other person. Section 2(a)(9) defines ''control'' to mean ''the power to exercise a controlling influence over the management or policies of a company, unless such power is solely the result of an official position with such company.''

2. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if the terms of the proposed transaction, including the consideration to be paid or received, are fair and reasonable and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of each registered investment company involved and with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any person or transactions from any provisions of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

3. Applicants state that the sale by TCLP of its Units to a Fund or the repurchase by TCLP of its Units from a Fund may be deemed to be prohibited by section 17(a) of the Act, as TCLP and each Fund may be deemed to be affiliated persons, or affiliated persons of affiliated persons, of each other under multiple theories. For example, the Fund may be deemed to be an affiliated person of TCLP in the event that it owns 5% or more of the Units in TCLP. In addition, TCLP could be deemed to be an affiliated person of an affiliated person of the Fund, if it is deemed to be under the control of or under common control with Advisors.

4. Applicants believe that the proposed transactions among the Funds and TCLP satisfy the requirements for relief from section 17(a) of the Act under both sections 17(b) and 6(c) of the Act.

5. Applicants submit that the proposed transactions are reasonable and fair and would not involve overreaching on the part of any person concerned. Before investment by a Fund in TCLP, the Fund's board of trustees (the ''Board''), including a majority of the Independent Trustees, would have made the determinations required under condition 1 below.[13] The Board, including the Independent Trustees, will review these determinations on at least an annual basis. Applicants represent that, currently, the Board is made up of ten trustees, all of whom are Independent Trustees. Further, Applicants notes that Advisors' ability to allocate a Fund's assets to investments in TCLP would be limited to address any potential for overreaching because (a) the allocation would be determined either by the Fund's glide path or would be within a range of permissible allocations approved in advance by the Board and (b) the Fund's investment would be limited under condition 3 below.

6. In addition, Applicants state that each Fund would purchase and sell Units on the same terms as each other Fund and any Other Account, and on terms that are at least as favorable as the terms on which Outside Investors would purchase and sell Units. TCLP also would sell its shares to or purchase its shares from a Fund at the next-calculated NAV per Unit. This value, which would be provided to the Funds on a daily basis, would be determined based on the valuations of the assets of TC REIT, which would be determined by using valuation methodologies that are consistent with section 2(a)(41) of the Act except that the TCLP Committee will, in reliance on independent appraisals obtained at least quarterly, make determinations that would otherwise be made by a board of directors.[14]

7. Applicants further submit that the proposed transactions would be consistent with the policies of each Fund. Applicants represent that the investment by a Fund in TCLP would be effected in accordance with the investment policies, objective, strategies and restrictions contained in the registration statement of the Fund.

8. Finally, Applicants submit that, for these reasons, as well as the benefits shareholders in the Funds would

[11] Applicants anticipate that the Tax Holders will invest, in aggregate, approximately $125,000 and will represent much less than 1% of the expected aggregate net assets of TC REIT.

[12] The Tax Holders' interests in TC REIT and the Tax Holder Limitations are discussed in greater detail in the application.

[13] The ''Independent Trustees'' are the trustees who are not interested persons of the Trust within the meaning of section 2(a)(19) of the Act.

[14] Applicants note that, in accordance with condition 9, TCLP will consolidate TC REIT for reporting purposes and the consolidated financial statements of TCLP will be prepared in accordance with Regulation S–X, will be audited by an independent auditor, and, if practicable, will be prepared as of the same date and for the same periods as the investing Funds. Applicants state that the Public Company Accounting Oversight Board auditing standards applicable to the audit of TCLP would be the same standards as those applicable to a registered investment company. Further, Applicants state that the U.S. Generally Accepted Accounting Principles and Regulation S–X would apply to the financial statements of both TCLP and a registered investment company. Thus, Applicants assert that critical accounting policies governing security valuation, accounting for investment transactions, recognition of investment income and of expenses, and accrual of expenses, which are often the critical policies applicable to investment companies, would apply in substantially the same manner for the financial statements of TCLP. Valuation of the assets of TCLP and TC REIT for which market quotations are not readily available will be overseen by a committee consisting of the employees and agents of TCLP, TIAA and/or its subsidiaries (the ''TCLP Committee'').

experience by reason of the Funds' investments in TCLP, the proposed transactions are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Section 17(d)

9. Section 17(d) of the Act and rule 17d–1 under the Act generally prohibit joint transactions involving registered investment companies and their affiliates unless the Commission has approved the transaction. In considering whether to approve a joint transaction under rule 17d–1, the Commission considers whether the proposed transaction is consistent with the provisions, policies, and purposes of the Act, and the extent to which the participation of the investment companies is on a basis different from or less advantageous than that of the other participants.

10. Applicants state that the sale of Units to a Fund, the Fund's holding of Units, the redemption of Units held by the Fund, an Other Account's purchase, holding and redemption of Units alongside a Fund, TCLP's purchase, holding and redemptions of interest in the TC REIT, and Advisors' management of the Funds, Other Accounts, TCLP and TC REIT at the same time that the Funds are investing in TCLP (directly) and TC REIT (indirectly) could be deemed to constitute a joint enterprise or joint arrangement among the Funds, Other Accounts, TCLP, TCGP, TC REIT, and Advisors because the Funds may be presumed to be affiliated persons, or affiliated persons of affiliated persons, of Advisors, Other Accounts, TCLP or TC REIT.

11. For the reasons discussed above, Applicants submit that the proposed transactions are consistent with the provisions, policies and purposes of the Act. Applicants further believe that, based on the terms of the proposed transactions and the conditions set forth below, the participation by the Funds in the proposed transactions would be on a basis no different from that of other Funds or Other Accounts or less advantageous than that of other Funds, Outside Investors or Other Accounts. A Fund will hold Units of TCLP only if it will at all times have identical rights, duties and obligations under the limited partnership agreement as each other Fund limited partner and Other Account limited partner. If Outside Investors or Other Accounts are permitted to invest in TCLP, the Funds will be entitled to purchase, hold and redeem Units on terms that are at least as favorable, including (without limitation) the expenses associated with an investment in TCLP, as the terms on which any Outside Investor purchases, holds or redeem Units and on terms that are the same as the terms on which any Other Account purchases, holds or redeems Units. TCLP and the Tax Holders will be the only investors in TC REIT, and the Tax Holders' interests will be subject to the Tax Holder Limitations. All transactions in Units would be priced in the same manner and would be redeemable under the terms discussed herein and disclosed to investors. In addition, any investment by a Fund in TCLP would be subject to oversight by the Fund's Board.

Section 17(a)—Cross Transactions

12. Applicants also propose that the Funds and Other Accounts be permitted to engage in certain purchase and sale cross transactions in securities (''Cross Transactions''). Applicants expect that these transactions will be between a Fund seeking to implement a portfolio strategy and an Other Account seeking to raise or invest cash, or vice versa. Applicants represent that the Funds currently are able rely on rule 17a–7 to engage in such Cross Transactions. However, if a Fund and an Other Account were deemed to be affiliated persons of an affiliated person of each other by virtue of their ownership or control affiliations with TCLP, the Funds may not be entitled to rely on rule 17a–7 because they would no longer be affiliated solely for the reasons permitted by the rule. Applicants represent that Funds and Other Accounts will not engage in Cross Transactions involving Units, and to the extent any Future LPs are created, TCLP and the Future LPs (and their respective subsidiaries) will not engage in cross-trades with each other.

13. Applicants represent that, when engaging in Cross Transactions, the Funds and Other Accounts will comply with the requirements set forth in rule 17a–(7)(a) through (g), as interpreted by the Commission staff. Applicants assert that the potential affiliations created by the TCLP structure do not affect the other protections provided by the rule, including the integrity of the pricing mechanism employed and oversight by each Fund's Board. Applicants also note that no brokerage commission, fee or other remuneration will be paid in connection with the transactions. Applicants, therefore, believe that Cross Transactions will be reasonable and fair, will not involve overreaching, and will be consistent with the purposes of the Act and the investment policy of each Fund.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. Advisors will not implement an initial decision to invest the assets of a Fund in TCLP unless prior to the Fund's initial investment in TCLP, the Board, including a majority of the Independent Trustees, has determined that: (a) Investment in TCLP (and indirectly in TC REIT) is an appropriate means to implement an investment decision made by Advisors for the Fund to seek real estate exposure; (b) investment in TCLP (and indirectly in TC REIT) is in the best interests of the Fund and its shareholders, taking into account, among other things, the management and administration fees of TCLP and TC REIT; (c) the management and administration fees to be charged by TCLP and TC REIT are for services in addition to, rather than duplicative of, services rendered to the Fund directly; and (d) the management and administration fees to be charged by TCLP and TC REIT are fair and reasonable in light of the usual and customary fees charged by others for services of the same nature and quality. The Board, including the Independent Trustees, will review these determinations on at least an annual basis. The basis for each of the Board's determinations required by this condition will be recorded in its minutes. If the Board does not make the determinations in clauses (c) and (d) in a review subsequent to the initial investment, Advisors will reimburse the Fund the amount of any management and administrative fee borne by the Fund as a direct investor in TCLP and an indirect investor in TC REIT charged since the most recent date on which the Board did make these determinations.

2. Prior to any initial or additional investments in Units, Advisors will determine that each Fund's investment in TCLP will be consistent with the Fund's investment policies, objective, strategies and restrictions, and purchases of Units will be determined either by the Fund's glide path or be limited such that total holdings remain within a range of permissible allocations approved in advance by the Board. For purposes of determining consistency with a Fund's investment policies, objective, strategies and restrictions, a Fund will look through its investment in TCLP (and indirectly in TC REIT) and apply its investment policies, objective, strategies and restrictions (except for any restriction relevant to the direct ownership of real estate assets) in such a manner that the Fund will not do

indirectly through TCLP and TC REIT that which it cannot do directly. For purposes of applying its investment policies, objective, strategies and restrictions, a Fund will be considered as owning its *pro rata* portion of the portfolio holdings of TCLP and TC REIT.

3. Each Fund that is an open-end investment company will treat its entire investments in TCLP and any Future LPs as investments that are not liquid for purposes of any applicable rules or guidance of the Commission or its staff regarding the management of liquidity. For example, under current guidelines, each such Fund must limit its aggregate holdings of illiquid assets, which for purposes of the requested relief include any investments in TCLP and any Future LPs, to 15% of its net assets. In addition, each Fund, including any open- or closed-end investment company, will, at all times, limit its holdings in TCLP (together with any Future LPs) to no more than 15% of its net assets.[15]

4. At all times that any Fund or other registered investment company holds an interest in TCLP, each of TCLP and TC REIT: (a) Will determine its respective net asset value per Unit or membership interest, as applicable, each Business Day; and (b) will maintain and comply with policies and procedures for valuing its assets that are consistent with section 2(a)(41) of the Act except that the TCLP Committee will, in reliance on independent appraisals obtained at least quarterly, make determinations that would otherwise be made by a board of directors (as if TCLP and TC REIT were subject to section 2(a)(41)) and with applicable U.S. generally accepted accounting principles (''U.S. GAAP'') (or successor accounting standards). For these purposes, ''Business Day'' means each day on which the Funds or other registered investment company determine net asset value per share, as disclosed in the Funds' or other registered investment company's registration statement.

5. A Fund will hold Units of TCLP only if it will at all times have identical rights, duties and obligations under the limited partnership agreement as each other Fund limited partner and Other Account limited partner. If Other Accounts or Outside Investors are permitted to invest in TCLP, the Funds will be entitled to purchase, hold and redeem Units on terms that are at least as favorable, including (without limitation) the expenses associated with an investment in TCLP, as the terms on which any Outside Investor purchases, holds or redeems Units and on terms that are the same as the terms on which any Other Account purchases, holds or redeems Units. Other than the Tax Holders' interests, which will be subject to the Tax Holder Limitations, TCLP will own at all times 100% of the voting and economic interests in TC REIT.

6. TC REIT and TCLP will be managed by an investment adviser that is registered as an investment adviser with the Commission. Any investment sub-adviser to TC REIT or TCLP will be registered as an investment adviser with the Commission or, if not registered, will consent to examination by the Commission staff with respect to the services it would provide to TC REIT or TCLP as if it were registered as an investment adviser.

7. The Funds' proposed investments in TCLP, and TCLP's investment in TC REIT, will not be subject to any sales load, redemption fee, distribution fee analogous to a 12b–1 fee, or service fee analogous to a FINRA Rule 2830 service fee imposed by TCLP or TC REIT.

8. Advisors shall cause TCGP, TCLP and TC REIT to maintain books and records as is consistent with Internal Revenue Service guidance and U.S. GAAP, shall cause the books and records of TCGP, TCLP and TC REIT to be made available for inspection by the Commission staff as would be required by the Act if each of TCGP, TCLP and TC REIT was a registered investment company, and, if requested, shall furnish copies of the books and records to the Commission staff.

9. TCLP will prepare consolidated annual and semi-annual financial reports and, for each quarter for which a semi-annual or annual report is not required to be prepared, a consolidated schedule of investments for TCLP. The financial statements of TCLP will be prepared in accordance with Regulation S–X and U.S. GAAP, will be audited by an independent auditor (for annual financial statements), and, if practicable, will be prepared as of the same date and for the same periods as the investing Funds. TCLP will consolidate TC REIT for financial reporting purposes. Any consolidated schedule of investments of TCLP will disclose each position that TCLP and TC REIT hold. The Trust, on behalf of each Fund that has invested 5% or more of its net assets in TCLP[16] as of the end of a reporting period, will attach, as an exhibit to each of the Trust's shareholder reports with respect to such a Fund filed on Form N–CSR and each of the Trust's quarterly reports with respect to such a Fund filed on Form N–Q, TCLP's audited or unaudited financial statements (which will consist of financial statements, footnotes, thereto and a schedule of investments) or schedule of investments for the period most recently ended. TCLP will deliver such annual and semi-annual financial statements and schedules of investments to the Trust in time to allow the Trust to make such filings. The relevant Fund's shareholder reports and quarterly reports will cross-reference the TCLP financial statements (for annual and semi-annual reports) or schedule of investments (for other quarters) filed as an exhibit to the form. If a Fund is required to attach and cross-reference the financial statements of TCLP solely for purpose of complying with this condition 9, (a) the Fund may disclaim that (i) the TCLP financial statements or schedule of investments constitute part of the Fund's financial statements, shareholder report or quarterly report, and (ii) the TCLP financial statements or schedule of investments are incorporated therein by reference, and (b) the certifications for each principal executive and principal financial officer required by rule 30a-2(a) under the Act that accompany Form N–CSR or Form N–Q filings with respect to such a Fund may make clear that the TCLP financial statements or schedule of investments that accompany the Form N–CSR or Form N–Q filings do not constitute part of the report to which the certificate relates.[17]

10. Neither TCLP nor TC REIT will acquire securities of any other investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent that TCLP or TC REIT: (a) Receives securities of another investment company as a dividend or as a result of a plan of reorganization of a company (other than a plan devised for the purpose of evading section 12(d)(1) of the Act); or (b) acquires (or is deemed

[15] Although closed-end Funds do not present the same concerns with respect to liquidity as open-end Funds, Applicants believe that it is nonetheless appropriate to limit the investments of these Funds in TCLP (and Future LPs) to address concerns that may arise regarding complex structures and the use of leverage, among other things.

[16] Investments in any Future LPs will be aggregated with investments in TCLP to determine whether a Fund has invested 5% or more of its net assets. If the aggregate investments are 5% or more, then the disclosure requirements under this condition will apply (for that Fund) with respect to information about TCLP and each Future LP in which that Fund is invested.

[17] As noted above, the requested order does not include relief from any existing disclosure requirements. Accordingly, the disclaimer and clarification contemplated in clauses (a) and (b) could not be included if the Fund is required to disclose information regarding the financial statements of TCLP for any purpose other than complying with this condition 9.

to have acquired) securities of another investment company pursuant to exemptive relief from the Commission permitting TCLP or TC REIT to (i) acquire securities of one or more investment companies for short-term cash management purposes, or (ii) engage in interfund borrowing and lending transactions.

11. A Fund will treat any leverage that TCLP or TC REIT incurs as though such leverage were incurred by the Fund for purposes of determining compliance with applicable restrictions under the Act relevant to the Fund's use of leverage. Under no circumstances will a Fund guarantee, or otherwise be responsible for the satisfaction of, any loan or obligation incurred by TCLP or TC REIT.

12. The TCLP and TC REIT will comply with the following sections of the Act as if the TCLP and TC REIT each were an open-end management investment company registered under the Act, except as noted: Section 9; section 12 (except that, to the extent necessary to implement the arrangements described herein, (i) the Funds may invest in Units issued by TCLP in accordance with condition 3, (ii) TCLP may issue Units to the investing Funds subject to the limits in condition 3, and (iii) TCLP may invest in TC REIT beyond the limits of sections 12(d)(1)(A) and (B)); section 13 (provided that section 13(a)(4) will apply as though it read only ''change the nature of its business''; the interests issued by TCLP and TC REIT will be regarded as voting securities under section 2(a)(42) of the Act for purposes of applying this condition; and the offering memoranda utilized by TCLP and TC REIT to offer and sell their interests will be regarded as registration statements for purposes of applying this condition); section 17(a) (except insofar as relief is provided by the order requested herein); section 17(d) (except insofar as relief is provided by the order requested herein); section 17(e); section 17(f); section 17(h); section 18 (although (a) the interests issued by TCLP and TC REIT will be regarded as voting securities under section 2(a)(42) of the Act for purposes of applying this condition, (b) TC REIT will be permitted to incur loans from Non-bank Commercial Lenders, subject to the asset coverage limit, and (c) TC REIT will not be required to restore 300% asset coverage within three days, as required under section 18(f), if such asset coverage falls below 300% solely as a result of a decline in the value of TC REIT's real estate holdings); section 21; section 36; and sections 37–53. In addition, the TCLP and TC REIT will comply with the rules under section 17(f)[18] and section 17(g) of the Act, as well as rule 22c-1 under the Act as if each of the TCLP and TC REIT were an open-end management investment company registered under the Act.

Advisors will cause TCGP, TCLP and TC REIT to, and TCGP, TCLP and TC REIT will, adopt policies and procedures designed to ensure that each of TCLP and TC REIT complies with the aforementioned sections of the Act and rules under the Act. Advisors will cause TCGP, TCLP and TC REIT to, and TCGP, TCLP and TC REIT will, periodically review and periodically update as appropriate such policies and procedures, maintain books and records describing such policies and procedures, and maintain the records required by rules 31a-1(b)(1), 31a-1(b)(2)(ii) and 31a-1(b)(9) under the Act. All books and records required to be made pursuant to this condition will be maintained and preserved for a period of not less than six years from the end of the fiscal year in which any transaction occurs, the first two years in an easily accessible place, and will be subject to examination by the Commission and its staff.

For purposes of implementing condition 12, any action that the above-referenced statutory and regulatory provisions require to be taken or made by the directors, officers and/or employees of a registered investment company will be performed by TCGP with respect to TCLP, and by Advisors (or its successor),[19] as managing member with respect to TC REIT. As noted in this Application, the TCLP Committee will oversee the valuation of the assets of TCLP and TC REIT for which market quotations are not readily available, which also will be relevant to the implementation of condition 12.

13. To engage in Cross Transactions, the Funds will comply with rule 17a-7 under the Act in all respects other than the requirement that the parties to the transaction be affiliated persons (or affiliated persons of affiliated persons) of each other solely by reason of having a common investment adviser or investment advisers which are affiliated persons of each other, common officers, and/or common directors, solely because a Fund and Other Account might become affiliated persons within the meaning of section 2(a)(3)(A), (B) or (C) of the Act because of their investments in TCLP.

[18] Applicants note that they will operate TCLP and TC REIT such that rules under section 17(f) will not be applicable to either entity.

[19] *See supra,* note 2.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–23093 Filed 9–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, September 17, 2015 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Aguilar, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Opinion;

Post-Argument Discussion;

Resolution of litigation claims; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: September 10, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–23221 Filed 9–11–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75863; File No. SR–NASDAQ–2015–082]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Approving a Proposed Rule Change To Introduce an Additional Data Element to the IPO Indicator Service

September 9, 2015.

I. Introduction

On July 15, 2015, The NASDAQ Stock Market LLC (''Nasdaq'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce an additional data element, the ''IPO Book Viewer,'' to its existing IPO Indicator Service. The proposed rule change was published for comment in the **Federal Register** on July 24, 2015.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Description of the Proposal

The Exchange proposes to adopt Exchange Rule 7015(j) to include the IPO Book Viewer as new data element as part of the IPO Indicator Service.[4] According to the Exchange, the IPO Indicator Service currently assists Nasdaq participants in monitoring the orders they have entered for execution in the Nasdaq Halt Cross for an IPO (''IPO Cross'').[5] The Exchange states that the IPO Indicator Service provides a market participant with information about the number of shares of its orders that would execute in the IPO Cross at the Current Reference Price.[6] Under the proposal, the IPO Book Viewer would be available only to the Exchange member that is acting as the stabilizing agent for the IPO security.[7] Access to the IPO Book Viewer will be limited through a secure entitlement process to designated individuals employed by the stabilizing agent.[8]

According to the Exchange, following the completion of the IPO Cross, the stabilizing agent [9] may enter a stabilizing bid into the market for the purpose of supporting the price of the IPO security during the remainder of its first day of trading.[10] The Exchange further states that the stabilizing agent stands ready during the course of the day to commit its capital in support of the IPO security, buying from investors that wish to sell the IPO security to realize short-term gains (or to minimize short-term losses).[11]

The Exchange states that on the day of an IPO, beginning with the start of the ''Display-Only Period,'' [12] and ending upon the completion of the IPO Cross for an IPO security, the IPO Book Viewer would display aggregated buying and selling interest information for the IPO security, reflecting all orders on the Nasdaq Book,[13] and consisting of the total number of orders and the aggregate size of all orders, grouped in $0.05, $0.10, or $0.25 price increments.[14] Under the proposal, the pricing increments could be adjusted by the stabilizing agent during the period that the IPO Book Viewer is available.[15] Under the proposal, the placement of the price bands will be standardized, beginning at $0.[16] The Exchange states that the aggregated information that would be provided through this data element would include all orders and size, including orders with a time-in-force of immediate or cancel; orders with reserve size; and non-displayed orders.[17] Under the proposal, the information provided through the IPO Book Viewer would be updated every five seconds, along with updates to the NOII.[18]

In addition, under the proposal, the stabilizing agent receiving the IPO Book Viewer would be required to maintain and enforce written policies and procedures reasonably designed to achieve the following purposes: (i) Restrict electronic access to aggregated information only to associated persons of the stabilizing agent who need to know the information in connection with establishing the opening price of an IPO security and stabilizing the IPO security; (ii) except as may be required for purposes of maintaining books and records for regulatory purposes, prevent the retention of aggregated information following the completion of the IPO Cross for the IPO security; and (iii) prevent persons with access to aggregated information from engaging in transactions in the IPO security other than transactions in the IPO Cross; transactions on behalf of a customer; or stabilizing.[19] Under the proposal, however, nothing contained in the proposed rule would be construed to prohibit the member acting as the stabilizing agent from (i) engaging in stabilizing consistent with that role, or (ii) using the information provided from the IPO Book Viewer to respond to inquiries from any person, including, without limitation, other members, customers, or associated persons of the stabilizing agent, regarding the expectations of the member acting as the stabilizing agent with regard to the possibility of executing stated quantities

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 75517 (July 24, 2015), 80 FR 45568 (''Notice'').

[4] *See* Exchange Rule 7015. Nasdaq notes that the IPO Indicator Service is available either as a feature of the Nasdaq Workstation product, or through a standalone product known as the Nasdaq IPO Workstation. *See* Notice, *supra* note 3, at 45568 n.4.

[5] *See id.* at 45568. The Exchange states that the Nasdaq Halt Cross is designed to provide for an orderly, single-priced opening of securities subject to an intraday halt, including securities that are the subject of an IPO. *See id.*

[6] *See id.* The Exchange states that prior to an IPO Cross, market participants enter eligible orders for participation in the IPO Cross, and the Exchange disseminates certain information regarding buying and selling interest entered and indicative execution price information, such information is known collectively as the Net Order Imbalance Indicator or ''NOII'', and includes, among other things, the Current Reference Price. *See id.* and Exchange Rules 4753(a)(3)(A) (defining ''Current Reference Price'') and 4753(a)(5) (defining ''Eligible Interest'').

[7] *See* proposed Exchange Rule 7015(j).

[8] *See* Notice, *supra* note 3, at 45569.

[9] The Exchange notes that the stabilizing agent is typically the lead underwriter and serves the function of being the designated representative of the underwriting syndicate that informs the Exchange that the IPO security is ready to commence trading, pursuant to the Exchanges rules governing the IPO Cross. *See* Notice, *supra* note 3 at, 45568.

[10] *See* Notice, *supra* note 3, at 45569. The Exchange notes that the stabilizing agent is subject to the requirements and limitations under Regulation M regarding ''stabilizing'' the IPO security. *See id.* at 45568 (citing 17 CFR 242.100).

[11] *See* Notice, *supra* note 3, at 45569.

[12] *See* Exchange Rule 4120(c)(7)(A) (describing ''Display Only Period'').

[13] *See* Exchange Rule 4701(a)(1) (defining ''Nasdaq Book'').

[14] *See* Notice, *supra* note 3, at 45569.

[15] *See* Notice, *supra* note 3, at 45569. For example, the Exchange states that if the IPO Book Viewer was configured to show $0.05 increments and the Nasdaq Book had 100 Orders to buy with a size of 200 shares each at each price from $39.99 to $39.95; and 100 Orders to buy with a size of 100 shares each at each price from $39.94 to $39.90, the IPO Book Viewer would show 500 Orders with an aggregate size of 100,000 shares for the $39.99 to $39.95 price band; and 500 Orders with an aggregate size of 50,000 shares for the $39.94 to $39.90 price band. *See id.* However, the Exchange notes that the stabilizing agent could not view multiple increments at the same time (*e.g.,* the viewer could view all $0.05 increments or all $0.25 increments, but could not view a $0.05 increment for prices near the NOII and wider increments for prices further away). *See id.* at, 45569 n.8.

[16] *See* Notice, *supra* note 3, at 45569. For example, the Exchange states that a stabilizing agent selecting $0.05 increments would always see orders priced from $20.00 to $20.04 and from $20.05 to $20.09, but could not modify the starting point of the price band to see orders priced from $20.01 to $20.05. *See* Notice, *supra* note 3, at 45569.

[17] The Exchange notes that the IPO Book Viewer would not provide any information regarding IOC or non-displayed orders or reserve size other than in the aggregated format described above, and will not provide any information regarding the identity of market participants posting orders. *See id.*

[18] *See id.*

[19] *See* proposed Exchange Rule 7015(j)(1)(A)(i)-(iii). *See also* Notice, *supra* note 3, at 45570.

of an IPO security at stated prices in the IPO Cross.[20] The proposal would also require that the aggregated information provided through the IPO Book Viewer would be available solely for display on the screen of a computer for which an entitlement has been provided by the Exchange and under no circumstances may a member redirect aggregated information to another computer or reconfigure it for use in a non-displayed format, including, without limitation, in any trading algorithm.[21] Finally, the Exchange proposes that if a member became aware of any violation of the restrictions contained in the proposed rule, it must report the violation promptly to the Exchange.[22]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[23] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[24] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and Section 6(b)(8) of the Act,[25] which requires that the rules of the exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

As described above, the proposed rule change would provide the Exchange member acting as stabilizing agent for an IPO security with access to the IPO Book Viewer, which would display aggregated buying and selling interest information for the IPO security, grouped in $0.05, $0.10, or $0.25 price increments. The Exchange believes that the IPO Book Viewer would, among other things, allow the stabilizing agent to respond in a more informed way to questions from its customers and other market participants regarding expectations that an order to buy or sell with a stated price and size may be executable in the IPO Cross and would assist the stabilizing agent in making decisions about the appropriate level of capital to commit to support the IPO security once trading commences.[26] The Exchange proposes to provide access to the IPO Book Viewer only to the Exchange member acting as stabilizing agent for the IPO security because of the unique role played by the stabilizing agent on the day of an IPO.[27]

The Commission notes that the Exchange has proposed a number of safeguards to help ensure that the aggregated information is not misused, including that the stabilizing agent maintain and enforce written policies and procedures restricting electronic access to the information only to certain persons, preventing the retention of the information, and preventing those with access to the information from trading in the IPO security, except in limited circumstances.[28] In addition, the Commission notes that the information provided through the IPO Book Viewer would be available solely for display on the screen of a computer for which an entitlement has been provided by the Exchange, access to the IPO Book Viewer will terminate immediately upon the completion of IPO Cross, and an Exchange member must report promptly to the Exchange any violation of the restrictions contained in proposed Exchange Rule 7015(j). The Commission also notes that the proposed rule change is similar to an existing rule on another exchange,[29] but is generally more restrictive with respect to the use of information about orders.[30] Accordingly, the Commission believes that the proposed rule change to add the IPO Book Viewer to the IPO Indicator Service is designed to protect investors and the public interest by providing the Exchange member acting as stabilizing agent with additional information that could, among things, assist the stabilizing agent in responding to questions from customers and market participants regarding expectations that a particular order may execute in the IPO Cross.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[31] that the proposed rule change (SR–NASDAQ–2015–082) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–23096 Filed 9–14–15; 8:45 am]

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[20] *See* proposed Exchange Rule 7015(j)(1)(D). *See also* Notice, *supra* note 3, at 45570.

[21] *See* proposed Exchange Rule 7015(j)(1)(B). *See also* Notice, *supra* note 3, at 45570.

[22] *See* proposed Exchange Rule 7015(j)(1)(C). *See also* Notice, *supra* note 3, at 45570. The Exchange also proposes to define the terms ''IPO security,'' ''stabilizing,'' ''stabilizing agent,'' ''IPO Indicator Service,'' and ''IPO Book Viewer.'' *See* proposed Exchange Rule 7015(j)(2).

[23] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[24] 15 U.S.C. 78f(b)(5).

[25] 15 U.S.C. 78f(b)(8).

[26] *See* Notice, *supra* note 3, at 45569.

[27] *See id.* (noting that the stabilizing agent stands ready during the course of the day to commit its capital in support of the IPO security and thereby serves to dampen volatility in the IPO security and promote the maintenance of a fair and orderly market. Nasdaq believes that providing additional information about the pre-opening interest in the stock to the stabilizing agent will help it to optimize the opening of the stock and manage its own risk, which will assist it in promoting a fair and orderly market for the IPO security).

[28] *See supra* note 19 and accompanying text.

[29] *See* NYSE Rule 104. *See also* Securities Exchange Act Release No. 71175 (December 23, 2013), 78 FR 79534 (December 30, 2013) (SR–NYSE–2013–21 and SR–NYSEMKT–2013–25).

[30] For example, NYSE Rule 104 permits Designated Market Makers to access disaggregated information about the price and size of any individual order and to disclose disaggregated information about the price and size of any individual order to floor brokers in response to an inquiry in the normal course of business. *See id.* at 79538. In contrast, the Exchange's proposal would only permit the stabilizing agent to access aggregated order information and share such aggregated information with others in response to inquiries. *See* proposed Exchange Rule 7015(j).

[31] 15 U.S.C. 78s(b)(2).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75865; File No. SR–FINRA–2015–031]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Establish an Administration and Delivery Fee for the Municipal Advisor Representative Examination (''Series 50 Examination'')

September 9, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 1, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Section 4(c) of Schedule A to the FINRA By-Laws to establish an administration and delivery fee for the new Municipal Advisor Representative Examination (''Series 50 examination'').

Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

SCHEDULE A TO THE BY-LAWS OF THE CORPORATION

* * * * *

Section 4—Fees

(a) through (b) No Change.

(c) The following fees shall be assessed to each individual who registers to take an examination as described below. These fees are in addition to the registration fee described in paragraph (b) and any other fees that the owner of an examination that FINRA administers may assess.

Series 4—Registered Options Principal—$105
Series 6—Investment Company Products/Variable Contracts Representative—$100
Series 7—General Securities Representative—$305
Series 9—General Securities Sales Supervisor—Options Module—$80
Series 10—General Securities Sales Supervisor—General Module—$125
Series 11—Assistant Representative—Order Processing—$80
Series 14—Compliance Official—$350
Series 16—Supervisory Analyst—$240
Series 17—Limited Registered Representative—$80
Series 22—Direct Participation Programs Representative—$100
Series 23—General Securities Principal Sales Supervisor Module—$100
Series 24—General Securities Principal—$120
Series 26—Investment Company Products/Variable Contracts Principal—$100
Series 27—Financial and Operations Principal—$120
Series 28—Introducing Broker-Dealer Financial and Operations Principal—$100
Series 37—Canada Module of S7 (Options Required)—$185
Series 38—Canada Module of S7 (No Options Required)—$185
Series 39—Direct Participation Programs Principal—$95
Series 42—Registered Options Representative—$75
Series 50—Municipal Advisor Representative—$115
Series 51—Municipal Fund Securities Limited Principal—$105
Series 52—Municipal Securities Representative—$130
Series 53—Municipal Securities Principal—$115
Series 55—Limited Representative—Equity Trader—$110
Series 62—Corporate Securities Limited Representative—$95
Series 72—Government Securities Representative—$110
Series 79—Investment Banking Qualification Examination—$305
Series 82—Limited Representative—Private Securities Offering—$95
Series 86—Research Analyst—Analysis—$185
Series 87—Research Analyst—Regulatory—$130
Series 99—Operations Professional—$130

(1) through (4) No Change.

(d) through (i) No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA is proposing amendments to Schedule A to the FINRA By-Laws to establish an administration and delivery fee for the Series 50 examination. On February 26, 2015, the Commission approved amendments to Municipal Securities Rulemaking Board (''MSRB'') Rule G–3 to establish two new registration classifications for municipal advisors: [3] (1) Municipal advisor representatives (*i.e.,* those individuals who engage in municipal advisory activities); and (2) municipal advisor principals (*i.e.,* those individuals who engage in the management, direction or supervision of the municipal advisory activities of the municipal advisor or its associated persons).[4] To qualify as a municipal advisor representative or municipal advisor principal, an individual must pass an appropriate qualification examination (the Series 50 examination) before his or her registration can become effective.

Because the Series 50 examination is a new examination for two new registration classifications for municipal advisors, the MSRB plans to launch a pilot test of the examination in early 2016 to validate its bank of test questions and set the passing score for the permanent examination. A permanent Series 50 examination is expected to be in place in 2016.

FINRA develops, maintains and delivers all FINRA qualification examinations for individuals who are registered or seeking registration with FINRA. FINRA also administers and delivers examinations developed by the MSRB and other self-regulatory organizations.[5] The SEC has designated FINRA to administer and deliver the Series 50 examination for municipal advisors.[6]

FINRA currently administers examinations electronically through the PROCTOR® system [7] at testing centers operated by vendors under contract

[3] The term ''municipal advisor'' is defined to mean a person that: (i) Provides advice to or on behalf of a municipal entity or obligated person with respect to municipal financial products or the issuance of municipal securities, including advice with respect to the structure, timing, terms, and other similar matters concerning such financial products or issues; or (ii) undertakes a solicitation of a municipal entity. The definition includes financial advisors, guaranteed investment contract brokers, third-party marketers, placement agents, solicitors, finders, and swap advisors that are engaged in municipal advisory activities, unless they are statutorily excluded. The definition does not include a municipal entity or an employee of a municipal entity. *See* 15 U.S.C. 78*o*–4(e)(4).

[4] *See* Securities Exchange Act Release No. 74384 (February 26, 2015), 80 FR 11706 (March 4, 2015) (Order Approving File No. SR–MSRB–2014–08).

[5] In this regard, the Exchange Act provides that a registered securities association shall administer required qualification examinations for municipal securities brokers and municipal securities dealers who are members of the association. *See* 15 U.S.C. 78*o*–4(c)(7)(A)(i).

[6] *See* Securities Exchange Act Release No. 75714 (August 17, 2015), 80 FR 50883 (August 21, 2015) (Designation of the Financial Industry Regulatory Authority to Administer Professional Qualification Tests for Associated Persons of Registered Municipal Advisors). Section 15B(c)(7)(A)(iii) of the Exchange Act requires that the SEC or its designee administer qualification examinations for municipal advisors. The SEC previously designated FINRA to examine FINRA members' activities as registered municipal advisors and evaluate compliance by such members with federal securities laws, SEC rules and regulations, and MSRB rules applicable to municipal advisors. *See* Securities Exchange Act Release No. 70462 (September 23 [sic], 2013), 78 FR 67467 (November 12, 2013) (Registration of Municipal Advisors).

[7] PROCTOR is a computer system that is specifically designed for the administration and delivery of computer-based testing and training.

with FINRA. For qualification examinations sponsored by a FINRA client and administered by FINRA, FINRA charges an administration and delivery fee that represents either a portion of or the entire examination fee. Consistent with this practice, FINRA will charge an administration and delivery fee of $115 for the Series 50 examination.[8] The proposed administration and delivery fee will offset FINRA's costs associated with the administration and delivery of the Series 50 examination and contribute to FINRA's overall revenue. The administration and delivery fee charged by FINRA for the Series 50 examination will be used, in part, to cover the fees that vendors charge FINRA for delivering qualification examinations through their networks of test delivery centers and PROCTOR system maintenance and enhancement expenses.

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the implementation date of the proposed rule change will be September 21, 2015.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[9] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.

FINRA believes that the proposed rule change constitutes an equitable allocation of fees as the administration and delivery fee, in part, will be used to cover FINRA's costs in administering and delivering the examination and will be assessed only on those individuals who take the Series 50 examination. FINRA further believes that the proposed administration and delivery fee for the Series 50 examination is reasonable because it is aligned with the overall cost associated with the Series 50 examination program.

Accordingly, FINRA believes that the proposed administration and delivery fee for the Series 50 examination is equitably allocated and reasonable.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that the establishment of the administration and delivery fee for the Series 50 examination will have a limited economic impact on the industry.

FINRA would administer this examination as a service provider to the MSRB as designated by the SEC. In providing this service, FINRA is not exercising regulatory discretion and therefore is not itself imposing burdens on those individuals who may choose to sit for the examination.

FINRA does exercise discretion in establishing the administration and delivery fee. However, in establishing an administration and delivery fee of $115 for the Series 50 examination, FINRA applied the same criteria as it does for establishing the fees for other examinations with similar characteristics related to test length and projected volume. The MSRB has indicated that approximately 3,900 individuals will be taking the examination for the initial round of testing. Based on FINRA's experience with other industry tests, FINRA projects that the annual testing volumes will be approximately five to ten percent of the total registrant volume. The administration and delivery fees may be paid by the individuals taking the examination or their associated firms. The proposed administration and delivery fee will also offset FINRA's costs associated with the administration and delivery of the Series 50 examination and contribute to FINRA's overall revenue. The Series 50 examination is anticipated to have the same number of questions (and thus seat time at test centers) as the Series 53 (Municipal Securities Principal) examination, which is sponsored by the MSRB and administered and delivered by FINRA for a fee of $115.

Economic Impact Assessment

Need for the Rule

This proposal is in response to amendments to MSRB Rule G–3. As discussed above, the Commission approved amendments to MSRB Rule G–3 to establish two new registration classifications for municipal advisors: Municipal advisor representatives and municipal advisor principals. To qualify as a municipal advisor representative or municipal advisor principal, an individual must pass an appropriate qualification examination before his or her registration can become effective. The SEC has designated FINRA to administer and deliver the examination for municipal advisors. Accordingly, FINRA needs to establish the administration and delivery fee for the examination.

Regulatory Objective

FINRA aims to establish an administration and delivery fee that would allow FINRA to recover its costs for providing this service and to contribute to FINRA's overall revenue.

Economic Baseline

The Series 50 examination is a new examination for two new registration classifications for municipal advisors established by amendments to MSRB Rule G–3. The economic impact of the amendments depends on the current classifications and qualification requirements for municipal advisor professionals engaging in or supervising municipal advisory activities. As noted above, FINRA would administer this examination as a service provider to the MSRB as designated by the SEC. Accordingly, the scope of the economic impact assessment of this proposal is limited to the impact of the establishment of the administration and delivery fee.

Economic Impacts

The impact of the proposed administration and delivery fee on the industry will depend on the demand for the examination. The MSRB has indicated that approximately 3,900 individuals will be taking the examination for the initial round of testing. Based on FINRA's experience with other industry tests, FINRA projects that the anticipated annual testing volumes will be approximately five to ten percent of the total registrant volume. The administration and delivery fees may be paid by the individuals taking the examination or their associated firms.

The proposed administration and delivery fee will offset FINRA's costs associated with the administration and delivery of the Series 50 examination and contribute to FINRA's overall revenue. FINRA has based its administration and delivery fee on costs related to test delivery (which are primarily driven by the length of the testing appointment), annual testing volumes, operational support costs and a nominal margin. The pricing was also evaluated against testing programs of comparable test length, annual projected testing volumes and support services to ensure comparability. FINRA staff

[8] The administration and delivery fee represents a portion of the entire examination fee when a FINRA client has established an additional fee for an examination that it sponsors. The fee to take the Series 50 examination will be $265. Of this amount, $115 is the FINRA administration and delivery fee, and $150 is the development fee determined by the FINRA client, the MSRB. *See* MSRB Rule A–16.

[9] 15 U.S.C. 78*o*–3(b)(5).

review revenue and expenses annually to determine if any adjustments should be made to account for changes in expenses associated with the delivery and support of all testing programs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and paragraph (f)(2) of Rule 19b–4 thereunder.[11] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2015–031 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2015–031. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2015–031, and should be submitted on or before October 6, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–23095 Filed 9–14–15; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of NMI Health, Inc., Order of Suspension of Trading

September 11, 2015.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of NMI Health, Inc. (CIK No. 1088213), a Nevada corporation with its principal place of business listed as Reno, Nevada with stock quoted on OTC Link (previously, ''Pink Sheets'') operated by OTC Markets Group, Inc. (''OTC Link'') under the ticker symbol NANM, because it has not filed any periodic reports since it filed a Form 10–K for the period ended December 31, 2013. On August 15, 2014, a delinquency letter was sent by the Division of Corporation Finance to NMI Health, Inc. requesting compliance with their periodic filing obligations, and the letter was received by NMI Health, Inc. on August 18, 2014.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of NMI Health, Inc.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of NMI Health, Inc. is suspended for the period from 9:30 a.m. EDT on September 11, 2015, through 11:59 p.m. EDT on September 24, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–23238 Filed 9–11–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Order of Suspension of Trading

September 11, 2015.

In the Matter of American Smooth Wave Ventures Inc., ASA International Ltd., Baker Manufacturing Co., Center For Wound Healing, Inc. (The), China Interactive Education, Inc., China Now, Inc., China Prosperous Clean Energy Corp., Cleopatra International Group, Inc., Craft College, Inc., Denia Enterprises, Inc., English Language Learning & Instruction System, Inc., Garman Cabinet & Millwork, Inc., KBK Capital Corp., LeapLab Corp., Lee Fine Arts, Inc. (a/k/a Commerce Holdings, Inc.), Maplex Alliance, Ltd., Obsidian Enterprises, Inc., Octavian Global Technologies, Inc., Ostashkov Industrial, Inc., Single Source Investment Group, Inc., Tupper, Inc., UBK Resources Co., Vomart International Auto Parts, Inc., Wilson Creek Mining Corp., Yuanwang Rich Selenium Agricultural Products Group Holding Co., Zhongbao International, Inc.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate public information concerning the securities of each of the issuers detailed below because questions have arisen as to their operating status, if any. Each of the issuers below is quoted on OTC Link operated by OTC Markets Group, Inc. The staff of the Securities and Exchange Commission has independently endeavored to determine whether any of the issuers below are operating. Each of the issuers below either confirmed they were now private companies or failed to respond to the staff's inquiry about their operating status, did not have an operational address, or failed to provide their registered agent with an operational address. The staff of the Securities and Exchange Commission also determined that none of the issuers below has filed any information with OTC Markets Group, Inc. or the

Securities and Exchange Commission for the past two years.

Issuer	Ticker	Information regarding operating status *
1. American Smooth Wave Ventures Inc.	ASWV	1
2. ASA International Ltd.	ASAL	2
3. Baker Manufacturing Co.	BKRM	2
4. Center for Wound Healing, Inc. (The)	CFWH	1
5. China Interactive Education, Inc.	CIVN	1
6. China Now, Inc.	CINW	1
7. China Prosperous Clean Energy Corp.	CHPC	1
8. Cleopatra International Group, Inc.	CLIN	1
9. Craft College, Inc.	CRAF	1
10. Denia Enterprises, Inc.	DNIA	1
11. English Language Learning & Instruction System, Inc.	ELLG	1
12. Garman Cabinet & Millwork, Inc.	GNTM	1
13. KBK Capital Corp.	KBKC	1
14. LeapLab Corp.	LLAB	1
15. Lee Fine Arts, Inc. (a/k/a Commerce Holdings, Inc.)	LEFA	1
16. Maplex Alliance, Ltd.	MAPX	1
17. Obsidian Enterprises, Inc.	OBDE	1
18. Octavian Global Technologies, Inc.	OCTV	1
19. Ostashkov Industrial, Inc.	OSKV	1
20. Single Source Investment Group, Inc.	SGSP	1
21. Tupper, Inc.	TPPR	1
22. UBK Resources Co.	UBKR	1
23. Vomart International Auto Parts, Inc.	VOMT	1
24. Wilson Creek Mining Corp.	WCRE	1
25. Yuanwang Rich Selenium Agricultural Products Group Holding Co.	YUNW	1
26. Zhongbao International, Inc.	ZBIT	1

* Below are explanations for each of the codes used in the above table:
1 = The staff of the Securities and Exchange Commission attempted to contact the issuer and either the staff did not receive a response to its letter, the letters were returned as undeliverable, or the registered agent responded that they had no forwarding address for the issuer.
2 = The staff of the Securities and Exchange Commission was able to contact the issuer, which informed the staff that it was now a private company.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on September 11, 2015, through 11:59 p.m. EDT on September 24, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–23237 Filed 9–11–15; 4:15 pm]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration by the Final Order of the United States District Court for the Eastern District of Tennessee (Chattanooga), entered September 19, 2011, the United States Small Business Administration hereby revokes the license of Valley Capital Corporation, a Tennessee Corporation, to function as a small business investment company under the Small Business Investment Company License No. 04/04–5216 issued to Valley Capital Corporation, on October 8, 1982, and said license is hereby declared null and void as of September 28, 2011.

United States Small Business Administration.

Dated: September 8, 2015.

Javier E. Saade,

Associate Administrator for Investment.

[FR Doc. 2015–22978 Filed 9–14–15; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day Notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before October 15, 2015.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: On October 1, 2014, the Small Business Administration (SBA)'s Office of Entrepreneurial Development (OED) began the ScaleUp America initiative to expand the delivery of proven best practices in entrepreneurship education to reach more growth-oriented small business owners. Through this initiative, organizations in eight communities across the U.S. have been selected to deliver targeted and intensive assistance to established, growth-oriented small businesses and entrepreneurs. ScaleUp program goals include the growth of participating businesses, the strengthening of local entrepreneurial ecosystems (*e.g.* the network of supportive resources available to the entrepreneur), and the creation of jobs and economic growth in targeted communities.

SBA is conducting an evaluation of the ScaleUp America initiative to assess the education services provided to the participants, the effect of the assistance on achieving the business goals of the participants, participant satisfaction with the assistance, and lessons learned and recommendations provided by the participants. Through the quarterly and annual reports provided by ScaleUp administrators, SBA has the ability to collect some data on the participants and program activities. However, in order to develop a more systematic analysis on the full range of topics mentioned above, including the participants' feedback, SBA needs to collect survey and interview data from participants who attended the program, as well as from individual entrepreneurs who are recruited as members of a community-specific comparison group.

Specifically, SBA proposes the use of four instruments for data collection and analysis. These instruments are: (1) Participant Intake Survey, (2) Comparison Group Member Intake Survey and (3) Participant Follow-up Survey. SBA plans to administer each of these survey instruments to more than nine individuals. In addition, SBA plans to interview two participants or community members in each of the eight ScaleUp communities regarding program impact and successes or challenges.

Each of the proposed surveys will be administered electronically and will contain both open- and close-ended questions. The types of information that will be collected in the instruments can be found in the ''Summary of Information Collection'' section below. Quantitative analysis (the primary method of data analysis for the survey data) and qualitative analysis (the primary method of data analysis for the interview data) will be used on the data collected. Quantitative analysis will consist of univariate and multivariate statistical analyses, while qualitative analysis will consist of establishing clear rules for interpretation and finding themes in the qualitative data. The information collected and analyzed from these instruments will contribute to performance metrics and program goals, as well as recommendations on improving program practices.

Solicitation of Public Comments: Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collections:

Title: Scaleup America Initiative.

Description of Respondents: Growth oriented Small Business Owners.

Form Number: N/A.

Estimated Annual Responses: 1,792.

Estimated Annual Hour Burden: 1,232.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2015–23098 Filed 9–14–15; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 9271]

Culturally Significant Object Imported for Exhibition Determinations: ''Judith and Holofernes'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the object to be included in the exhibition ''Judith and Holofernes,'' imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at The Metropolitan Museum of Art, New York, New York, from on or about December 1, 2015, until on or about December 1, 2018, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a description of the imported object, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: September 9, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–23262 Filed 9–14–15; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Pilot Program for Transit-Oriented Development Planning Project Selections

AGENCY: Federal Transit Administration, DOT.

ACTION: Pilot program for transit-oriented development planning announcement of project selections.

SUMMARY: The U.S. Department of Transportation's (DOT) Federal Transit Administration (FTA) announces the selection of projects for Fiscal Year 2013 and 2014 funds under the Pilot Program for Transit-Oriented Development Planning, as authorized under Section 20005(b) of the Moving Ahead for Progress in the 21st Century Act (MAP–21), Public Law 112–141. On September 4, 2014, FTA published a Notice of Funding Availability (NOFA) (79 FR 171) announcing the availability of $19.98 million in funding for this program. This program supports comprehensive planning efforts associated with new fixed guideway and core capacity improvement projects to assist project sponsors in the development of information to address FTA's Capital Investment Grant (CIG) Program evaluation criteria.

FOR FURTHER INFORMATION CONTACT: Successful applicants should contact the appropriate FTA Regional Office for information regarding applying for the

funds. For program-specific information, applicants may contact Benjamin Owen, FTA Office of Planning and Environment, at (202) 366–5602 or *benjamin.owen@dot.gov*. A list of Regional Offices can be found at *www.fta.dot.gov*. A TDD is available at 1–800–877–8339 (TDD/FIRS).

SUPPLEMENTARY INFORMATION: In response to the NOFA, FTA received 28 project proposals from project sponsors located in 20 States. Project proposals were evaluated based on each applicant's responsiveness to the program evaluation criteria as detailed in the NOFA. Four of the 28 projects were deemed ineligible to receive funds because they did not meet the eligibility requirements described in the NOFA. Two of the 28 projects were cancelled by the project sponsors during the course of the evaluation process, and a third was under review by local decision-makers for possible cancellation or advancement, but with a significantly altered project scope. The remaining 21 projects were eligible and consistent with the goals of the NOFA, and FTA is funding each of these projects as shown in Table I for a total of $19.49 million.

Grantees selected for competitive discretionary funding should work with their FTA Regional Office to submit a grant application in FTA's electronic grants management system so that funds can be obligated expeditiously. Grant applications must only include eligible activities applied for in the original project application. Funds must be used consistent with the competitive proposal and for the eligible purposes established in the NOFA and described in FTA Circulars 5010 and 9300.1B. In cases where the allocation amount is less than the proposer's requested amount, grantees should work with FTA's Office of Planning and Environment to reduce the work scope appropriately such that the intent of the original proposal will be accomplished. Grantees are reminded that program requirements are detailed in the NOFA. The maximum Federal funding share for this program is 80 percent. A discretionary project identification number has been assigned to each project for tracking purposes and must be used in the grant application. FTA is not extending pre-award authority for selected projects prior to grant awards. Local funds must be committed and grants awarded by September 30, 2016. Post-award reporting requirements include submission of the Federal Financial Report and Milestone reports in FTA's electronic grants management system as appropriate (see FTA Circulars 5010.1D and 9030.1E). The grantees must comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal requirements in carrying out the project supported by the FTA grant. FTA emphasizes that grantees must follow all third-party procurement guidance, as described in FTA.C.4220.1F. Funds allocated in this announcement must be obligated in a grant by September 30, 2016.

Therese W. McMillan,

Acting Administrator.

TABLE I—FY 2015 PILOT PROGRAM FOR TRANSIT-ORIENTED DEVELOPMENT PLANNING PROJECT SELECTIONS

State	Recipient	Project ID	Project description	Allocation
AZ	City of Phoenix Public Transit Department (Valley Metro).	D2015–TODP–0001	Tempe Streetcar Corridor Transit-Oriented Development (TOD) Planning.	$250,000
CA	Bay Area Rapid Transit District	D2015–TODP–0002	Transbay Corridor TOD Implementation Strategies.	1,100,000
CA	Peninsula Corridor Joint Powers Board.	D2015–TODP–0003	Caltrain Station Management Toolbox.	600,000
CA	Sacramento Area Council of Governments.	D2015–TODP–0004	Streetcar Toolkit—Stitching Together Two River Cities through TOD.	1,118,720
CA	San Diego Association of Governments.	D2015–TODP–0005	Mid-Coast Corridor Mobility Hub Implementation Strategy.	429,635
CT	Connecticut Department of Transportation.	D2015–TODP–0006	Creating TOD Opportunity for New Stations within the New Haven-Hartford-Springfield Rail Corridor.	700,000
FL	City of Fort Lauderdale	D2015–TODP–0007	Catalyzing TOD Along and Adjacent to the Wave Streetcar Extensions.	1,250,000
FL	South Florida Regional Transportation Authority.	D2015–TODP–0008	South Florida Regional TOD Pilot Program.	1,250,000
GA	City of Atlanta	D2015–TODP–0009	Atlanta BeltLine Transit Supportive Land Use Implementation Plan.	500,000
GA	Metropolitan Atlanta Rapid Transit Authority.	D2015–TODP–0010	Strategic Plan for TOD in the I–20 East Corridor.	1,600,000
IL	Chicago Transit Authority	D2015–TODP–0011, D2015–TODP–0012.	Red and Purple Modernization Phase One TOD Plan.	1,250,000
IN	Northern Indiana Commuter Transportation District.	D2015–TODP–0013	West Lake Extension TOD Planning.	300,000
MI	Capital Area Transportation Authority (CATA).	D2015–TODP–0014	CATA Bus Rapid Transit TOD-Form Based Zoning Code.	1,250,000
MI	Southeast Michigan Council of Governments.	D2015–TODP–0015	City of Detroit/Oakland County Coordinated Land Use Planning for the Woodward Avenue BRT Corridor.	250,000
MN	Metropolitan Council	D2015–TODP–0016	Gateway Corridor: BRTOD (Bus Rapid Transit Oriented Development) Planning.	1,000,000

TABLE I—FY 2015 PILOT PROGRAM FOR TRANSIT-ORIENTED DEVELOPMENT PLANNING PROJECT SELECTIONS—Continued

State	Recipient	Project ID	Project description	Allocation
NC	GoTriangle (formerly known as Triangle Transit).	D2015–TODP–0017	Durham-Chapel Hill TOD Planning and Implementation Framework.	1,691,615
NM	City of Albuquerque	D2015–TODP–0018	Central Avenue TOD Planning via Comprehensive Plan Update and Unified Development Ordinance.	860,000
NY	Niagara Frontier Transportation Authority.	D2015–TODP–0019	Comprehensive TOD Planning for Transit Options Amherst-Buffalo.	640,765
PA	Urban Redevelopment Authority of Pittsburgh.	D2015–TODP–0020	Pittsburgh Uptown and Fifth/Forbes Corridor Bus Rapid Transit TOD Project.	1,200,000
UT	Utah Transit Authority	D2015–TODP–0021	Provo/Orem BRT—TOD Analysis and Implementation Plan.	250,500
WA	Sound Transit	D2015–TODP–0022	Links to Opportunity: A mobility and economic development plan for Tacoma Link Expansion communities.	2,000,000

[FR Doc. 2015–23154 Filed 9–14–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Order 13224

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (OFAC) is publishing the names of four individuals and one entity whose property and interests in property are blocked pursuant to Executive Order (E.O.) 13224 and whose names have been added to OFAC's list of Specially Designated Nationals and Blocked Persons (SDN List).

DATES: OFAC's actions described in this notice were effective September 10, 2015.

FOR FURTHER INFORMATION CONTACT: Associate Director for Global Targeting, tel.: 202/622–2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC sanctions programs are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Notice of OFAC Actions

On September 10, 2015, OFAC blocked the property and interests in property of the following four individuals and one entity pursuant to E.O. 13224, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism.''

Individuals

1. SALAH, Mahir Jawad Yunis (a.k.a. SALAH, Maher Jawad Younes; a.k.a. SALAH, Maher Jawad Yunes; a.k.a. SALAH, Maher Jawad Yunis; a.k.a. SALAH, Mahir Jawwad Yunis; a.k.a. SALAH, Mahir Yunus; a.k.a. ''AKRAM, Abu''; a.k.a. ''AREF, Abu''; a.k.a. ''ARIF, Abu''; a.k.a. ''SALAH, Mahir''; a.k.a. ''SHACKER, Abu''), Saudi Arabia; DOB 22 Oct 1957; alt. nationality United Kingdom; alt. nationality Jordan; Passport 012855897 (United Kingdom); alt. Passport D126889 (Jordan); National ID No. 9571015241 (Jordan) (individual) [SDGT] (Linked To: HAMAS).
2. AWAD, Mohammed Reda Mohammed Anwar (a.k.a. AWAD, Hamid Rida Muhammad; a.k.a. ''AWAD, Rida''; a.k.a. ''REDA, Haj''), United Kingdom; DOB 24 Sep 1954; nationality Egypt (individual) [SDGT] (Linked To: HAMAS).
3. AL-ARURI, Salih (a.k.a. AL-ARORI, Salih; a.k.a. AL-AROURI, Salah; a.k.a. AL-AROURI, Saleh; a.k.a. AL-AROURI, Saleh Muhammad Suleiman; a.k.a. AL-ARURI, Salah; a.k.a. AL-ARURI, Saleh; a.k.a. AL-ARURI, Salih Muhammad Sulayman; a.k.a. SULAYMAN, Salih Muhammad; a.k.a. ''MUHAMMAD, Abu''; a.k.a. ''SULAIMAN, Salih Dar''; a.k.a. ''SULEIMAN, Salih''); DOB 19 Aug 1966; POB Ramallah, West Bank; Passport 2525897 (Palestinian); alt. Passport 3580327 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).
4. AL-AGHA, Abu Ubaydah Khayri Hafiz (a.k.a. AGHA, Abu Obaida Khairy Hafiz; a.k.a. AGHA, Abu Ubaydah Khayr; a.k.a. AL AGHA, Abu Obaida Khairi Hafiz; a.k.a. AL AGHA, Abu Ubaida Khairee Hafez; a.k.a. AL AGHA, Abuobaidah Kh H; a.k.a. ALAGHA, Abu Obaida Khairy; a.k.a. ALAGHA, Abu Obaidah Khairy Hafiz; a.k.a. ALAGHA, Abu Obeidah Kheiri; a.k.a. ALAGHA, Abu Obidah Khairi Hafez; a.k.a. AL-AGHA, Abu Ubayda Khayri; a.k.a. AL-AGHA, Abu Ubaydah Khayri; a.k.a. ALAGHA, Abuobaida Khairy Hafez; a.k.a. EL AGHA, Abou Oubida Khairy Hafiz; a.k.a. HAFAZ, Abu Ubayda Hairi; a.k.a. HAFEZ, Abu-Obaidah Khairy; a.k.a. HAFIZ, Abu Ubaydah Khayr; a.k.a. HAFIZ, Abu 'Ubaydah Khayri; a.k.a. ''ALAGHA, Abu Obaida''; a.k.a. ''AL-AGHA, Abu-'Ubaydah''; a.k.a. ''HAFETH, Abu Ubaydah''; a.k.a. ''HAFEZ, Abo Obeida''; a.k.a. ''HAFEZ, Abu Obaida''; a.k.a. ''HAFEZ, Abu-Obaidah K.''; a.k.a. ''HAFITH, Abu Ubaydah''; a.k.a. ''HAFIZ, Abu Obidah K''; a.k.a. ''HAFIZ, Abu Ubayda''), P.O. Box 8800, Jeddah 21492, Saudi Arabia; Al Rawdah, Jeddah 21492, Saudi Arabia; Pr. Amir Sultan Street, Khalidiya Business Center, 3rd Floor, Khalidiya, Jeddah 21492, Saudi Arabia; Ar Rawdah Quarter, Near An Nuwaysir Mosque, Jeddah, Saudi Arabia; Ar Rawdah Quarter, Near Mosque Mujib Al Maddah, Jeddah, Saudi Arabia; DOB 03 May 1964; alt. DOB 02 May 1964; POB Taif, Saudi Arabia; nationality Saudi Arabia; Passport H376590 (Saudi Arabia) expires 16 Oct 2012; alt. Passport B912630 (Saudi Arabia); National ID No.

1020539712 (Saudi Arabia) (individual) [SDGT] (Linked To: HAMAS).

Entity

1. ASYAF INTERNATIONAL HOLDING GROUP FOR TRADING AND INVESTMENT (a.k.a. AL-OSAMA TRADING CO. LTD.; a.k.a. AL-'USAMA TRADING COMPANY; a.k.a. ASYAF GROUP; a.k.a. ASYAF INTERNATIONAL HOLDING GROUP; a.k.a. ASYAF INTERNATIONAL HOLDING GROUP FOR TRADING & INVESTMENT; a.k.a. DAN ISDICO; a.k.a. M/S OSAMA KHAIRY HAFEZ TRADING EST.; a.k.a. OSAMA TRADING COMPANY LTD; a.k.a. ''AL-'USAMAH COMPANY''; a.k.a. ''ASAMA COMMERCIAL COMPANY''; a.k.a. ''ASAMA COMPANY''; a.k.a. ''NURIN COMPANY''), P.O. Box 8800, Jeddah 21492, Saudi Arabia; 504 & 7102, Ibrahim Shakir Building, Hail Street Rowais, Near Caravan Center, Jeddah 21492, Saudi Arabia; Pr. Amir Sultan Street, Khalidiya Business Center, 3rd Floor, Khalidiya, Jeddah, Saudi Arabia; Riyadh 14213, Saudi Arabia; Dammam, Saudi Arabia; Al Kharaj, Saudi Arabia; Qasim, Saudi Arabia; Khartoum, Sudan [SDGT] (Linked To: AL-AGHA, Abu Ubaydah Khayri Hafiz; Linked To: HAMAS).

Dated: September 10, 2015.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2015–23109 Filed 9–14–15; 8:45 am]

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Part II

Department of Justice

Drug Enforcement Administration
Masters Pharmaceuticals, Inc.; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–39]

Masters Pharmaceuticals, Inc.; Decision and Order

On August 9, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Masters Pharmaceuticals, Inc. (hereinafter, Respondent). ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration Number RD0277409, pursuant to which it is authorized to distribute controlled substances in schedules II through V, at the registered location of 11930 Kemper Springs, Cincinnati, Ohio, and the denial of any pending application to renew or modify its registration, on the ground that its ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4)).

The Show Cause Order specifically alleged that on April 21, 2009, Respondent entered into a Memorandum of Agreement (MOA) with DEA, pursuant to which it agreed ''to 'maintain a compliance program to detect and prevent [the] diversion of controlled substances as required under the [Controlled Substances Act] and applicable DEA regulations.' '' *Id.* (quoting MOA at ¶ II.1.a). The Order also alleged that in the MOA, Respondent '' 'acknowledg[ed] and agree[d] that the obligations undertaken . . . do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.' '' *Id.*

The Order then alleged that notwithstanding ''the MOA, the specific guidance provided to [Respondent] by DEA, and the public information readily available regarding the oxycodone epidemic in Florida, and in the United States, [Respondent] failed to maintain effective controls against the diversion of controlled substances . . . in violation of 21 U.S.C. 823(b)(1) and (e)(1).'' *Id.* at 1–2. The Order then alleged that from April 1, 2009 through December 31, 2009, Respondent distributed more than 37 million dosage units of oxycodone nationally and that nearly 25 million dosage units ''were distributed to its Florida customers,'' and that the latter distributions ''well exceeded'' its distributions to customers in other States.[1] *Id.* at 2. The Order further alleged that during 2010, Respondent distributed 37.86 million dosage units of oxycodone nationally, of which nearly 24.4 million dosage units ''were distributed to its Florida customers.'' [2] *Id.* Finally, the Order alleged that between January 1 and March 31, 2011, Respondent distributed 6.1 million dosage units of oxycodone nationally, of which approximately 2.76 million dosage units ''were distributed to its Florida customers.'' [3] *Id.*

Next, the Show Cause Order alleged that ''[s]ince at least 2009, the majority of [Respondent's] largest purchasers of oxycodone . . . have been retail pharmacies in the State of Florida who [it] knew or should have known were distributing controlled substances based on . . . prescriptions that were issued for other than a legitimate medical purpose and outside [of] the usual course of professional practice.'' *Id.* at 3. The Order then made allegations regarding Respondent's distributions of oxycodone 30 mg to eight pharmacies. More specifically, the Order alleged that:

1. ''From April 1, 2009 through November 30, 2010, [it] distributed approximately 591,800 dosage units . . . to Tru-Valu Drugs'';
2. ''From April 1, 2009 through January 31, 2011, [it] distributed approximately 993,100 dosage units . . . to The Drug Shoppe'';
3. ''From April 1, 2009 through March 31, 2011, [it] distributed approximately 333,000 dosage units . . . to the Medical Plaza Pharmacy'';
4. ''From April 1, 2009 through September 30, 2010, [it] distributed approximately 1.275 million dosage units . . . to Englewood Specialty Pharmacy'';
5. ''From April 1, 2009 through December 31, 2010, [it] distributed approximately 570,700 dosage units . . . to City View Pharmacy'';
6. ''From January 1, 2009 through November 30, 2010, [it] distributed approximately 1.7 million dosage units . . . to Lam's Pharmacy'';
7. ''From April 1, 2009 through August 31, 2009, [it] distributed approximately 637,400 dosage units . . . to Morrison's RX''; and
8. ''From January 1, 2009 through December 2009, [it] distributed approximately 351,600 dosage units . . . to Temple Terrace Pharmacy.''

Id.

The Show Cause Order then alleged that Respondent ''consistently ignored and/or failed to implement its own due diligence and suspicious order monitoring policies, compromising the effectiveness of those policies.'' *Id.* Continuing, the Order alleged that ''notwithstanding the large quantities of controlled substances ordered by [its] retail pharmacy customers, [Respondent] failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted'' and ''ignor[ed] and/or fail[ed] to document red flags of diversion present at many of its retail pharmacy customers.'' *Id.* Finally, the Order alleged that Respondent ''failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 CFR 1301.74(b).'' *Id.*

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. ALJ Ex. 3. The matter was placed on the docket of the Office of Administrative Law Judges, and assigned to ALJ Gail Randall (hereinafter, ALJ). ALJ's Recommended Decision (R.D.), at 1. Following pre-hearing procedures, *see generally* ALJ Exs. 5–11, the ALJ conducted an evidentiary hearing on February 24 through 28 and March 3 through 4, 2014, in Arlington, Virginia. Following the hearing, both parties filed briefs containing their proposed findings of fact and conclusions of law.

On June 19, 2014, the ALJ issued her Recommended Decision. Applying the public interest standard of 21 U.S.C. 823(b), the ALJ noted that the relevant factors were factors one—the maintenance of effective controls against diversion—and four—Respondent's experience in the distribution of controlled substances.

The ALJ rejected the Government's contention that Respondent had failed to report numerous suspicious orders, which it filled and shipped, upon subsequently determining that the customer was likely engaged in diverting controlled substances. R.D. at 154–61. Noting that the relevant regulation requires the reporting of a suspicious order ''when discovered,'' 21 CFR 1301.74(b), the ALJ opined that neither the regulation's language nor its purpose ''supports the conclusion that a registrant is required to review past orders from pharmacies the registrant later learns may be diverting controlled

[1] By contrast, the Order alleged that during this period, Respondent distributed approximately 1.47 million dosage units of oxycodone to its Nevada customers, 1.27 million to its Tennessee customers, 1.14 million to its Pennsylvania customers, and 1.09 million to its New Jersey customers. ALJ Ex. 1, at 2.

[2] By contrast, the Order alleged that during 2010, Respondent distributed approximately 2.8 million dosage units of oxycodone to its Nevada customers, 2.14 million to its Tennessee customers, 1.7 million to its New Jersey customers, and 1.37 million to its Pennsylvania customers. ALJ Ex. 1, at 2.

[3] By contrast, the Order alleged that during this period, Respondent distributed approximately 600,000 dosage units of oxycodone to its Tennessee customers, 415,000 to its New Jersey customers, 304,000 to its Pennsylvania customers, and 192,000 to its Nevada customers. ALJ Ex. 1, at 2.

substances.'' *Id.* at 157. The ALJ did, however, conclude that the regulation ''impose[s] a duty to report past orders [that] the registrant *actually* discovers were suspicious.'' *Id.* at 158. However, based on her review of the record, the ALJ concluded that Respondent had only failed to report a single suspicious order. *Id.*

Turning to the Government's contention that Respondent had failed to maintain effective controls against diversion, the ALJ concluded that the Government's evidence as to the volume of Respondent's sales to Florida and the eight pharmacies in particular did not support a finding that it was in violation of this duty. *Id.* at 164–67. As the ALJ explained, ''the sheer volume of a respondent's controlled substances sales or purchases, without some kind of contextual background to link the sales to the respondent's duty under the CSA, cannot be used to indicate that the distributor's registration would be against the public interest.'' *Id.* at 164. The ALJ further noted that the Government did not present a ''statistical expert or any other evidence to explain why the volume of Respondent's sales was necessarily indicative of diversion.'' *Id.* at 166. She also credited the testimony of Respondent's statistical expert that the ''shipments to the DEA-identified pharmacies rarely stand out from the rest of the monthly shipments''; that because Respondent does not have access to the Agency's ARCOS database, ''it cannot compare its shipments to [those] made by other distributors''; that ''Respondent's business model as a secondary supplier made comparisons across pharmacies practically useless''; and that comparing its distributions to Florida customers with those in other States was not ''very meaningful because there [are] so many factors that are relevant.'' *Id.* at 167 (citations omitted).

Next, the ALJ rejected the Government's contention that Respondent failed to follow its own policies and procedures. *Id.* at 170–79. The ALJ first found that Respondent's Policies and Procedures required that an order placed on compliance hold by its Suspicious Order Monitoring System (SOMS) be subject to additional due diligence which included: (1) Contacting the customer to discern the reason for the deviation in size, pattern, or frequency; (2) independently verifying the reason stated by the customer; and (3) conducting a complete file review. *Id.* at 73–74, 76–77. While the Government cited numerous instances in which Respondent's employees released orders without documenting having performed the above steps, the ALJ rejected its contention, reasoning that Respondent's Policies and Procedures did ''not require documentation of the reasons for the release of a held order.'' *Id.* at 171. And while noting ''that Respondent documented some reasons for abnormal orders,'' she further reasoned that ''[t]he mere absence of documentation—documentation that is not required by Respondent's Policies and Procedures, DEA regulations, or any established industry standard—does not constitute substantial evidence that the undocumented act did not occur.'' *Id.* at 172; *see also id.* at 173–74, 176.

Next, the ALJ addressed the Government's contention that Respondent failed to properly use the Utilization Reports (URs) which it obtained from its pharmacy customers. *Id.* at 179–95. While the ALJ found that Respondent was required under its policies and procedures to obtain a UR from a pharmacy customer whenever it placed an order on compliance hold and yet repeatedly failed to do so, *id.* at 181, she otherwise rejected the Government's contention that Respondent did not properly utilize the URs in its review of the held orders. *Id.* at 181–92.

In rejecting the Government's contention, the ALJ explained that because DEA was obligated under a Memorandum of Agreement (MOA) to conduct a compliance review and notify Respondent of any deficiencies in its policies and procedures and failed to do so with respect to its use of the URs, the MOA bars the Agency ''from sanctioning Respondent for not implementing additional UR analyses into its Policies and Procedures.'' R.D. at 186. While noting the parties' agreement ''that controlled substance ratios are an important aspect that should be investigated prior to shipping controlled substances,'' the ALJ then reasoned that ''[t]he Government offered no evidence that accurate information regarding controlled substance ratios can *only* be acquired through URs.'' *Id.* at 188–89. She also rejected the Government's contention that Respondent's actions in editing or deleting orders that were placed on hold by the SOMS established that it did not maintain effective controls against diversion or failed to report suspicious orders, noting that Respondent edited and deleted orders ''for business reasons.'' *Id.* at 196.

While acknowledging that the Government had proved that Respondent had failed to report a single suspicious order, the ALJ reasoned that ''Respondent fills many orders each year and has reported hundreds of suspicious orders, so one minor oversight does not render the entire system ineffective.'' *Id.* at 201. The ALJ thus concluded that Respondent had ''substantially complied with 21 CFR 1301.74(b),'' and that its failure to report the suspicious order did not justify the revocation of its registration. *Id.*

As for her finding that Respondent had violated its own policies and procedures by failing to obtain a UR every time an order was held by the SOMS, the ALJ reasoned that ''the relevant question . . . is not simply whether Respondent failed to follow its policies, but whether such failure rendered [its] system [for maintaining effective controls] ineffective . . . and/or constituted negative experience distributing controlled substances so as to justify revocation.'' *Id.* The ALJ then explained that Respondent's failure to follow its policies and procedures did not render them ineffective *per se* and that the Government was required to show that diversion was the ''direct and forseeable consequence'' of its failure to follow its policy in order to establish that its due diligence program was ineffective. *Id.* at 202. Because ''the Government made no showing that the shipments Respondent made without requiring URs were likely to be diverted,'' or ''that updated URs, had they been requested, would have indicated that the drugs were likely to be diverted,'' the ALJ concluded that Respondent's failure to obtain the URs did not ''justify revocation.'' *Id.* The ALJ thus recommended that Respondent be allowed to retain its registration and that the Administrator approve any pending renewal application. *Id.* at 203.

Both parties filed Exceptions to the ALJ's Recommended Decision. Thereafter, the record was forwarded to me for final agency action. Having reviewed the record in its entirety, and having carefully considered the ALJ's Recommended Decision as well as the parties' Exceptions,[4] I respectfully reject the ALJ's decision for reasons explained throughout this decision.

To summarize my reasons, I do agree with the ALJ that the Government's evidence as to the volume of Respondent's sales to the Florida pharmacies and the State in general does not constitute substantial evidence that the pharmacies were likely diverting controlled substances. I also agree with the ALJ's rejection of the Government's contention that Respondent, upon terminating a customer because it was likely diverting controlled substances, was obligated to review the customer's past orders and

[4] I address the various exceptions raised by the Parties throughout this decision.

determine whether any of them were suspicious and, if so, report them. However, I do so because, even assuming that the Government's interpretation is a reasonable reading of the suspicious order regulation, the Government has not provided pre-enforcement notice to the regulated community of this obligation.

Moreover, while I agree with the ALJ that ''a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or for frequency,'' I respectfully disagree with her conclusion that these characteristics must ''make it likely that controlled substances will be diverted'' to trigger the reporting requirement. R.D. at 155. In short, the ALJ's interpretation imposes a higher standard than that of the plain language of the regulation, which requires only that the order be suspicious, a standard which is less than that of probable cause.

Although I agree with the ALJ that upon investigating an order, a distributor may determine that an order is not suspicious, I respectfully disagree with her conclusion that ''Respondent provided ample evidence that the pharmacies had legitimate reasons for the high percentage of controlled substances dispensed by the pharmacies in dispute.'' R.D. at 189. Indeed, I find the evidence offered by Respondent on this point to be seriously lacking in probative force.[5]

I also respectfully disagree with the ALJ's conclusion that the Government did not prove that Respondent repeatedly failed to contact the pharmacies and obtain an explanation for those orders which were held by the SOMS because they were of unusual size, deviated substantially from a normal pattern, or were of unusual frequency. Rather, I find that the record contains substantial evidence that Respondent represented to the Agency that it would document the reason why it filled those orders that were held by the SOMS. Thus, where there is no such documentation that Respondent contacted the pharmacy, I find that Respondent did not contact the pharmacy. Moreover, while in many instances there is no documentation that Respondent contacted the pharmacy, Respondent's records document a reason for filling the order that is extraneous to the reason one would expect to be provided by a pharmacy. Accordingly, I find that in numerous instances, the record supports a finding that Respondent failed to contact the pharmacy and obtain an explanation for those orders.

I also respectfully disagree with the ALJ's conclusion that Respondent's actions in editing or deleting orders that had been held by the SOMS (typically because they were of unusual size) does not establish that the orders were suspicious. While the ALJ reasoned that ''orders were edited and deleted for business reasons,'' I find that the weight of evidence is to the contrary and that most of the edited and deleted orders were suspicious and should have been reported.

Further, I respectfully disagree with the ALJ's rejection of the Government's contention that Respondent failed to properly use the URs because it did not use them to analyze the pharmacies' ratio of controlled to non-controlled dispensings. As for the ALJ's reasoning that the 2009 Memorandum of Agreement (MOA) bars the Government from sanctioning Respondent for failing to use the URs in this manner, nothing in the MOA provided Respondent with immunity for violations of DEA regulations occurring after March 31, 2009. Moreover, I conclude that the ALJ did not apply the correct legal standard in evaluating Respondent's contention that it reasonably relied on the Government's failure to identify the manner in which it used the URs as a deficiency in the compliance review and that therefore, the Government should be barred from sanctioning it based on this conduct. Instead, I conclude that Respondent's defense should have been evaluated under the doctrine of equitable estoppel and I reject its contention.

I also respectfully disagree with the ALJ's conclusion that use of the URs was not necessary to obtain accurate information regarding the pharmacies' dispensing ratios. Rather, I conclude that a distributor is required to use the most accurate information available to it. Because the URs show the actual dispensing level of each drug, and questionnaires and surveys provide only estimates, I conclude that a distributor must use the URs in evaluating whether a customer's dispensing ratio is suspicious.

Next, I respectfully disagree with the ALJ's conclusion that Respondent's failure to obtain a new UR every time an order was held by the SOMS did not render its policies and procedures ineffective. R.D. 202. Contrary to the ALJ's understanding, the Government was not required to show that the shipments Respondent made without requiring a new UR ''were likely to be diverted,'' *id.,* but rather, only that its failure to obtain a new UR rendered its system for detecting suspicious orders ineffective. For reasons explained in this decision, I conclude that Respondent's repeated failure to obtain new URs, both when orders were held, as well as when its own inspector recommended that it do so, rendered its suspicious order monitoring system defective.

Finally, I respectfully disagree with the ALJ's conclusion that the Government has proven only that Respondent failed to report a single suspicious order. To the contrary, I find that each of the seven pharmacies submitted numerous suspicious orders which should have been reported but were not. Accordingly, I respectfully disagree with the ALJ's ultimate conclusion that Respondent has substantially complied with the Agency's suspicious order rule and her recommendation that revocation of its registration is not warranted.

Having reviewed the entire record including the ALJ's Recommended Decision and the Parties' Exceptions, as ultimate factfinder, *see* 5 U.S.C. 557(b), I make the following factual findings.

Findings

Respondent is a secondary or ''tertiary'' wholesaler of various pharmaceutical products including controlled substances; ''[t]he vast majority of [its] customers are independent, retail pharmacies located throughout the United States,'' which are ''[o]ften . . . small, family owned and operated stores.'' RX 104, at 6–7; Tr. 994. According to its CEO and owner, it ''is not a primary or full line wholesaler'' and ''carries far fewer products than primary wholesalers.'' *Id.* Moreover, ''none of [its] customers use [it] as the sole source for all the pharmaceutical products they dispense.'' RX 104, at 7. And according to its owner, its ''business model tends to make its customers' purchasing patterns more difficult to predict and more variable than they would be if Masters were a full-line wholesaler.'' *Id.*

[5] Respondent's evidence on this point was largely comprised of the declaration of the head of its Compliance Department, Ms. Jennifer Seiple, regarding its due diligence efforts. I acknowledge that the ALJ found Ms. Seiple's testimony credible and clearly gave it substantial weight. However, for reasons explained throughout this decision, I find that much of Ms. Seiple's testimony as to the reasons why Respondent did not report the various pharmacies' orders as suspicious is unpersuasive. In other instances, her testimony is refuted by other evidence. Accordingly, I decline to give Ms. Seiple's testimony substantial weight. *See Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951) (''The substantial evidence standard is not modified in any way when the [Agency] and its [ALJ] disagree. . . . The findings of the [ALJ] are to be considered along with the consistency and inherent probability of testimony. The significance of [her] report, of course, depends largely on the importance of credibility in the particular case.'').

at 8; *see also* Tr. 997 (testimony of Respondent's former Vice-President that because it was a tertiary supplier, demand ''is very elastic'' and that ''it was very hard to pinpoint a demand from a customer who bought from you very infrequently'').

Respondent is the holder of DEA Certificate of Registration Number RD0277409, pursuant to which it is authorized to distribute controlled substances in schedules II through V, at the registered location of 11930 Kemper Springs, Cincinnati, Ohio. GX 1. While this registration was due to expire on January 31, 2014, on December 10, 2013, Respondent filed a timely renewal application. 21 CFR 1301.36(i). Accordingly, Respondent's registration has remained in effect pending this Decision and Final Order. 5 U.S.C. 558(c); 21 CFR 1301.36(i).

DEA Guidance to Distributors on Reporting Suspicious Orders and Maintaining Effective Controls Against Diversion

Prior to the events at issue here, the Deputy Assistant Administrator, Office of Diversion Control, wrote two letters which were sent to all registered distributors including Respondent. GXs 3 & 4. The letters discussed the requirements imposed by 21 CFR 1301.74 for reporting suspicious orders and the scope of a registrant's obligation ''to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels.'' GX 3, at 2. The first letter, which was dated September 27, 2006, set forth the text of 21 CFR 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Id. (quoting 21 CFR 1301.74(b)). Continuing, the letter noted that ''in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate . . . channels.'' *Id.* The letter then explained that ''a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances'' and that a ''distributor should exercise due care in confirming the legitimacy of all orders prior to filling.'' *Id.*

The letter also set forth various characteristics found by the Agency to be present in pharmacies engaged in diverting controlled substances. These included, *inter alia,* ''[o]rdering excessive quantities of a limited variety of controlled substances . . . while ordering few, if any, other drugs,'' and ordering the controlled drugs ''in quantities disproportionate to the quantity of non-controlled medications ordered.'' *Id.* at 3.

The letter also provided a list of suggested questions for distributors to ask in ''determin[ing] whether a suspicious order is indicative of diversion of controlled substances.'' *Id.* While most of these questions focused on whether a pharmacy was engaged in the unlawful distribution of controlled substances through internet schemes in which physicians prescribed drugs to patients with whom they had not established a legitimate doctor-patient relationship, some of the questions were applicable to all pharmacies. These included: (1) ''[w]hat percentage of the pharmacy's business does dispensing controlled substances constitute?'' (2) ''[a]re one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?'' and (3) ''[d]oes the pharmacy charge reasonable prices for controlled substances?'' *Id.*

The letter then explained that ''[t]hese questions [were] not all-inclusive'' and that ''the answer to any of the[ ] questions'' would not ''necessarily determine whether a suspicious order is indicative of diversion.'' *Id.* Finally, the letter concluded by advising that ''[d]istributors should consider the totality of the circumstances when evaluating an order for controlled substances.''

Id.

On December 27, 2007, the Deputy Assistant Administrator sent a second letter to all registered distributors including Respondent, the purpose of which was ''to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).'' GX 4, at 1.

After reciting the regulatory text that ''suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency,'' the letter explained that ''[t]hese criteria are disjunctive and are not all inclusive.'' *Id.* (quoting 21 CFR 1301.74(b)). Continuing, the letter explained that:

> If an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a ''normal pattern'' to develop over time before determining where a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of a particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Id.

The letter further explained that a registrant's ''responsibility does not end merely with the filing of a suspicious order report'' and that a ''[r]egistrant[] must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.'' *Id.* Continuing, the letter warned that ''[r]eporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.'' *Id.* The letter thus advised that a registrant which ''routinely report[s] suspicious orders, yet fill[s] these orders without first determining that [the] order[s] [are] not being diverted . . . may be failing to maintain effective controls against diversion'' and engaging in acts which are ''inconsistent with the public interest.'' *Id.* at 2.

The Previous Agency Proceeding Against Respondent

On October 17, 2008, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Respondent alleging that it had ''failed to maintain effective controls against diversion of particular controlled substances'' in that it ''distributed large amounts of hydrocodone,'' then a schedule III narcotic,[6] ''to customers it knew, or should have known, were diverting the [drug] into other than legitimate medical, scientific and industrial channels.'' GX 5, at 1. The Order further alleged that Respondent ''distributed extraordinarily large amounts of hydrocodone to'' two pharmacies, which were ''rogue Internet pharmacies that filled prescriptions that were not issued for a legitimate medical purpose

[6] Combination hydrocodone products have since been placed into schedule II of the CSA. *See Rescheduling of Combination Hydrocodone Products From Schedule III to Schedule II,* 79 FR 11037 (2014).

in the usual course of professional practice.'' *Id.* The Government alleged that Respondent's sales to the two pharmacies ''were consistently high compared to [its] sales of hydrocodone to other customers,'' with one of the pharmacy's purchases ''increase[ing] dramatically'' to a peak of more than 1.1 million dosage units in a single month, and the other pharmacy's purchases increasing from 30,000 to more than 156,000 dosage units in one month. *Id.* at 2. The Government also alleged that ''based upon the amounts and patterns of the hydrocodone orders and because DEA made [Respondent] aware of illegal Internet activity just prior to the unusual increases in distributions of hydrocodone to these customers,'' Respondent ''knew or should have known'' that the pharmacies ''were engaged in illegal activity'' and yet it ''failed to report [their] orders . . . as 'suspicious,' as required by'' 21 CFR 1301.74(b). *Id.*

The Government further alleged that Respondent distributed hydrocodone to two other pharmacies, with common ownership, notwithstanding that it had obtained information ''that clearly indicated that these pharmacies were operating as . . . rogue Internet pharmacies . . . and failed to report such orders as suspicious.'' *Id.* Finally, the Government alleged that ''[t]hroughout 2007 and 2008, [Respondent] . . . continued to fill orders for controlled substances from rogue Internet pharmacies and . . . failed to file suspicious order reports on such orders, in circumstances in which [it] knew or should have known that the pharmacies were operating illegally.'' *Id.*

On April 1, 2009, the Government and Respondent resolved the allegations by entering a settlement and release agreement, as well as an Administrative Memorandum of Agreement (MOA). GX 6. While Respondent was not required to admit to any of the allegations, it agreed to pay the Government the amount of $500,000 to settle ''claims or potential claims for civil penalties . . . for failing to report suspicious orders of controlled substances'' in violation of 21 U.S.C. § 842(c). *Id.* at 2, 4.

Respondent also ''agree[d] to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable regulations.'' *Id.* at 2. The program was to ''include procedures to review orders for controlled substances,'' and further provided that orders ''exceed[ing] established thresholds and meet[ing] other criteria as determined by [Respondent would] be reviewed by [an] employee trained to detect suspicious orders for the purposes of determining'' either that the ''order[] should not be filled and reported to . . . DEA'' or that order was ''not likely to be diverted into other than legitimate medical, scientific or industrial channels.'' *Id.* Respondent further agreed that these obligations ''do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.'' *Id.*[7]

Pursuant to the MOA, DEA agreed to ''conduct a review of the functionality of [Respondent's] diversion compliance program at [its] distribution center,'' including a ''review [of] the investigatory files maintained by [it] of the customers serviced by the distribution center.'' *Id.* at 4–5. DEA also agreed to ''conduct an exit interview with [Respondent's] representatives to provide DEA's preliminary conclusions regarding the Compliance Review.'' *Id.*

The MOA further provided that that review would be ''deemed satisfactory unless DEA determine[d] that the facility'' did not ''maintain effective controls against diversion,'' ''failed to detect and report . . . suspicious orders . . . after April 1, 2009,'' or ''failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances.'' *Id.* Moreover, the MOA provided that ''[t]he Compliance Review shall be deemed 'not satisfactory' if DEA provides written notice with specificity to [Respondent] on or before 220 days from the Effective Date of [the MOA], stating that [Respondent had] failed to meet any of the requirements,'' apparently pertaining to maintaining effective controls against diversion, failing to detect and report suspicious orders, and failing to meaningfully investigate its customers.[8] *Id.* However, DEA also agreed that it would not ''find the Compliance Review 'not satisfactory' unless the failure(s) [we]re sufficient to provide . . . a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against the inspected facility.'' *Id.* Moreover, the MOA provided that ''[a] finding of 'satisfactory' does not otherwise express DEA's approval of Master's compliance program.'' *Id.*

Finally, DEA agreed to release Respondent from administrative claims ''within [its] enforcement authority under 21 U.S.C. 823, 824 and 842, based on the Covered Conduct,'' as well as ''the conduct alleged in [the first] Order to Show Cause.'' *Id.* at 6. However, the MOA further provided that ''[n]otwithstanding the releases by DEA contained in this Paragraph, DEA reserved the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties (*i.e.,* Respondent) for non-covered conduct.'' *Id.*

On August 17, 2009, two DEA Diversion Investigators (DIs) went to Respondent's Kemper Springs location to conduct the compliance review and provide training to Respondent regarding its obligations under the Controlled Substances Act. Tr. 90, 92–93. Respondent's attendees included Dennis Smith, CEO; Wayne Corona, then Vice-President; Matt Harmon, then Compliance Manager; Jennifer Seiple, Vice-President of Compliance; and Eric Schulze, Compliance Clerk.

As part of the review, one of the DIs reviewed the CSA's requirements for inventories; records, including the use of schedule II order forms; and reports, including the regulation governing the reporting of suspicious orders. GX 11. The other DI, who had queried DEA's Automation of Reports and Consolidated Orders System (hereinafter, ARCOS), a database used to track the acquisition and distribution of various controlled substances including, *inter alia,* all schedule II drugs and schedule III narcotics, obtained data of Respondent's distributions between January 2007 and June 2009 and created several charts, which he presented to Respondent's representatives. GX 48A. According to the DI, he intended to show Respondent that oxycodone (a schedule II narcotic drug) and hydrocodone (then a schedule III narcotic drug when combined typically with acetaminophen but now a schedule II narcotic drug) comprised the majority of the controlled substances it distributed during this period; that the majority of the oxycodone and hydrocodone it distributed was in ''the

[7] Respondent also agreed that it would review its distributions of oxycodone, hydrocodone, alprazolam, and phentermine to its retail pharmacy and physician customers for the 18-month period prior to the signing of the MOA and identify those current customers which ''exceeded the thresholds or met other criteria established in its compliance program on the date of such review.'' GX 6, at 3. Respondent agreed that ''[t]o the extent it has not otherwise done so, [it] shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns observed . . . for that customer, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Masters' compliance program.'' *Id.*

[8] The MOA specifically referred to ''the requirements in either subsections II(2)(d)(i),(ii), or (iii) of this Agreement.'' GX 6, at 5. The provisions this sentence references are simply clauses within a single sentence and are not separate subsections.

most commonly abused dosage strengths''; and that the majority of the oxycodone it sold was distributed to its customers in Florida, which he characterized as ''the epicenter of the oxycodone epidemic.'' [9] GX 48A, at 3. The DI also testified that he presented Respondent with data and a chart showing its distributions of oxycodone to several of the pharmacies during the period of January through June 2009, including Morrison's RX (672,600 dosage units), Lam's Pharmacy (522,500), Englewood Specialty Pharmacy (262,700), and The Drug Shoppe (242,700). *Id.* at 5; GX 12, at 23. The DI testified that his intent in doing so ''was to alert [Respondent] to potentially problematic trends that [he] perceived based upon [its] ARCOS reporting.'' GX 48A, at 5–6.[10]

Consistent with the DI's testimony, a former employee of Respondent who attended the briefing testified that the DI very clearly expressed his concerns about Respondent's continued sales of oxycodone 30 mg, which he explained was the most abused form of oxycodone, to Morrison's, Englewood, The Drug Shoppe, and Lam's. Tr. 1155. The former employee further testified that as the DI reviewed Respondent's files for these pharmacies and looked at their sales volume, he would turn and look at Ms. Seiple (the Compliance Director) and ask: ''You're not selling to this guy, are you, Jennifer?'' *Id.* at 1156.[11]

Also, at the hearing, Mr. Corona admitted that oxycodone 30 mg ''was a highly abused substance'' and that it was ''being obtained surreptitiously and unlawfully down in Florida.'' *Id.* at 1071–72. Mr. Corona acknowledged that Respondent and its CEO were ''aware of the 'oxycodone epidemic' stemming from Florida'' and that ''[t]his was common knowledge at [Respondent] as well as in the pharmaceutical industry in general.'' GX 51B, at 9 ¶ 31. He further testified that Florida was ''the 'wild west' and . . . a 'free for all' when it came to sales and dispensing of oxycodone.'' *Id.*

The DI also testified that a document entitled ''Suggested Questions a Distributor should ask prior to shipping controlled substances'' was presented to Respondent at the review. Tr. 223–24; *see also* RX 13. One of the suggested questions was: ''What is the pharmacy's ratio of controlled v. non-controlled orders?'' RX 13, at 1. Next to it is the handwritten notation: ''RATIO C20—NC 80.'' *Id.* However, on cross-examination, the DI testified that nothing in the ''training materials,'' *i.e.,* the PowerPoint presentation, *see* GX 11, addressed how Respondent should evaluate the ratios of controlled to non-controlled drugs ordered by a pharmacy, Tr.114, and he did not recall what specific discussions he had with Respondent's representatives regarding the ratio of controlled to non-controlled substances. *Id.* at 182. He also acknowledged that he did not provide training ''concerning the proper use of drug utilization reports,'' *id.* at 114, and that he was not asserting that Respondent was using the utilization reports in a manner inconsistent with its written policies and procedures. *Id.* at 132. Nor did he tell Respondent that it was analyzing the information contained in the customer files incorrectly, *id.* at 115, including the URs which were in the due diligence files Respondent kept for Morrison's, Englewood, The Drug Shoppe, and Lam's. *Id.* at 141.

However, recalling the briefing provided by DEA, Mr. Corona testified that:

> DEA provided information regarding specific questions to ask Masters' customers on due diligence questionnaires and during site visits. These questions were designed to gather information to allow Masters to identify ''red flags'' that may indicate that a particular customer was involved in illegitimate dispensing of controlled substances. In particular, DEA advised us to focus on whether a customer had a high percentage of cash for controlled substance prescriptions (as compared to third-party insurance payment), refused to accept insurance for the payment of controlled substance prescriptions, and/or dispensed a high percentage of controlled substances as compared to non-controlled substances.

GX 51B, at 4 ¶ 12.

During the review, Respondent also made a presentation to the DIs regarding its controlled drug handling policies and procedures. RX 12. As part of the presentation, Respondent stated that all new controlled substance customers were required to provide ''a valid DEA registration number,'' which it verified using the National Technical Information Service database. *Id.* at 11–12. Also, new customers were required to ''[c]omplete a survey designed to screen customers for inappropriate business activity,'' which included questions as to how many prescriptions the customer filled per day and how many were for controlled substances, whether the pharmacy did mail order or internet business, and whether the pharmacy filled prescriptions for out-of-area or out-of-state doctors or patients. *Id.* at 15. Respondent further represented that it reviewed the survey responses to determine if the customer was engaged in ''inappropriate business practices'' ''[]prior to shipping even one controlled drug,'' and that if the responses were ''not indicative of inappropriate practice,'' it would approve the customer to purchase controlled substances. *Id.* at 16.

As for its existing customers, Respondent stated that beginning in October 2008, it had conducted more than 5,800 surveys and that ''[a]ll customers eligible to purchase controlled drugs . . . ha[d] undergone [its] due diligence process and been approved by [the] Compliance Department.'' *Id.* at 19. Respondent further represented that since January 1, 2008, it had conducted 346 site visits of customers located in California, Florida, Kentucky, Nevada, Ohio, Tennessee, and West Virginia. *Id.* at 20.

Respondent also briefed the DIs regarding its Suspicious Order Monitoring System (hereinafter, SOMS). More specifically, Respondent explained that every order containing at least one controlled substance was tracked by calendar month and that any time a customer placed a new order that would result in the customer receiving more controlled drugs (by drug family) in the past 30 days than its highest monthly total in any of the previous six calendar months, the order was held for review and could not be shipped until it was released by the Compliance Department.[12] *Id.* at 25–29. Respondent

[9] Other testimony described the extent of the oxycodone epidemic in Florida during this period, including that between 2005 and 2010, the State experienced a 345 percent increase in narcotic-related overdose deaths, with 11 people dying per day in 2010, as well as an increase from 250 to 1,400 in the number of newborns who were addicted to oxycodone per year. Tr. 28.

The State eventually enacted legislation requiring that a physician and clinic ''primarily engaged in the treatment of pain by prescribing or dispensing controlled substance[s]'' register as a pain management clinic with the Florida Department of Health and limited the authority of dispensing physicians in such clinics to dispensing a 72-hour supply of narcotics to those patients who paid for the drugs ''by cash, check, or credit card.'' Fla. Stat. §§ 458.3265(1)(a) (2010), 465.0276(1)(b) (2010). The following year, the State enacted legislation which barred physicians from dispensing schedule II and III controlled substances except in even more limited circumstances. Fla. Stat. § 465.0276 (2011); *see also* Tr. 31. Based on the extensive abuse of oxycodone in Florida, in July 2011 the State's Surgeon General declared a public health emergency. Tr. 30–31; GX 47.

[10] The DI further testified that he specifically identified Lam's as a customer they ''[s]hould be 'looking at.''' GX 48A, at 6.

[11] I have considered Respondent's contention that the ALJ ''incorrectly found that DEA very clearly expressed concerns about'' these four pharmacies during the Compliance Review. Resp. Exceptions, at 19. Having reviewed the record, I reject the contention.

[12] Under the SOMS, Respondent assigned a Controlled Substance Limit (CSL) for each drug family ordered by a customer. According to a

Continued

also stated that the SOMS was designed to place holds based on a change in a customer's order patterns. *Id.* at 27.

Respondent represented that every controlled substance order ''go[es] through SOMS even before our system checks to see if we have the ordered items in stock,'' and that ''[i]f the order and the account history meets [sic] or exceeds [sic] the criteria set in [the] SOMS, the order is held for review,'' which involved the Compliance Staff conducting ''additional due diligence'' and determining whether the order could be shipped. *Id.* at 30. Respondent further represented that if its Compliance Staff ''reject[ed] the order,'' it was ''considered 'suspicious' '' and would be ''reported to . . . DEA'' and the customer's controlled substance ordering privileges would be ''suspended indefinitely.'' *Id.*

Finally, Respondent represented that ''[d]ocumentation on all orders held for review and their dispositions are permanently retained.'' *Id.* (emphasis in original). *See also* GX 51B, at 6 ¶ 19 (testimony of Wayne Corona) (''The compliance department would contact the customer, advise that the order was held and request a reason why the order exceeded SOMS parameters. The reason *would be documented in the due diligence files, specifically in the 'Memos for Record' (MFRs).* It may also have been electronically documented in the 'Ship to Memos' which were also part of the due diligence file.'') (emphasis added)).

Of further note, during the briefing, Respondent provided the DIs with a six-page Appendix which explained the operations of the SOMS. RX 78, at 59–64. On the issue of the documentation of those orders that were held for review, the Appendix stated:

> All orders have a full audit trail as related to SOMS. Each order that is processed through the system will show the status of the three parts of the SOMS system along with the customer's current limits and the results of the limits as related to this order. The ultimate status, accept or reject, will be shown along with the date/time and user associated with the action. A reason code and notes will also be provided as additional detail supporting the decision.

Id. at 64.

In addition to the SOMS Appendix, Respondent provided the DIs with a copy of its compliance manual, which included its policies and procedures for evaluating its controlled substance customers and their controlled substance orders; its policy on site visits (including its site visit and due diligence survey forms); and the operation of the SOMS. GX 48A, at 8; *see also* RX 78. Because the written policy and procedures provide additional detail beyond that which was discussed in the slides used in Respondent's PowerPoint briefing, relevant provisions are discussed below.

Respondent's Policy 6.1 set forth the requirements to purchase controlled drugs. RX 78, at 30. These requirements included that any customer ''possess a valid, unexpired DEA registration'' in the appropriate drug schedules; that it provide its ''registration number and/or a copy of the registration''; and that Respondent would validate the customer's registration though the NTIS (National Technical Information Service) database. *Id.*

The Policy also required Respondent to ''perform sufficient due diligence on all customers in order to prevent the diversion of controlled drugs.'' *Id.* This included a survey; the authentication of the licenses of the facility, pharmacist-in-charge, and practitioners; a check of publicly available disciplinary records for recent disciplinary actions; and review by a compliance manager. *Id.*

The Policy further provided that ''[a]dditional due diligence shall be required of any customer when any of the following issues are indicated'' to include that: (1) There were ''[s]ignificant, recent, and/or relevant disciplinary actions relating to the handling of controlled drugs''; (2) a customer was distributing controlled substances over the internet or by mail order; (3) a customer was ''diverting controlled drugs through any other means''; (4) a ''customer place[d] a potentially suspicious order''; and (5) the compliance manager conducting the review required more information. *Id.* at 30–31. The Policy then stated that the additional due diligence could ''include any or all of the following steps, as determined by the compliance manager'': (1) Obtaining ''[d]rug [u]tilization [r]ecords''; (2) conducting a site visit; (3) inquiring of law enforcement agencies; (4) checking with ''common carriers to determine if the [customer] is using their services; and (5) ''[a]cquiring a commercial credit report . . . to verify the survey information provided by the customer.'' *Id.* at 31.

Respondent's Policy 6.2 sets forth its requirements and procedures for monitoring and reporting suspicious orders. *Id.* at 32. According to Respondent, the SOMS did four things: (1) It ''[t]racks each customer's purchase history for controlled drugs''; (2) it ''[r]eviews every order for controlled drugs . . . prior to shipment''; (3) it ''[h]olds all orders for controlled drugs that meet or exceed the criteria set forth in 21 CFR 1301.74(b)'' (the suspicious order reporting regulation); and (4) it ''[r]equires each order to be individually reviewed prior to shipment.'' *Id.* The Policy then set forth Respondent's procedures for those orders that were placed on hold by the SOMS. *Id.* These procedures required that ''[a] compliance staff member call[] the customer and request[]'' both: (1) ''[a]n explanation for the order,'' which was to be ''independently verified''; and (2) ''[a] current utilization report, listing all of the pharmaceuticals'' (including both controlled and non-controlled) dispensed by the pharmacy ''in the most recent calendar month.'' *Id.* The procedures also required that ''[t]he customer's entire file'' be reviewed, including its ''initial survey,'' its ''order

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document describing the SOMS, upon the completion of the initial due diligence, the Compliance Department would assign a default monthly limit for each control [sic] drug group based on the ''information derived from the initial due diligence.'' GX 35, at 15. This limit would set the number of doses that a customer could receive at a particular registered location ''in any given 30 day period,'' but could ''be edited for a period of six months after the first purchase of each control [sic] [drug] group.'' *Id.*

However, according to its policies and procedures, Respondent did not require that new controlled substance customers provide a utilization report showing their actual dispensings of prescription products prior to setting the initial monthly limit. Rather, under its policies and procedures, obtaining a UR was a discretionary act even when Respondent deemed it necessary to conduct additional due diligence on a new customer. RX 78, at 30–31.

According to the testimony of a former compliance department employee, based on the number of prescriptions a customer reported that it filled on a daily basis (which was typically only an estimate), Respondent would place the customer in one of three tiers and assign the initial monthly limit of dosage units for each controlled substance family (*e.g.,* oxycodone). Tr. 1380–82. While there is testimony to the effect that the tiers were set at either ''5, 10, or 15'' thousand dosage units, it is unclear whether this applied to each controlled substance family. Tr. 627 (testimony of DI). Of further note, there is no evidence as to how Respondent determined the number of dosage units for each controlled substance family and tier.

According to the materials Respondent provided (*i.e.,* the SOMS Appendix), ''[a]fter six months of full history for a control [sic] [drug] group, the customer invoice history will be used to determine the monthly limit for each control [sic] [drug] group,'' with an ''update . . . occur[ing] on the first of every month.'' RX 78, at 59–60. However, ''[t]he highest monthly total [including product that was returned] from the preceding six months will be used as the new Monthly Limit for [a] control [sic] [drug] group.'' *Id.* at 60.

As for the determination of whether an order ''is invalid'' because of its ''size,'' Respondent represented that this is made by adding ''the total number of doses invoiced in the past 30 days [on a rolling basis] plus the total doses on open orders plus the number of doses on the received order[s] and compar[ing] it to the monthly limit.'' *Id.* According to Respondent's former Vice President, even if an order placed a customer one pill over its CSL for a controlled drug group, the order would be placed on hold and trigger a review. Tr. 1001.

history with'' Respondent, and ''[t]he site visits report(s),'' if available.'' *Id.*

According to the Policy, orders held for review would be released and filled when the order was found to be ''consistent with the customer's utilization report,'' and the review of ''the customer's file, including [its] survey responses and site visits'' was found to be ''consistent with legitimate business practices.'' *Id.* The Policy further directed that a held order would not be filled upon a finding that the order was inconsistent with the utilization report, the file review ''indicate[d] that the customer may be engaged in inappropriate business practices,'' or ''[t]he customer refuses to provide . . . the information necessary to complete its evaluation.'' *Id.* at 32–33. Moreover, the Policy directed that ''[a]ll orders . . . held for review that [Respondent did] not fill for [these] reasons . . . shall be considered 'Suspicious Orders' according to 21 CFR 1301.74(b) and reported to'' DEA. *Id.* at 33. Finally, upon the determination that an order was suspicious, Respondent's policy required that ''the customer's ordering privileges for controlled drugs . . . be suspended indefinitely.'' *Id.* [13]

Respondent's Policy and Procedures included its Policy 6.5, which applied to site visits. *Id.* at 37. The Policy stated that it was Respondent's policy to conduct site visits for ''all'' customers purchasing large quantities of controlled substances, as well as when its Compliance Department determined that ''additional due diligence [was] necessary prior to'' filling a controlled substance order. *Id.* The purpose of the site visits was to verify the customer's location; its ''trade class'' (whether it was a closed door, wholesale, or community pharmacy); the representations it made during ''the due diligence process,'' such as its proximity to health care providers; and finally, to ''look[] for indications of inappropriate business activity.'' *Id.*

The Policy required that those conducting the site visits ''take comprehensive notes'' and complete a ''Pharmacy Evaluation Form.'' [14] *Id.* It also instructed that photographs should be taken of the pharmacy's exterior, as well as ''any other feature in or around the pharmacy'' that would ''be helpful in making compliance decisions about the customer.'' *Id.* Finally, the Policy directed that if the inspector ''identifie[d] anything about the pharmacy or its staff that indicated . . . that the pharmacy is currently engaged in inappropriate business activity,'' this was to be reported to the Compliance Department ''as soon as possible after the visit.'' *Id.* (emphasis in original).

As found above, the MOA required that DEA ''conduct an exit interview . . . to provide [its] preliminary conclusions regarding the Compliance Review.'' GX 6, at 5. The DI did not, however, do a formal exit interview. GX 48A, at 8. Indeed, the DI testified that because the new policies had been implemented on August 14, 2009, only four days before the Compliance Review, there was not enough time to determine if the policies were being properly implemented. Tr. 230. However, the DI testified that at the conclusion of the review, he ''explained to [Respondent] that a review of all the information and material provided indicated that Masters ha[d] progressively engaged in actions to implement policies and procedures to promote an effective system to detect and prevent diversion of controlled substances.'' GX 48A, at 8. The DI further explained that he ''based this conclusion on the written policies and procedures provided . . . by [Respondent], and [his] assessment that, if properly implemented, these policies and procedures could promote an effective system to detect and prevent diversion of controlled substances.'' *Id.* Also, although the MOA stated that if DEA found the Compliance Review to be ''not satisfactory,'' it was to ''provide[ ] written notice with specificity to [Respondent] on or before 220 days from [the MOA's] [e]ffective [d]ate,'' GX 6, at 5; DEA did not provide any such notice. Tr. 120–25.

On August 18, 2009, the same day that the review concluded, Matt Harmon, Respondent's Compliance Manager, prepared a memorandum which he provided to both Wayne Corona (Vice-President) and Dennis Smith (owner and CEO). GX 38; *see also* Tr. 1161–62. Therein, Harmon proposed various steps which Respondent should take in response to the DEA review. Harmon proposed that Respondent use the pharmacies' utilization reports to ''[i]dentify pharmacies'' whose dispensings of controlled drugs and other drugs of concern (tramadol and carisoprodol) comprised ''50% or more of their'' dispensings and if so, then determine if ''over half of their purchases in each drug family [were of] either the highest strength or otherwise frequently diverted drug products.'' *Id.* Harmon then listed five products: ''oxycodone 30 mg,'' ''methadone 10 mg,'' ''hydrocodone 10 mg,'' ''alprazolam 2 mg,'' and ''codeine syrup,'' both ''with or without promethazine.'' *Id.* at 1. Harmon then proposed that if both conditions were present with respect to a pharmacy, Respondent ''need[ed] to suspend controlled sales to'' the pharmacy until it concluded an investigation. Harmon also explained that ''[w]e should assume that every pharmacy meeting the above criteria is engaged in inappropriate business activity until proven otherwise.'' *Id.*

Harmon further proposed that Respondent's investigation of such pharmacies focus on four questions: (1) Was there ''a strong independently verifiable, legitimate reason for this pattern?''; (2) was the pharmacy ''selling a full range of non-controlled pharmaceuticals?''; (3) were ''the

[13] *See also* GX 51B, at 6 ¶ 19 (declaration of Wayne Corona) (''The compliance department would contact the customer, advise that the order was held and request a reason why the order exceeded SOMS parameters. The reason would be documented in the due diligence files. . . . The compliance department was supposed to independently verify the reason given by the customer. If the reason was valid, the order would be released. If the reason could not be validated, it was supposed to be reported as suspicious.'').

[14] A copy of the Pharmacy Evaluation Form (which was revised on May 27, 2009) and the Due Diligence Survey—For Pharmacies (which was revised on May 14, 2009) are found at RX 78, at 51–57. The Pharmacy Evaluation Form is six pages long, with questions regarding ownership information, years in business, the licenses of the pharmacy, its pharmacist-in-charge, its pharmacy staff, and the nature of its practice. As for the latter section, the pharmacy was required to list all of the pharmaceutical distributors it had purchased from in the last 24 months; answer questions regarding ''the average number of prescriptions filled per day,'' ''[w]hat percentage are ANY CONTROLLED DRUG (CII–V),'' ''[w]hat percentage are ANY SCHEDULE II DRUG (CII)''; and list the percentage of prescription revenue from private insurance, Medicare/Medicaid, cash, and other sources. *Id.* at 51–55. The pharmacy was also required to disclose if it had a Web site or was affiliated with any Web sites and, if either question was answered in the affirmative, list the URL(s). *Id.* at 55. The pharmacy was further required to disclose if it ''fill[ed] prescriptions for practitioners in the primary business of pain management,'' and if so, ''list all such practitioners and their DEA numbers.'' *Id.* Finally, the form included a section titled as ''Inspector's Notes.'' *Id.* at 55–56.

As for the Due Diligence Survey, it asked similar questions, including whether the pharmacy had a Web site; whether it did mail order; if it had a primary wholesaler and, if so, the wholesaler's name; the daily script average and daily script average of schedule II drugs; the percentage of scripts that were for controlled drugs; the percentage of scripts that were for schedule IIs; and whether the pharmacy accepted insurance and Medicare/Medicaid, and, if so, the percentage paid by insurance. *Id.* at 57. The form also asked questions regarding what the pharmacy did to prevent doctor shopping; how the pharmacy ensured that doctors were ''exercising proper standards of care for their patients''; if the pharmacy had ''ever refused to fill a prescription,'' and if so, what were ''the most common reasons''; whether it had ''ever decided to permanently stop filling'' prescriptions written by a physician, and if so, ''the reason for doing so''; whether it filled prescriptions written by out-of-area or out-of-state doctors; whether it filled prescriptions for out-of-area or out-of-state patients; and whether it filled prescriptions ''via the internet.'' *Id.*

majority of the[] controlled drug prescriptions paid for with insurance?''; and (4) did the pharmacy ''sell front-store items?'' Harmon added that those customers who met ''only some of these criteria should be subjected to additional due diligence prior to any sale.'' *Id.*

The Government's Evidence of Respondent's Sales of Oxycodone During the Period of April 1, 2009 Through March 31, 2011 to the Seven Florida Pharmacies

The main focus of the Government's case was Respondent's sales of oxycodone to seven Florida-based pharmacies during the height of the State's oxycodone crisis. Based on data submitted by Respondent through ARCOS, the Government prepared a spreadsheet of the purchases of oxycodone 15 and 30 mg by the seven pharmacies (as well as Lam's Pharmacy, which was located in Las Vegas, Nevada) identified in the Show Cause Order during the following periods: (1) April 1, 2009 through December 31, 2009; (2) calendar year 2010; and (3) January through March 2011. It also prepared spreadsheets listing the pharmacies' monthly purchases of both drugs from Respondent.[15]

In December 2010, a DI with the Detroit Field Division was directed to conduct an investigation as to whether Respondent was complying with the 2009 MOA. GX 49B, at 7, ¶ 10. After reviewing data showing Respondent's distributions of various controlled substances (which showed that oxycodone comprised more than 60 percent of its distributions during 2009 and 2010, and that 44 of its top 50 oxycodone customers were located in Florida), on Feb 8, 2011, the DI (accompanied by two other DIs) went to Respondent's Kemper Springs facility to determine whether Respondent had ''created and implemented a system designed to maintain effective controls against diversion.'' *Id.* at 8. The DIs met with Wayne Corona (Respondent's President and Chief Operating Officer), Jennifer Seiple, and Matthew Harmon, and reviewed various records. *Id.* at 8–9.

According to a DI, Corona stated that Respondent's ''employees were aware of the diversion problems with oxycodone in Florida'' but did not ''consider the geographic locations of its Florida pharmacy customers.'' *Id.* at 9.[16] Corona also stated that he was aware of the fact that DEA had suspended the registration of Harvard Drug Group, L.L.C., based on its distributions of oxycodone to Florida and that Respondent had been ''flooded with contacts from Harvard['s] customers inquiring about oxycodone products after'' the suspension of Harvard's registration. *Id.*

As part of the investigation, the DI served several administrative subpoenas on Respondent and obtained the record for 21 pharmacies including Tru-Valu Drugs, Inc.; The Drug Shoppe, Inc.; Morrison's RX, Inc.; City View Pharmacy; CIFII Corp, d/b/a Lam's Pharmacy; Englewood Specialty Pharmacy, Inc.; Medical Plaza Pharmacy of Plantation, L.L.C.; and Temple Terrace Pharmacy, d/b/a Superior Pharmacy. GX 49B, at 14; 59 n.15; 87 n.18. The DI reviewed these files, which were maintained by Respondent's compliance department and contained customer questionnaires, pharmacy evaluations, site visit forms, Memos for Record (MFRs), Ship to Memos, SOMS

[15] The Government also submitted two tables purporting to show the total number of oxycodone dosage units Respondent sold to its customers in each State during the years 2009 through 2012, as well as its average monthly sale per customer during each year. *See* GXs 10B & 10L. The ALJ found the data unreliable because the first of these tables shows that Respondent distributed nearly 25 million dosages in 2009 to its Florida customers, which was approximately 67 percent of its total oxycodone distributions, while the second of these tables, which was submitted as a rebuttal exhibit—after Respondent discredited the Government's calculation of its average monthly sale per customer in each State—shows that Respondent had sold an additional 7.6 million dosage units to its Florida customers and that this comprised approximately 66 percent of its total distributions. However, there was little change between the data in the two exhibits for calendar years 2010 and 2011. The 2010 data show that Respondent distributed 24,389,400 dosage units to its Florida customers (according to GX 10B) and 24,387,800 to its Florida customers (according to table 10L); the tables show that Respondent's total distributions were 37,866,700 (according to GX 10B) and 37,859,300 (according to GX 10L). The ALJ did not address why this portion of the data is unreliable. Moreover, Respondent did not dispute that it ''distribute[d] a lot of oxycodone to the state, lots of it.'' Tr. 1837 (closing argument of Respondent's counsel).

However, I agree with the ALJ that the data as to its total sales in Florida do not establish that Respondent failed to maintain effective controls against diversion. R.D. at 27 n.22, 164–67. I also find unpersuasive the Government's proffered comparison of Respondent's Florida sales with its sales to its customers in other States including Texas, California, and New York, which the Government argues were ''similarly situated'' in terms of demographics and the number of medical establishments. Gov. Post-Hrng. Br. 104–06. Accordingly, I reject the allegation that the volume of dosage units distributed to the pharmacies alone establishes that Respondent ''knew or should have known'' that the ''prescriptions were issued for other than a legitimate medical purpose and outside the usual course of professional practice.'' ALJ Ex. 1, at 3 (Order to Show Cause, at ¶ 5).

I also agree with the ALJ's conclusion that the Government's calculations of the average monthly purchase of oxycodone by Respondent's customers (as reflected in both exhibits) are flawed. R.D. 27 n.22. As for the calculations in GX 10B, the Government conceded that these were erroneous because each transaction was treated as if it was made by a separate pharmacy, Tr. 1736, and thus the number of pharmacies used to calculate the average was off by a factor of 14 for the 2009 calculation and 24 for the 2010 calculation. *Compare* GX 10B *with* GX 10L.

Similarly, while the calculations in GX 10L may have been based on an accurate number of pharmacies, I agree with the ALJ that the calculations are flawed because they did not take into account that Respondent's customers did not necessarily purchase oxycodone each month and thus suffer from aggregation bias. R.D. 27 n.22; *see also* Tr. 1625–26, 1755–57. Indeed, I note that while GX 10L was submitted after Respondent's expert pointed out this flaw in the Government's initial calculations, the Government still submitted calculations that did not correct for aggregation bias.

[16] Indeed, at the hearing, both Messrs. Corona and Smith testified that in early 2009, Smith, accompanied by another employee, travelled to Florida to check out the situation. Tr. 1033, 1665. At the time, Respondent was supplying pain clinics which engaged in the direct dispensing of controlled substances to patients. On his return, Smith decided to cut off the pain clinics. As Corona explained:

He [Smith] said he couldn't believe what was going on in Florida with respect to the pain clinics because he had seen park benches and bus stop benches advertising pain clinics, and he brought back a copy of City Beat with I forget how many pages of nothing but ads for pain clinics with young kids sitting around a pool in bathing suits with big smiles on their face [sic], and he said this was an issue and we're not going to participate in this anymore. So he effectively that day cut everybody off.

Tr. 1074. In his testimony, Smith confirmed Corona's recollection of the impetus for the decision to cut off the pain clinics. He testified that:

I was down there a couple of days, two or three days. We looked at the pain clinics. We looked at certain areas of town that some of the pain clinics were located in. We also got a copy of City Beat, which was a monthly or a weekly—one of those free catalogs you often see outside of restaurants—and started going through it and identified that towards the back there were a lot of advertisements for pain clinics that I thought were very unethical. It would show young people sitting around a pool and it named the pain clinic and say [sic] we dispense on site, and that really hit home hard.

Tr. 1665–66; *see also* RX 104, at 19 (Smith Decl. at ¶ 73).

Smith did not, however, cut off the pharmacies. According to Corona, this was because Smith believed that Respondent could rely on the pharmacies to vet the physicians who were writing the prescriptions. Corona then asserted that ''[w]e all knew that a licensed professional in the health care field would for the most part behave ethically and legally,'' *id.* at 1075, even though Smith testified that he had concerns about the ethics and legality of the conduct engaged in by pain-clinic physicians. *Id.* at 1665–66.

So too, while Smith admitted that he knew that oxycodone was the primary drug being sought for illicit use in Florida, *id.* at 1668, he asserted that he ''put a lot of thought into it, and I just felt that there should be segregation of duties, that the physician should write and the pharmacy should dispense, and that was an added line of due diligence on the part of the pharmacy.'' *Id.* at 1666. Apparently, the possibility that pharmacists might also act unethically or illegally never occurred to him, even though Smith was obviously aware of this possibility from his experience in addressing the allegations of the previous Show Cause Order that Respondent supplied pharmacies that were unlawfully distributing controlled substances via the internet.

Notes, Utilization Report (URs), and other forms and emails. *Id.* at 16.

According to the DI, his review showed that Respondent ''regularly ignored inconsistencies in information provided by controlled substance customers, including extremely high percentages of controlled substances being distributed by the pharmacy, significant percentages of cash sales, and other indicators of potential diversion.'' *Id.* at 16–17. The DI further asserted that the documents showed that Respondent ''deleted or edited orders that would bring customers above their threshold limit'' and that it also ''routinely utilized a 'release with reservation' or 'ship with reservation' ('RWR or SWR') designation and thus allowed orders that [it] should have viewed as potentially suspicious [to] be shipped.'' *Id.* at 17. Finally, the DI alleged that Respondent ''ignored or failed to act on information it reviewed during on-site inspections that were significant indicators of potential diversion.'' *Id.*

The Pharmacy Specific Evidence

Before proceeding to make findings specific to each of the Florida pharmacies,[17] a discussion of the parties' exceptions which bear directly on the weight to be given to the pharmacy-specific evidence is warranted. These include the Government's exception to the ALJ's finding that it failed to prove that Respondent did not comply with the provisions of its policies and procedures which required it to contact the pharmacy whenever an order was held by the SOMS and obtain an explanation for the order, which it then independently verified, as well as to obtain a new UR. Gov. Exceptions, at 43–56. As for Respondent, it asserts that ''the ALJ assumed that *all* orders identified on the SOMS notes were held by SOMS,'' and that ''[a]s a result of this misinterpretation, the ALJ vastly overstated the number of orders held by the SOMS.'' Resp. Exceptions, at 13. Respondent also argues that ''the ALJ incorrectly concluded that the . . . Order to Show Cause was not based on 'Covered Conduct' '' and that she ''failed to make factual findings required to protect [its] interests under the'' MOA. *Id.* at 16. Respondent further asserts that the ''ALJ should not have allowed evidence regarding [its] failure to review [the utilization reports] regardless of whether it was part of [its] policies and procedures.'' *Id.* at 19.

The Government's Exception

As noted above, Respondent's Policies and Procedures required that an order placed on compliance hold by the Suspicious Order Monitoring System (SOMS) be subject to additional due diligence which included: (1) contacting the customer to discern the reason for the deviation in size, pattern, or frequency; (2) independently verifying the reason stated by the customer; (3) obtaining a new utilization report; and (4) conducting a complete file review to determine if the pharmacy's order was consistent with legitimate business practices. As will be shown below, while the SOMS held numerous orders placed by the Florida pharmacies, in only rare instances do Respondent's records document that it contacted the pharmacy to obtain an explanation for the order, let alone that it independently verified that explanation.[18]

The Government points to the frequent absence of documentation showing that Respondent contacted the pharmacies, obtained an explanation for these orders, and independently verified that explanation. The Government contends that the reason there is no such documentation is because Respondent's employees did not do it.

The ALJ rejected the Government's contention, asserting that the Government acknowledged in its brief that Respondent's ''Policies and Procedures do not require documentation of the reasons for the release of a held order.'' R.D. at 171. I need not decide whether this is a fair reading of the Government's brief because, as found above, the ALJ ignored the evidence that Respondent, in its presentation to the Agency regarding ''The Process'' for monitoring controlled substance orders, represented that ''[d]ocumentation on all orders held for review and their dispositions are permanently retained.'' RX 12, at 30 (emphasis in original).

Moreover, while the ALJ acknowledged Mr. Corona's testimony that documentation was the '' 'lynchpin [sic] of the whole system in terms of explaining our behavior,' '' the ALJ then characterized his testimony as ''not[ing] that the reasons for exceeding SOMS would *often* be documented in [the] MFRs and Ship to Memos.'' R.D. at 171 (citing Tr. 1094; GX 51B at 6 ¶ 19) (emphasis added). Yet Mr. Corona actually testified that ''[t]he compliance department would contact the customer, advise that the order was held and request a reason why the order exceeded SOMS parameters. The reason *would be documented in the due diligence files, specifically in the 'Memo for Record' (MFRs).* It may also have been electronically documented in the 'Ship to Memos' which were also part of the due diligence file.'' GX 51B, at 6 ¶ 19 (emphasis added). While the ALJ also cited Mr. Corona's oral testimony as support for her characterization of his testimony that the reasons ''would often be documented,'' I reject this because it is based on a misreading of Mr. Corona's testimony.[19]

The ALJ also asserted that another witness (Mr. Schulze), who had worked in the Compliance Department, ''testified that not all research the Compliance Department conducted was documented in the MFRs or Ship to Memos, and that he did not feel that leaving some research out of the due diligence files violated Respondent's Police and Procedures.'' R.D. at 172–73. However, the thrust of Mr. Schulze's testimony was that the Compliance Department would not necessarily document in the MFRs or the SOMS notes having performed Google searches or having obtained a fax from the customer; instead, it would simply place the information in the customer's due diligence file. Tr. 1337–39. Thus, this testimony simply does not address the issue.

While Mr. Schulze also testified that he would ''not necessarily'' document ''every single time'' he made a phone call to a customer, this was in response to Respondent's counsel's suggestion that it was ''[o]ften very difficult to get in touch with pharmacists'' because they are ''very busy people'' and ''don't sit at the end of the phone and take calls from [Respondent's] compliance department all the time.'' *Id.* at 1335–36.

[17] Having reviewed the entire record, I limit my discussion of the pharmacy specific evidence to the Florida pharmacies.

[18] While Policy 6.2 required Respondent to obtain a new UR whenever an order was held by the SOMS, it is beyond dispute that Respondent rarely obtained a new UR.

[19] The actual question (by Respondent's counsel), which was based on a hypothetical, as it is not supported by any facts in evidence and is not even probative on this point, and Corona's answer follows:

Q. Now, if Jennifer Seiple made that phone call and the pharmacist said I ordered a day early because I'm going on vacation next week and she didn't document that on an MFR, you would trust her to know that that was an appropriate reason? I mean, if she didn't document it, that doesn't indicate to you that she was attempting to do anything nefarious, does it?

A. No, it does not. What I would do is ask her under the assumption that she was well within her guidelines to do that and then ask her to please document it for future reference or go back and document it because documentation was the linchpin of this whole system in terms of explaining our behavior, especially in our environment.

Tr. 1094.

Most significantly, Respondent's counsel then asked Mr. Schulze if ''[i]t was your understanding that when compliance had significant or important information or contact with a customer, that type of information should be documented in the compliance file in either the MFRs, or the SOMS notes, or the ship to notes, or somewhere, correct?'' *Id.* at 1336–37. Mr. Schulze answered: ''Yes.'' *Id.*[20]

In addition to her failure to acknowledge Respondent's representation to the Agency that ''[d]ocumentation on all orders held for review and their disposition are permanently retained,'' RX 12, at 30; the ALJ also failed to acknowledge both the representations made by Respondent in the SOMS Appendix and what the SOMS notes actually showed. As found above, the SOMS Appendix states that: ''[t]he ultimate status, accept or reject, will be shown along with the date/time and user associated with the action. *A Reason code and notes will also be provided as additional detail supporting the decision.''* RX 78, at 64 (emphasis added). Thus, I respectfully reject the ALJ's premise that Respondent's Policies and Procedures did not require it to document the inquiries it made of the pharmacies in the course of reviewing those orders that were held by the SOMS.

Moreover, as will be explained in the findings made with respect to each pharmacy, the SOMS notes did typically contain an explanation regarding the review of those orders that were held by the SOMS. However, that explanation invariably did not reflect that Respondent had contacted the pharmacy and obtained an explanation for why the order had exceeded the SOMS parameters, but rather, some other explanation, such as that the order was released because it was supported by the pharmacy's utilization report (which the evidence will show was infrequently obtained). This begs the question, which the ALJ did not answer: why, if the Compliance Department had actually contacted the pharmacy and obtained a legitimate explanation for why the order exceeded the SOMS parameters, it then documented a reason for releasing the order which had nothing to do with anything the pharmacy may have told it?

As for the ALJ's reliance on the fact that such documentation is not required by DEA regulations or any established industry standard, this is beside the point given that Respondent represented to the Agency that it would maintain such documentation. Moreover, there is ample authority to support the Government's position that the absence of such documentation proves that the pharmacies were not contacted.

As a leading authority explains: ''The *absence of an entry,* where an entry would naturally have been made if a transaction had occurred, should ordinarily be equivalent to an assertion that no such transaction occurred, and therefore should be admissible in evidence for that purpose.'' V Wigmore, Evidence § 1531, at 463 (Chadbourn rev. 1974) (citing cases); *see also United States* v. *De Georgia,* 420 F.2d 889, 891 (9th Cir. 1969) (noting that Wigmore ''expressed the view that the absence of an entry concerning a particular transaction in a regularly-maintained business record of such transactions, is equivalent to an assertion by the person maintaining the record that no such transaction occurred''); *A.Z.* v. *Shinseki,* 731 F.3d 1303, 1311 (Fed. Cir. 2013) (''The absence of certain evidence may be pertinent if it tends to disprove (or prove) a material fact.'') (other citation and quotation omitted); *cf.* Fed. R. Evid. r. 803(7).

Accordingly, as a general matter, I respectfully reject the ALJ's conclusion that the Government's reliance on the lack of documentation in Respondent's records does not prove that its compliance department failed to contact the pharmacy and obtain an explanation for the orders that were held by the SOMS (as well as that it failed to independently verify any such explanation) but were subsequently released.[21] To the contrary, where there is an absence of documentation that Respondent performed the respective act, that absence is substantial evidence that Respondent did not perform the act. And as will be shown below, with respect to most of the orders that were held by the SOMS, there is additional evidence that supports the conclusion that Respondent failed to contact the pharmacies and obtain an explanation for the orders, as most of the relevant entries provide a justification for shipping the order which has nothing to do with the type of explanation one would expect from a pharmacist.

Respondent's Exceptions

As noted above, Respondent takes exception to the ALJ's findings as to the number of orders placed by the various pharmacies that were held by the SOMS for review. Resp. Exceptions, at 13–16. While Respondent acknowledges that ''there was no direct evidence presented on this point,'' it argues that ''the ALJ incorrectly assumed that *all* orders identified on the SOMS notes were held'' for review. *Id.* at 13. Respondent contends that ''the only orders that were held by SOMS were those that also have the name of a Compliance Department employee in the 'Decision By' column and, in most cases, notes in the 'Notes' column.'' *Id.* Respondent contends that the ALJ's misinterpretation of the SOMS notes led her to ''vastly overstate[ ] the number of orders'' that were held. *Id.*

Notwithstanding that Respondent put forward no direct evidence as to the interpretation of the SOMS notes, having reviewed the entire record I agree with Respondent that the ALJ misinterpreted the notes and overstated the number of held orders. Indeed, Respondent's materials indicated that all controlled substances orders were evaluated by the SOMS, and it seems logical that if an order did not exceed one of the three parameters, a review of the order would not be conducted and no name would be listed in the ''Decision By'' column. I find this conclusion to be supported by my review of the numerous oxycodone orders set forth in the Government's ARCOS data in light of the SOMS parameters. Accordingly, I do not adopt the ALJ's findings as to the number of held orders and instead, I make findings specific to the respective orders. *See also* RX 78, at 64.

Next, Respondent argues that the ALJ erred in concluding that the Show Cause Order was not based on the covered conduct (*i.e.,* those claims based on Respondent's conduct prior to April 1, 2009) which was resolved by the MOA. *Id.* at 16. Respondent argues that, because following the August 2009 Compliance Review, the Agency ''never advised [it] of any deficiencies in its compliance program, its suspicious order reporting, or its due diligence investigations as required under the MOA,'' the Agency ''breached the terms of the MOA by . . . asserting claims for which [the Agency] has already provided a release, and by seeking to impose liability for conduct [it] took in reliance on its successful Compliance Review.'' *Id.* at 16–17. Respondent further argues that ''while the ALJ excluded some so-called 'Period of Review' evidence, she failed to make

[20] Nor did Ms. Seiple, who headed the Compliance Department, assert that its employees actually contacted the pharmacies whenever the SOMS held orders but simply failed to document doing so. *See* RX 103.

[21] Even if the Agency's regulations do not require a distributor to document the reason provided by a customer to justify a suspicious order, documenting that reason is still an essential part of maintaining effective controls against diversion because subsequent events may provide information which show that the reason was false.

factual findings . . . to ensure that [it] received the full benefit of its bargain set forth in the 2009 MOA.'' *Id.* at 17–18.

More specifically, Respondent argues that ''[t]he due diligence [it] conducted on its customers was deemed satisfactory in 2009, but DEA now deems it insufficient.'' *Id.* at 18. Respondent further contends that ''DEA expressed no concern about any order for controlled substances [it] shipped in 2009, but [DEA] now claims Masters should have reported many of those same orders as suspicious.'' *Id.* Continuing, Respondent argues that ''[t]he policies and procedures DEA deemed satisfactory in 2009 are now deemed inadequate'' and that ''DEA has built its entire case on actions Masters took in reliance on that MOA.'' *Id.* Respondent then argues that, to protect its rights under the MOA and the Due Process Clause, the ALJ should have made the following three findings:

> That as of August 18, 2009, it ''had enacted policies and procedures that constituted effective controls against diversion regarding the distribution of any controlled substance'';
>
> That as of August 18, 2009, it ''had detected and reported to DEA suspicious orders of controlled substances after April 1, 2009''; and
>
> That as of August 18, 2009, it ''had meaningfully investigated all new or existing customers, including each of the . . . pharmacies identified in the'' Show Cause Order, ''regarding the customer's legitimate need to order or purchase controlled substances.''

Id. Respondent thus contends that because the ALJ ''fail[ed] to make these findings, [it] was required to defend conduct that it took in reliance on DEA's inaction following the Compliance Review.'' *Id.* It therefore requests that I make these findings and hold ''that this proceeding was based, at least in material part, on 'Covered Conduct' as defined in the MOA.'' *Id.* at 18–19.

I reject Respondent's request. Contrary to Respondent's contention, the MOA granted Respondent immunity only for its conduct prior to April 1, 2009, and none of the orders which are at issue in this proceeding occurred before this date. Moreover, to the extent Respondent's due diligence efforts prior to April 1, 2009, are at issue (*i.e.,* to justify Respondent's failure to report an order as suspicious and/or to ship the orders which are at issue), the MOA specifically provides that ''[n]otwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes *in any other administrative proceeding against the Released Parties for non-covered conduct.*'' GX 6, at 6 (emphasis added).

As for Respondent's contention that the ALJ failed to make findings to ensure that it received ''the full benefit of its bargain,'' Resp. Exceptions, at 17–18; nothing in the MOA provides a remedy in the event the Government's representatives provided an inadequate compliance review.[22] Because the MOA provides no such remedy, Respondent's contention that it should be afforded immunity for its conduct after April 1, 2009 because it relied on the Government's failure to identify any deficiencies in its procedures following the compliance review must be evaluated by applying the principles of equitable estoppel. *See, e.g., Dantran, Inc.,* v. *U.S. Dept. of Labor,* 171 F.3d 58, 66 (1st Cir. 1999) (applying equitable estoppel and rejecting contractor's contention ''that the government should be estopped from pursuing an action based on practices . . . that drew no criticism at that time'' because it ''reasonably relied'' on ''the clean bill of health'' it received following investigation and compliance officer's failure to question its practices).

Under the traditional principles of equitable estoppel, '' 'the party claiming the estoppel must have relied on its adversary's conduct 'in such a manner as to change [its] position for the worse,' and that reliance must have been reasonable in that the party claiming the estoppel did not know nor should it have known that its adversary's conduct was misleading.'' *Heckler* v. *Community Health Services of Crawford Cty., Inc.,* 467 U.S. 51, 59 (1984) (quoting *Wilber Nat'l Bank* v. *United States,* 294 U.S. 120, 124–25 (1935)). Moreover, with respect to claims of estoppel against the Government, the Supreme Court has explained that:

> [w]hen the Government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined. It is for this reason that it is well settled that the Government may not be estopped on the same terms as any other litigant.

Id. at 60.

Accordingly, the D.C. Circuit has explained that:

> [a] party attempting to apply equitable estoppel against the government must show that ''(1) there was a definite representation to the party claiming estoppel, (2) the party relied on its adversary's conduct in such a manner as to change [its] position for the worse, (3) the party's reliance was reasonable[,] and (4) the government engaged in affirmative misconduct.''

Keating v. *FERC,* 569 F.3d 427, 434 (D.C. Cir. 2009) (quoting *Morris Comm. Inc.* v. *FCC,* 566 F.3d 184, 191–92 (D.C. Cir. 2009)).

Applying this test, Respondent cannot prevail.[23] Even assuming that Respondent has made the requisite showing as to the first two prongs, its contention fails because its reliance on the DIs' failure to identify specific deficiencies in its policies was not reasonable and there is no evidence that

[22] Respondent actually got more than it bargained for, at least from the ALJ, when she ''ruled that the Government will be precluded from asserting any evidence of [Respondent's] failures to report suspicious orders during the Period of Review,'' the period from April 1, 2009 through the Compliance Review. Order Granting In Part Respondent's Motion in Limine to Preclude Admission of Irrelevant, Immaterial, and/or Incompetent Evidence and to Adopt Findings, at 14. Nothing in the MOA provided Respondent with immunity for potential violations during this additional period, and the ALJ's ruling ignores that even if Respondent was unclear as to what its regulatory obligations were, it always had the option not to accept and/or fill orders from the seven pharmacies during this period.

Moreover, even though the Government did not take exception to the ALJ's ruling, in its Exceptions, Respondent specifically requests that I make the factual finding that ''[a]s of August 18, 2009, [it] had detected and reported to DEA suspicious orders of controlled substances after April 1, 2009.'' Resp. Exceptions, at 18. While I consider the suspicious order reports which are contained in RX 61, I conclude that any such finding should be based on a consideration of the entire record in this proceeding. Accordingly, I also consider the evidence as to whether the orders placed by the seven Florida pharmacies during the period from April 1 through August 18, 2009 were suspicious and, if so, whether Respondent ''detected and reported'' them to DEA.

As for the facts that the MOA provided that ''[t]he Compliance Review will be deemed satisfactory unless DEA determines that [Respondent] failed to detect and report to DEA suspicious orders of controlled substances after April 1, 2009,'' GX 6, at 5; and that the DI did not specifically identify any such orders as suspicious either at the time of the briefing or thereafter, Respondent's argument fails for the same reasons that I reject its contention regarding the DI's failure to identify specific deficiencies in its policies and procedures. As explained above, its contention that it relied on the DI's failure to identify any order as suspicious must rest on the principles of equitable estoppel. *See, e.g., Dantran,* 171 F.3d at 66.

In short, Respondent's reliance on the DI's failure to identify any specific order as suspicious was not reasonable given that the DI identified its sales to several of the pharmacies as being of concern and asked its Compliance Director if she was still selling to them. Moreover, even were I to conclude otherwise on the issue of the reasonableness of its reliance, Respondent cannot claim that the DIs engaged in affirmative misconduct when they failed to identify any specific orders as suspicious.

For the same reasons, I reject the ALJ's ''find[ing] that DEA is barred by the MOA from sanctioning Respondent for not implementing additional UR analyses into its Policies and Procedures.'' R.D. at 186.

[23] Notably, while in its Exceptions, Respondent argues that it engaged in ''conduct that it took in reliance on DEA's inaction following the Compliance Review,'' it does not acknowledge that its claim is subject to the principles of equitable estoppel.

the Government's representatives engaged in affirmative misconduct.

As the Supreme Court has explained, to establish that one's reliance was reasonable, ''the party claiming the estoppel [must show that it] did not know nor should it have known that its adversary's conduct was misleading.'' *Heckler,* 467 U.S. at 59 (citing *Wilber Nat'l Bank,* 294 U.S. at 124–25). Moreover, '' 'if, at the time when [the party] acted, [it] had knowledge of the truth, or had the means by which with reasonable diligence [it] could acquire the knowledge so that it would be negligence on [its] part to remain ignorant by not using those means, [it] cannot claim to have been misled by relying upon the representation or concealment.' '' *Id.* at 59 n.10 (quoting 3 J. Pomeroy, *Equity Jurisprudence* § 810, at 219 (S. Symons ed. 1941)).

As found above, while the DI did not identify any specific deficiencies in Respondent's policies and procedures, he advised Respondent's employees that he perceived ''potentially problematic trends'' in its sales to several of the pharmacies of various highly abused controlled substances including oxycodone 30 mg, methadone 10 mg, alprazolam 2mg, and hydrocodone. The DI also identified the expected ratio of controlled to non-controlled dispensings at pharmacies. This testimony was corroborated by the testimony of Messrs. Harmon and Corona. Indeed, as found above, Mr. Harmon testified that as one of the DIs reviewed Respondent's files, with respect to several of the pharmacies whose orders are at issue in this proceeding, he turned to Ms. Seiple and specifically asked her if Respondent was still selling to them.

As also noted above, after the Compliance Review, Mr. Harmon also wrote a memo setting forth various steps Respondent should undertake, including using the utilization reports submitted by the pharmacies whose dispensings of controlled substances comprised more than 50 percent of their dispensings and thus, in the memo's words, suggested that they were ''engaged in inappropriate business activity.'' GX 38. Thus, the fact that the DI did not specifically instruct Respondent's employees that the procedures were deficient because they did not use the URs to analyze whether the respective pharmacies' controlled substance dispensing ratios were consistent with legitimate dispensing activity provides no support to Respondent. As will be shown below, the URs provided extensive evidence that the identified pharmacies were placing suspicious orders and potentially diverting controlled substances. Respondent cannot credibly argue that it reasonably relied on the DI's failure to object to the limited manner in which it used the URs or that it had the right to ignore the evidence it obtained through the URs because the DI did not specifically instruct its employees to use the URs in this manner.

Nor does the evidence support a finding that Respondent was affirmatively misled by either the DI's statement at the completion of the review or by the Government's failure to subsequently identify any deficiencies in Respondent's policies and procedures. As the First Circuit has explained, ''[i]t is common ground that affirmative misconduct requires something more than simple negligence.'' *Dantran,* 171 F.3d at 67; *see also U.S.* v. *Hemmen,* 51 F.3d 883, 892 (9th Cir. 1995) (''When a party seeks to invoke equitable estoppel against the government, we . . . require a showing that the agency engaged in affirmative conduct going beyond mere negligence[.]'') (other citations and internal quotations omitted).

In this case, there is simply no evidence that the DI's statement at the conclusion of the compliance review (that Respondent ''ha[d] progressively engaged in actions to implement into [sic] policies and procedures to promote an effective system'' to prevent diversion, GX 48A, at 8 ¶ 15) was made with the ''intent to mislead [Respondent] about [its] responsibilities.'' *Dantran,* 171 F.3d at 67. The same is true with respect to the Government's failure to identify any deficiencies in writing following the review. In short, ''there is not the slightest whiff of affirmative misconduct'' on the part of the DI. *Id.*

There is a further reason for rejecting Respondent's exception. As the DI testified, his statement that Respondent had ''progressively engaged in actions'' to implement an effective system of diversion controls was based on Respondent's policies and procedures being ''properly implemented.'' GX 48A, at 8 ¶ 15.

As found above, during the Compliance Review, Respondent represented to the Government that when an order was held for exceeding the SOMS parameters, it would take various actions to investigate whether the order was legitimate, which included contacting the pharmacy to obtain an explanation for the order, independently verifying the explanation, and obtaining a new UR. Yet, as demonstrated below in the discussion of the pharmacy-specific evidence, the record shows that Respondent rarely complied with its policies and procedures with respect to the seven Florida pharmacies.

Thus, while Respondent contends that DEA is improperly seeking to impose liability for failing to report orders as suspicious, claiming that ''[t]he policies and procedures . . . deemed satisfactory in 2009 are now deemed inadequate,'' its contention is unavailing given the extensive evidence that it repeatedly failed to comply with these policies. Moreover, as demonstrated below, Respondent repeatedly justified its failure to report these orders (as well as its subsequent filling of the orders), notwithstanding its failure to follow these policies, on the ground that as a part of its ongoing due diligence, it had conducted an extensive investigation and determined that the orders were not suspicious and were consistent with the respective pharmacy's business model. *See generally* RX 103 (Seiple Decl.). Respondent thus placed the adequacy of its due diligence efforts at issue. I therefore reject its contention.[24]

Having addressed the relevant exceptions, I now turn to the pharmacy-specific evidence.

Tru-Valu Drugs, Inc.

According to Respondent's due diligence file, Tru-Valu Drugs, Inc., was a pharmacy located in Lake Worth, Florida which had been in business for 43 years and had the same ownership for 32 years. RX 2A, at 76–77. According to a Pharmacy Evaluation done on May 28, 2008 by a consultant retained by Respondent, Tru-Valu filled 150 prescriptions per day, of which 40 percent were for controlled substances. *Id.* at 78–81. Tru-Valu reported that 60 percent of its business was cash and that insurance and Medicare/Medicaid together comprised 40 percent. *Id.* at 78.

[24] For the same reasons, I reject Respondent's further contention that because ''the Government failed to provide any notice to [it] regarding the use of [the] URs, the ALJ should not have allowed the Government to introduce any evidence in regard to such use'' to show that it did not ''comply with the MOA, or otherwise failed to maintain effective controls again diversion.'' Resp. Exceptions, at 19.

Respondent further ignores that it put in issue the manner in which used the URs. As will be shown in the discussion of the pharmacy-specific evidence, with respect to each of the pharmacies, Ms. Seiple stated that Respondent ''was aware of the volume of oxycodone and other controlled drugs being dispensed by [the pharmacy], and the percentage of controlled drugs dispensed relative to other drugs,'' that it ''specifically investigated the reasons why [each pharmacy's] ordering and dispensing patterns were as indicated on the URs,'' and that ''[t]he URs and other information provided by [the pharmacy] were consistent with the pharmacy's business model.'' *See, e.g.,* RX 103, at 40.

It also disclosed that it had purchased from four other pharmaceutical distributors in the last 24 months, including Amerisource Bergen, H.D. Smith, ANDA, and Mason Vitamin. *Id.* at 77.

Tru-Valu was not located in a medical center. *Id.* at 79. It did not serve nursing homes, hospice programs or inpatient facilities. *Id.* at 78. However, it did fill prescriptions for pain management clinics, and its owner and pharmacist-in-charge (PIC) advised that ''[t]hey do fill a large number of narcotic prescriptions each day'' and ''that he has pushed for this business with many of the area pain doctors.'' *Id.* at 79–81. Tru-Valu's owner also advised Respondent's consultant that ''[h]e is concerned about the current restrictions put on his buying by several suppliers.'' *Id.* at 81.

Tru-Valu provided the names of five pain management doctors whose prescriptions it filled. *Id.* at 79. Tru-Valu's due diligence file contains no evidence that Respondent performed any check on the licensure and registration status of these physicians and whether the physicians had any specialized training or held board certification in pain management or addiction medicine. Nor is there any evidence that Respondent inquired of Tru-Valu's pharmacist as to the nature of the prescriptions these physicians were writing (*i.e.,* the quantity and whether drug cocktails such oxycodone 30 mg and alprazolam were being prescribed for patients). Moreover, two of these doctors (Joel Panzer and Stephanie Sadick) appear on Respondent's list of terminated customers, the former having been terminated on September 3, 2008 and the latter on April 3, 2009. RX 62A, at 3; RX 62E, at 2.

Apparently seeking an increase in the amount of oxycodone it could purchase, on May 22, 2008, Tru-Valu provided Respondent with a utilization report for April 2008 which listed and ranked the top 300 prescription drugs (both the controlled and non-controlled) it dispensed by the quantity.[25] RX 2A, at 70–76. The report showed that oxycodone 30 mg was the top drug with 132,506 dosage units dispensed, followed by methadone 10 mg at 53,842 du, alprazolam 2 mg at 55,120 du, sterile water for irrigation at 24,000 units (a non-controlled prescription product), Endocet 10/325 mg (oxycodone/acetaminophen) at 4,146 du, Hibiclens 4% liquid (a non-controlled topical anti-microbial), carisoprodol 350 mg at 3,703 du (then controlled under Florida law and since placed in schedule IV of the CSA), valproic acid 250 mg (non-controlled) at 2,400, and OxyContin 80 mg (oxycodone continuous release) at 2,220 du. *Id.* at 70. Thus, oxycodone 30 mg, methadone 10 mg, and alprazolam 2 mg constituted more than 241,000 dosage units out of the total quantity of more than 340,000 du dispensed that month.[26] *Id.* at 70, 75. In contrast, Tru-Valu dispensed only 2,479 dosage units of hydrocodone 10 mg, 120 du of hydrocodone 7.5, and 390 du of hydrocodone 5 mg, even though hydrocodone was the most widely prescribed drug nationally from 2006 through 2010. *See id.* at 70–76; RX 81, at 46–47.

Tru-Valu's file also includes additional URs for the months of December 2008, October 2009, February 2010, July 2010, and September 2010. Tru-Valu's December 2008 UR listed the top 200 prescription drugs it dispensed, which totaled more than 300,000 units. *Id.* at 64. Notably, Tru-Valu dispensed more than 192,000 dosage units of oxycodone 30 during the month. *Id.* at 61. With the exception of carisoprodol (which was then non-controlled under federal law), each of the top ten drugs Tru-Valu dispensed was a controlled substance; these included alprazolam 2 mg (27,268 du), methadone 10 mg (11,848 du), and Endocet (oxycodone) 10/325 mg (6,976 du). *Id.*

While Tru-Valu's October 2009 UR showed a decline in its dispensings of oxycodone 30 mg to a total of 83,830 du out of its total dispensings of approximately 167,000 du, *id.* at 51, 58; its February 2010 UR showed that in just these four months, its dispensings of oxycodone 30 had more than doubled to 192,110 du.[27] *Id.* at 47. The UR also showed that Tru-Valu's dispensings of oxycodone 15 totaled 38,563 du and its dispensings of alprazolam 2mg totaled 30,655 du. *Id.* These three drugs alone accounted for more than 81 percent of Tru-Valu's dispensings. Moreover, the top ten drugs by dispensing volume were comprised entirely of oxycodone products in various dosages, methadone, and alprazolam, and 17 of the top 20 drugs were federally controlled substances. *Id.*

Tru-Valu's July 2010 UR showed a further increase in its dispensing of oxycodone 30 mg to 206,132 units out of total dispensings for all prescription products of 337,314.[28] RX 2A, at 29, 36. It also showed that Tru-Valu had dispensed 32,441 du of oxycodone 15 and 31,271 du of alprazolam 2 mg during the month. *Id.* at 29–30. With the exception of carisoprodol (which was the tenth-most dispensed drug), each of the top ten drugs was a formulation of oxycodone, methadone, or alprazolam. So too, with the exception of carisoprodol and ibuprofen, each of the top 20 drugs dispensed was either a schedule II narcotic or a schedule IV benzodiazepine (alprazolam or diazepam).

The final UR in Tru-Valu's file (Sept. 2010) showed that it dispensed 146,560 dosage units of oxycodone 30 mg during the month. *Id.* Of further note, for each of the five URs in Tru-Valu's file, controlled substances were predominant among the drugs dispensed.

Tru-Valu's file also includes a form entitled ''DEA Schedule Orders—Due Diligence Report Form,'' the purpose of which was ''to evaluate customers who demonstrate a pattern of large orders of control [sic] product.'' *Id.* at 41. This form, which is dated ''1–9–09,'' noted that Tru-Valu had requested an increase in its oxycodone purchases. *Id.* The form, which apparently reflected information the pharmacy provided in a phone survey, noted that Tru-Valu's daily script average was 200, that 50 percent of the prescriptions were for controlled drugs, and that 25 percent of the prescriptions were schedule II drugs. *Id.* The form also noted that 25 percent of the prescriptions were paid for by insurance. *Id.*

The form further noted various procedures employed by the pharmacy.

[25] Twelve days before the site visit, Tru-Valu had requested an increase in the quantity of solid dose oxycodone it could purchase from Respondent. According to the form, which appears to have been completed by an account manager, Tru-Valu was using 750 bottles per month and the account manager sought an exemption from Respondent's sales limit on the basis that it qualified as a ''[l]arge full line pharmacy.'' RX 2A, at 93.

According to the file, Respondent obtained a utilization report that listed only controlled substances and then requested a report which included non-controlled drugs as well. The form bears the notations: ''Approved 25k/mo'' and ''6/4/08.'' *Id.*

[26] These were not the only controlled substances listed on the report. The report lists additional dispensings of oxycodone 30 mg under different drug codes, likely because the products were manufactured by a company other than the manufacturer whose products comprised the bulk of Tru-Valu's dispensings. *See id.* at 70 (also showing at line 28, dispensing of 540 Roxicodone 30; at line 43, 360 oxycodone 30; at line 44, 354 oxycodone 40 mg).

[27] The Feb. 2010 UR listed the top 200 drugs and total dispensing of approximately 321,400 dosage units. RX 2A, at 47.

During the cross-examination of the DI, Respondent's counsel pointed out that some of the URs only listed the top 200 or 300 drugs that were dispensed. However, Respondent's Policy 6.2 directed that it obtain ''[a] current utilization report, listing all of the pharmaceuticals'' (including both controlled and non-controlled), dispensed by the pharmacy ''in the most recent calendar month.''

[28] The July 2010 UR listed 377 line items of dispensings down to a quantity of one. RX 2A, at 36.

For example, to prevent doctor shopping, the pharmacy stated that it did not fill prescriptions if patients changed doctors and that it kept a list of where patients were getting scripts; as to how the pharmacy ensured that the prescribers were exercising proper standards of care, the pharmacy replied that ''they set limits on what they fill and they watch there [sic] patients very careful [sic] and never do early refill. They also don't fill for some docs.'' *Id.* at 42.

With respect to whether it had ever refused to fill a prescription (to which the pharmacy's answers was ''yes, every day''), the pharmacy reported that the most common reasons were ''early refill[s],'' if the patients were ''under 21,'' if patients lived ''out of area,'' or if it did not fill for a doctor. *Id.* As for whether the pharmacy had ever ''stopp[ed] filling prescriptions for a certain physician,'' the pharmacy reported that it had when it was ''not comfortable with there [sic] prescribing license.'' *Id.* The pharmacy also stated that it did not fill prescriptions written by out-of-state and out-of-area doctors and that if it got a prescription from a new doctor, it would call the DEA and check the license, and that it ''belong[ed] to a network of pharmacies that warn each other.'' *Id.* Finally, the form noted that Tru-Valu had been asked to submit its most recent pharmacy inspection report; a UR, which ''should include all controls and non-controls''; and any written policies and procedures for controlled substances. *Id.* at 43.

Tru-Valu's controlled substance limit (the SOMS trigger) for oxycodone was initially set at 25,000 dosage units and, according to the SOMS notes, remained at this level through January 2010. *Id.* at 93; *see also* GX 15, at 111 (SOMS Notes of 10/27/09: ''Ok to ship . . . oxy @ limit 25k with this order'' and Jan. 29, 2010—''ok to ship, under the CSL of 25k''). However, in November 2009, Respondent filled orders totaling 26,200 du of oxycodone products, which included 1,200 du of oxycodone 80; 9,600 du of oxycodone 30; 14,400 du of oxycodone 15; and 1,000 du of oxycodone 10/325. GX 10F, at 1–2. All but 3,600 du were ordered on the last day of the month. *Id.* at 1–2. While these orders placed Tru-Valu over the 25,000 CSL, the SOMS notes do not contain the name of a reviewer or an explanation for why the orders were shipped. GX 15, at 111.[29]

In February 2010, Tru-Valu again submitted orders in excess of the 25,000 du threshold. According to Respondent's records, Mr. Schulze, a compliance clerk, called Tru-Valu and spoke with its pharmacist-in-charge about the oxycodone order. RX 2A, at 9. The pharmacist in charge reported that an Albertson's (a supermarket) had ''closed by him'' and that he was ''getting some of [its] business.'' *Id.*

However, even though Respondent's Policy 6.2 required that the pharmacist's explanation then be independently verified, there is no documentation to support that this was done. Moreover, while the SOMS note for this order states: ''Ship with reservation UR supports Oxy order reviewed by JEN,'' GX 15, at 111; Respondent did not obtain a new UR for ''the most recent calendar month'' as required by its Policy 6.2, and had last obtained a UR in October 2009. Notwithstanding its failure to comply with its policy, during February 2010, Respondent shipped Tru-Valu 39,600 dosage units of oxycodone 30 mg and 7,200 dosage units of oxycodone 15 mg for a total of 46,800 du. GX 10F, at 1–2. Although the orders exceeded the CSL by nearly 22,000 du, Respondent did not report any of the orders as suspicious.

Even assuming that this figure became the new CSL for Tru-Valu's oxycodone orders (notwithstanding Respondent's failure to verify the legitimacy of the order), in March 2010, Tru-Valu again ordered in excess of the CSL. According to an entry dated March 15, 2010 in the Memo for Records, compliance ''requested UR for file to support this. Need site visit. RWR [release with reservation] until site visit completed.'' RX 2A, at 9. The Memo for Records includes a further note on this date stating: ''Increase in Business Due to Albertson's Closing.'' *Id.* However, while a UR was obtained for the month of February 2010, it was not obtained until April 1, 2010. *Id.; see also id.* at 47. Once again, there is no evidence that Respondent independently verified that the Albertson's had closed. *See generally* RX 2A. Respondent nonetheless shipped to Tru-Valu 43,200 du of oxycodone 30 and 12,000 du of oxycodone 15 for a total of 55,200 du. GX 10F, at 1–2.

An MFR entry dated March 31, 2010, states: ''Called to mention Oxy 15 need to be deleted. Pharmacy closed.'' RX 2A, at 9. While there is no evidence establishing the size of the oxycodone 15 order, as explained above, even assuming that the CSL had been raised to 46,800 as a result of Tru-Valu's February orders, its March orders again exceeded the CSL. Yet, here again, Respondent failed to comply with its policy by verifying the reason for the increase in the orders. Moreover, this order was not reported as suspicious.

In April 2010, Tru-Valu did not place any orders until April 27, when it ordered a total of 36,000 oxycodone 30 and 12,000 oxycodone 15. GX 15, at 112; GX 10F, at 1–2. While the orders were held for review by the SOMS (either because of frequency or pattern), because the orders were under the previous month's total of 55,200, Respondent did not deem the order to be excessive and filled the orders. GX 15, at 112 (SOMS notes). Respondent did not, however, contact the pharmacy and obtain an explanation for the order, which it independently verified.

On May 10, Tru-Valu ordered 12,000 du of oxycodone 30. GX 10F, at 1. A notation in the SOMS Notes states: ''Ok to ship first monthly purchase of Oxy leaves 13k.'' GX 15, at 112. Additional SOMS notes dated May 13 and 14 indicate that Tru-Valu placed additional orders on these dates and a notation made on the latter date states: ''RWR do nto [sic] ship over 25k without review by committee see mas and mfr.'' *Id.*

As for the MFR, it contains a handwritten note (of marginal legibility) dated May 14, which states ''increase on oxy—why orders increasing'' and that Tru-Valu's pharmacist had stated that H.D. Smith (another distributor) had ''cut back 60–70k'' and from ''40 bottles to 8 bottles'' a day, as well as a note that ''Started to cut back in March/Feb?'' RX 2A, at 7. The MFR note then states that Tru-Valu had ''purchased 120 bottles on 5–10–10'' and that there was a ''change in buy[ing] patterns due to HD Smith dropping allocation.'' *Id.* The entry continues with the following notation: ''RWR 120 bottles of oxy under CSL of 25 k. Don't ship over 25 k w/out rev @ 61k rolling 30 high due to pattern change due to allocation decreasing from wholesaler.'' *Id.*

However, here again, while the SOMS had placed the order on compliance hold, there is no evidence that Respondent's compliance department independently verified Tru-Valu's claim that H.D. Smith had reduced its allocation to the pharmacy. Nor did Respondent obtain a new UR. Moreover, three days later (May 17), Respondent filled an additional order and shipped 12,000 du of oxycodone 30 to Tru-Valu. GX 10F.

On May 18, Tru-Valu apparently placed a further order. GX 15, at 112. According to the Memo for Records, the order was ''deleted due to past 30 days @73k.'' RX 2A, at 7. Continuing, the entry states: ''Can place order after 5–27–10 Committee Rev.'' *Id.* However,

[29] The actual oxycodone orders placed by Tru-Valu (as opposed to the amount shipped) are not in the record. However, various entries in the Memo for Records and SOMS notes include notations as to the size of various orders.

while the order again placed Tru-Valu well over its CSL, the order was not reported to DEA as suspicious.[30]

On May 27, Tru-Valu placed additional orders for both oxycodone 30 and 15. GX 10F, at 1–2. According to the Memo for Records, Tru-Valu requested 12,000 du of oxycodone 15 in addition to 24,000 du of oxycodone 30. RX 2A, at 7. The Memo for Record further includes an illegible word (or two) followed by the words ''allotment 55,200—Current size in Soms is @24 k/can get 31,200 for current period.'' *Id.* Further notations on the same day indicate that Respondent talked to the pharmacist and that he requested that 72 bottles (of 100 du each) ''be sent from the Oxy 15's of 120.0 requested,'' *id.,* and other evidence shows that Respondent shipped 24,000 du of oxycodone 30 and 7,200 du of oxycodone 15 to Tru-Valu on this date. GX 10F, at 1–2.

Thus, during May, Respondent had shipped 65,200 du of oxycodone to Tru-Valu; it had also deleted the May 18 order, the size of which is unknown, and edited 4,800 du off the May 27 order. Yet even though the orders clearly exceeded the CSL and Respondent had never verified Tru-Valu's explanation, it did not report the orders as suspicious.

A note in the Memo for Records dated June 2, 2010, states that ''this account to be reviewed @25 Do not ship over 25 w/out committee review. . . . order on 5–27 was released w/out review by committee/management this was a mistake the account can not [sic] receive any more.'' *Id.* The Memo for Records includes a notation that the committee conducted its review the next day and determined that ''25k is place for review.'' *Id.* The notes also indicate that Tru-Valu was contacted and told that ''the account has received over allotment mistake both months'' followed by illegible writing. *Id.*

Notwithstanding the above entry, Respondent shipped 12,000 du of oxycodone 30 and 9600 du of oxycodone 15 to Tru-Valu on June 9, followed by an additional 12,000 du of oxycodone 30 on June 15, for a total of 33,600 du. GX 10F, at 1–2. The SOMS notes for both orders include notations to the effect: ''release with reservation per committee.'' GX 15, at 112. Here again, while the orders exceeded the CSL as determined by the committee, there is no evidence that Tru-Valu was contacted after it placed the June 15 order for 12,000 oxycodone 30. Nor did Respondent obtain a new UR. And Respondent did not report the orders as suspicious.

According to an email train, on June 21, Tru-Valu placed an additional order for 120 bottles of oxycodone 30. RX 95, at 2. Here again, this order placed Tru-Valu's orders over its oxycodone CSL. While the order was cancelled, apparently at the request of the PIC because insurance paid less than Respondent's price, *id.* at 1–2, it was not reported as suspicious even though it placed Tru-Valu's orders over its CSL.

Still later that month, the Memo for Records includes a note for June 30, with the entry: ''order deleted placed too early[.] See SOMs review of last 30 days.'' RX 2A, at 2. Here again, even assuming that Respondent contacted Tru-Valu regarding this order before deleting it, there is no documentation as to what the pharmacist may have told Respondent as to why he placed the order, and a new UR was not obtained.

Tru-Valu apparently resubmitted the order the following day (July 1), as Respondent shipped to it 13,200 du of oxycodone 30. GX 10F, at 1. After noting ''RWR'' (release with reservation), the SOMS note states: ''order for 132.0 bottles from 288 per may-30 on the pattern high of 46,800 rest of order can be resubmitted for review after 7/15/10.'' GX 15, at 112. However, on shipping the 132 bottles, Respondent had shipped 46,800 du of oxycodone on a rolling 30-day basis and Tru-Valu's orders totaled 62,400 du. Even assuming that the CSL was raised to 33,600 du from the 25,000 du level (discussed in the notes for the June 3rd committee review) based on Tru-Valu's June orders, there is no documentation that Respondent contacted Tru-Valu to obtain an explanation for the increase in its orders or that it verified Tru-Valu's previous assertion that H.D. Smith had reduced its allocation. Nor did it obtain a new UR. And it did not report the orders as suspicious.

On July 15, 2010, Tru-Valu apparently resubmitted the rest of its order as Respondent shipped 20,400 du of oxycodone 30 to it. GX 10F, at 1. The corresponding note states: ''ok to ship a total of 204 Oxy,[31] order was edited from 336 to 204 to meet csl of 33600.'' GX 15, at 112. Moreover, a note in the Memo for Records for this date states: ''Oxy CSL is @ 33,600 do not go over this amount w/o review.'' RX 2A, at 2.

Even assuming that Tru-Valu's oxycodone CSL had been raised to 33,600 du (and excluding the deleted June 30 order and the amount deleted from the July 1 order), Tru-Valu's July 2010 orders still totaled 46,800 du and thus exceeded the CSL. Yet Respondent again failed to obtain an explanation from Tru-Valu for why it was ordering the quantities that it was, and obviously, having failed to obtain an explanation, there was nothing to independently verify. Nor did Respondent obtain a new UR. And it failed to report the order as suspicious.

On August 2, Tru-Valu ordered and Respondent shipped to it 25,200 du of oxycodone 30 and 1,200 du of oxycodone 15. GX 10F. The same day, Respondent obtained a UR for the month of July, and on August 6, its inspector conducted a site visit. RX 2A, at 2.

According to the site visit report, Tru-Valu was a retail community pharmacy filling 200 prescriptions per day, of which 60 to 80 percent were controlled substances and ''60% of total'' were schedule II drugs. RX 2A, at 12, 18. Tru-Valu reported that H.D. Smith was its primary wholesaler and that Amerisource and Respondent were its secondary wholesalers. *Id.* at 18. While Respondent's inspector noted that Tru-Valu appeared to have ''a full selection of pharmaceuticals'' and an ''extensive selection of front store merchandise,'' he also wrote that the pharmacy was ''very busy'' with a ''long line of mostly younger people'' who were ''thin, tattooed, casually dressed,'' and that there were ''10 people'' and ''more coming in.'' *Id.* at 19. The inspector noted the time of his report as 2:44 p.m. *Id.*

The inspector further documented that the pharmacy had posted signs stating ''No insurance for: Oxycontin, oxy solution, [and] oxycodone by Mallinckrodt, Actavis.'' *Id.* at 20. The pharmacist on duty had only worked at Tru-Valu for two months and did not know why the signs were posted. *Id.* According to an MFR note, several weeks later, a member of Respondent's compliance department spoke with Tru-Valu's PIC, who stated that insurance did not reimburse at ''high enough'' rate ''to make up for the expense.'' *Id.; see also* RX 2A, at 2. The inspector also observed signs stating that there was a ''pill limit'' of 180 du on oxycodone 30 and 90 du on oxycodone 15, as well as a sign stating: ''must have recent MRI report.'' *Id.* However, in contrast to the questions about whether Tru-Valu accepted insurance on oxycodone

[30] According to the SOMS Appendix, ''[t]o determine if an order . . . is invalid for size, the system calculates the total number of doses invoiced in the past 30 days plus the total doses on open orders plus the number of doses on the received order and compares it to the monthly limit.'' RX 78, at 60. While this suggests that quantities that were edited downwards or deleted from an order were not counted in evaluating a new order, it also suggests that the entire quantity of a new order was to be considered in determining whether a new order exceeded the CSL.

[31] This is a reference to 100 du bottles.

prescriptions, there is no evidence that Respondent asked about the pill-limit signs or the MRI requirement.

A note in the margin next to the August 2 MFR entry, which is dated August 16, states that an order, the size of which is unclear, was deleted ''per review until [the] review completed.'' RX 2A, at 2. However, the order was not reported as suspicious.

While no additional oxycodone orders were filled during August, on September 1, Respondent shipped to Tru-Valu 24,000 du of oxycodone 30 and 2,400 du of oxycodone 15. GX 10F. An MFR note of the same date states: ''under compliance for [illegible] of site visit.'' RX 2A, at 2. A second entry of the same date memorializes a discussion with Tru-Valu's PIC regarding why he did not accept insurance on oxycodone with the further notation of ''RWR Orders pending.'' *Id.* However, there is no evidence that Respondent questioned Tru-Valu's PIC about the other observations recorded by its inspector, including the signs imposing pill limits on oxycodone and requiring that the patients have a recent MRI, or the long line of mostly younger people who were apparently filling their prescriptions and doing so in the middle of the afternoon.

On September 21, Respondent shipped 7,200 du of oxycodone 30 mg. GX 10F, at 1. The SOMS note for this dates states: ''oxy edited for csl on product.'' GX 15, at 113. Likewise, the MFR notes include the notation ''RWR'' and the statements: ''order edited from 264—72 per SOMS'' and ''Do not release any more product [illegible] reservations addressed.'' RX 2A, at 2. Here again, Tru-Valu's orders had totaled 52,800 du and exceeded the CSL, yet Respondent did not contact the pharmacy to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

The next day, Respondent shipped an additional 13,200 du of oxycodone 30 to Tru-Valu. GX 10F. According to the MFR notes, on this day, Respondent contacted Tru-Valu's PIC to discuss the edit of his order and asked him if he got a lot of out-of-state customers. RX 2A, at 2. According to the notes, the PIC said: ''not any more since we stopped filling out of state scripts about a year ago.'' *Id.* Tru-Valu's PIC stated that he ''runs out of product'' and ''only fills for regulars,'' followed by the words ''in state customers w/Florida ID'' which is in clearly different handwriting.[32] *Id.* Respondent did not, however, obtain an explanation as to why Tru-Valu was running out of oxycodone product.

Additional notes for this date indicate that an account review was conducted, during which the compliance committee and Wayne Corona reviewed the site visit, the UR, and information about Tru-Valu's Web site.[33] *Id.* at 3. The MFR notes indicate that Corona directed that Tru-Valu be approved to increase its oxycodone purchases up ''to the pattern high of 46800 over the last 12 months.'' *Id.* at 2. Additional notes cryptically state: ''to pattern high of 46,800 less than 70% of UR [34] on fill with current allotment from Masters taken into consideration 46,800 42% of UR.'' *Id.* at 3. Respondent then approved the shipment of an additional 13,200 du of oxycodone 30 to Tru-Valu. *See id.* at 2–3; GX 10F, at 1.

Apparently, because Respondent had edited 19,200 du off the order Tru-Valu had placed the day before, the new order did not place Tru-Valu's orders over the new CSL of 46,800 du. Tru-Valu's file offers no explanation for why Corona disregarded the information as to the highly suspicious circumstances documented in the recent site visit report and the most recent UR. As for the latter, it showed that 18 of the top 20 drugs being dispensed were controlled substances, including 11 oxycodone products, three alprazolam products, two diazepam products, methadone, and dilaudid. Moreover, Tru-Valu's dispensings of oxycodone 30 mg products alone totaled 206,132 du and its dispensings of oxycodone 15 totaled 32,441 du. RX 2A, at 29–34. Thus, out of its total dispensings of 337,314 du, Tru-Valu's dispensings of oxycodone 30 alone comprised 61 percent of its dispensings of all prescription products, and its dispensings of both the 30 and 15 milligram dosages (which totaled 238,603 du) comprised nearly 71 percent of its total dispensings.

On October 1, 5, and 13, Respondent filled orders for oxycodone 30 in the amounts of 24,000 du, 14,400 du, and 6,000 du respectively; on October 1, it also filled an order for 2,400 du of oxycodone 15. GX 10F, at 2. Upon filling the October 5 order, Respondent had shipped 58,800 du on a rolling 30-day basis, thus exceeding the CSL of 46,800 du. Yet the only notation in the SOMS notes is ''RWR.'' GX 15, at 113. The order was not reported as suspicious.

A SOMS note of October 13, 2010 for an order placed the previous day states: ''order reviewed edited to 60 bottles to keep mfr csl of 46800.'' *Id.* Yet on filling the October 13 order, Respondent had actually shipped 64,800 du on a rolling 30-day basis. Here again, while Tru-Valu's filled orders exceeded the CSL by 18,000 du, there is no evidence that Respondent contacted Tru-Valu's PIC and asked why he was ordering in excess of this amount.[35]

On November 1, 2010, Tru-Valu placed orders, which Respondent filled, for 24,000 du of oxycodone 30 and 2,400 du oxycodone 15. GX 10F, at 2. Thereafter, on November 8, Tru-Valu placed additional orders, which Respondent filled, for 14,400 du of oxycodone 30. *Id.* A note dated November 9 states: ''CH Review Business Model Re-Review'' followed by the initials of JS. RX 2A, at 1. Notes dated November 10 state that the account was ''placed in non-control status permanently'' and that the ''account has been monitored closely on and off [compliance hold] monitoring business model'' and that ''the account was reviewed by'' the compliance committee, apparently after Respondent received a letter from Mallinckrodt (a manufacturer) raising ''concerns on the account.'' *Id.* An entry for the following day states that Tru-Valu was getting ''rebates'' from a ''buying group'' and that Ms. Seiple told the PIC that it was on non-controlled status. *Id; see also* GX 15, at 109.

There is no evidence that Respondent filled any more controlled substances thereafter. However, none of Tru-Valu's orders were ever reported as suspicious.

In her declaration, Ms. Seiple asserted that Tru-Valu's PIC explained that its ''business model included active marketing to various nearby pain clinics,'' and that he ''provided the names and DEA . . . numbers of the doctors writing prescriptions for patients of those clinics.'' RX 103, at 39. She then offered the conclusory assertion that ''[t]hese marketing efforts accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.*

[32] It is noted that the words ''a couple'' are written in the date column immediately preceding the words ''a year ago'' in the notes area of the MFR form, suggesting that these words were inserted after the initials of Mr. Corona and the words ''No Servicing Out of State.'' RX2A, at 2.

[33] There is no evidence that Tru-Valu was using its Web site to distribute controlled substances.

[34] A note on the previous page states: ''within parameters 70%.'' RX 2A, at 2.

[35] The records show that several weeks later, Respondent contacted Tru-Valu's PIC in response to his having placed orders for morphine and methadone for the ''first time . . . since 2009.'' RX 2A, at 1. The PIC stated that he ordered the drugs from Respondent because it had cheaper prices and Respondent obtained a new UR for the month of September 2010. *Id.* No explanation was offered as to why similar inquiries were not documented following the October 12 oxycodone order that took Tru-Valu over its limit.

Ms. Seiple further asserted that ''[a]fter Tru-Valu's account was approved, [Respondent's] SOMS system identified and held any order for controlled substances placed by Tru-Valu that deviated from its typical volume, pattern or frequency. All such orders were released only after review by [Respondent's] Compliance Department'' and that ''[o]n some occasions, the Compliance Department would request Tru-Valu to provide a UR as part of its review of orders that had been held.'' *Id.* Ms. Seiple's statement is misleading because the SOMS was not even in operation until August 2009.

Ms. Seiple further asserted that ''[a]s a result of our ongoing due diligence, [Respondent] was aware of the volume of oxycodone and other controlled drugs being dispensed by Tru-Valu, and the percentage of controlled drugs dispensed relative to other drugs. [Respondent] specifically investigated the reason why Tru-Valu's ordering and dispensings patterns were as indicated on the UR's.'' *Id.* at 40. She then asserted that ''[t]he UR's and other information provided by Tru-Valu were consistent with the pharmacy's business model as explained by [its PIC] and confirmed in the May 2008 site inspection. Tru-Valu appeared to be a full line pharmacy that was dispensing a large of variety of both controlled and non-controlled drugs, and that serviced the patients of several nearby pain management physicians.'' *Id.*

However, Tru-Valu had provided the names of only five pain management physicians. Moreover, while it dispensed a variety of non-controlled drugs, Ms. Seiple did not refute the DI's contention that ''oxycodone 30 [was] being dispensed in significantly larger volume than any other drug; [that] the majority of the top 20 drugs dispensed are controlled substances; [and that there was] an absence of more commonly dispensed drugs by a retail pharmacy.'' GX 49B, at 20–21.

Ms. Seiple further asserted that ''[b]ased on [Respondent's] extensive investigation, it determined that the orders it shipped to Tru-Valu were not suspicious.'' RX 103, at 41. Yet, as found above, Respondent repeatedly failed to comply with its policies and procedures when reviewing those orders that were held.

Finally, Ms. Seiple declared that she was concerned that during the August 6, 2010 site visit, Respondent's inspector had observed a sign stating that Tru-Valu did not accept insurance for oxycodone products manufactured by Mallinckrodt or Actavis. *Id.* Ms. Seiple stated that the PIC explained that because he ''had received insurance cards'' from some patients who actually did not ''have current valid insurance coverage'' and ''was concerned that if [he] submitted invalid claims, it would jeopardize [his] relationship with insurers.'' *Id.* According to Ms. Seiple, the PIC stated that ''he placed the sign to try and limit the number of new patients who attempted to use insurance'' for oxycodone but that he did accept insurance for oxycodone from those patients he knew had valid insurance. *Id.*

Yet this story was inconsistent with the PIC's previous explanation that the reason for the sign was that insurance did not pay enough. And even if the PIC's subsequent explanation was true, Ms. Seiple did not address why she did not find it concerning that the inspector had reported that the pharmacy had also posted signs stating that there was a pill limit of 180 du of oxycodone 30 (and 90 du of oxycodone 15) and that the patients ''must have a recent MRI report.'' Nor did Ms. Seiple address why she did not find it concerning that the inspector found the pharmacy was ''very busy'' with ''a long line of mostly younger people'' who were ''thin, tattooed, [and] casually dressed.'' Notably, even after the concerns raised during this site visit, Respondent continued filling Tru-Valu's orders for another three months and did not report a single order to DEA as suspicious.

The Drug Shoppe

According to Respondent's due diligence file, The Drug Shoppe is a retail or community pharmacy located in Tampa, Florida. RX 2B, at 27, 126. While it is unclear when The Drug Shoppe first began purchasing controlled substances from Respondent, the due diligence file includes a Dunn and Bradstreet Report dated March 28, 2008, along with printouts of the same date showing that Respondent verified that it had a valid Florida pharmacy license and DEA registration, and that its PIC had a valid pharmacist's license. *Id.* at 121–39.

The file also includes a Schedule Drug Limit Increase Request Form dated March 28, 2008 and a Due Diligence Report Form dated Mar 31, 2008. *Id.* at 120, 126–27. The Drug Limit Increase form shows that The Drug Shoppe was seeking an increase in solid dose oxycodone and noted that its monthly usage in February and March was ''323–192.'' *Id.* at 120. The form also includes the notation: ''CSOS Report Over Limit.'' *Id.* While the form includes a section in which the account manager could check various exemptions that a customer could qualify for, such as its having been a long-term customer (*i.e.,* more than one year), none of the exemptions was checked. *Id.*

The Due Diligence Report noted that The Drug Shoppe had a daily script average of 150, that 40 percent of the prescriptions were for controlled substances, that 20 percent of the prescriptions were for schedule II drugs, and that 70 percent of the prescriptions were paid by insurance. *Id.* at 126. The Report also stated that The Drug Shoppe prevented doctor shopping by verifying prescriptions and that its PIC knew ''most of his patients,'' that its PIC knew the doctors and that ''most are anesthesiologists,'' and that it was located ''next to [sic] hospital.'' *Id.* According to the form, the PIC had refused to fill a prescription for several reasons, including that a prescription was for ''too high Qtys.'' *Id.* at 127.[36]

On April 15, 2008, the Account Manager completed a second Drug Limit Increase Request, again indicating that The Drug Shoppe was seeking an increase in solid dose oxycodone, solid dose hydrocodone, and alprazolam. *Id.* at 119. A note on this form indicates that Respondent had ''already received'' a UR for ''all items . . . they fill.'' *Id.*

The UR, which covered the month of February 2008, showed that The Drug Shoppe dispensed 181 prescriptions totaling 38,689 du of oxycodone 30, for an average quantity of 214 du per prescription.[37] *Id.* at 214–15. It also showed that the pharmacy had dispensed 43 prescriptions totaling 8,239 du of oxycodone 15, for an average quantity of 192 du per prescription. The Drug Shoppe dispensed more than 56,600 du of oxycodone products (including Endocet) out of its dispensings of all prescription products, which totaled 165,068 du. *Id.* at 209, 214–15, 218.

The next day, Matt Harmon sent an email to The Drug Shoppe informing it that Respondent had reviewed its account and was increasing its ''purchase limit of Oxycodone solid dose products to 25,000 doses (pills) per calendar month.'' *Id.* at 219. While Respondent held off on The Drug Shoppe's requests to increase its hydrocodone and alprazolam purchases, it approved the oxycodone increase before it had even inspected the pharmacy.

[36] The Drug Shoppe's PIC also stated that he did not fill if a refill was ''too early,'' if he did not know the doctor and could not get hold of the doctor, and if a patient ''ha[d] been to too many docs.'' RX 2B, at 127. He also represented that he checked the doctor's license, and if a doctor was ''more than 20 miles away [he] will visit, call or not fill.'' *Id.*

[37] This total includes a 240 du prescription for Roxicodone 30 mg, a branded drug. RX 2B, at 215.

On April 28, 2008, Respondent's consultant conducted a site visit and determined that the pharmacy was a compounding pharmacy. *Id.* at 27. While the pharmacy reported that it did not engage in internet business, it acknowledged filling prescriptions for five pain management doctors, whose names were listed on the evaluation form; however, there is no evidence that Respondent verified that these physicians were properly licensed and registered, let alone whether they held any specialty training or board certification in pain management. *Id.* at 27–30.

According to the report, the pharmacy did not service nursing homes, hospice programs, or inpatient facilities. *Id.* at 29. The pharmacy reported that it filled 100 prescriptions per day, of which 50 percent were for controlled substances, and that cash and insurance each comprised 50 percent of the payments it received. *Id.*

Respondent's consultant reported that The Drug Shoppe ''appears to be a very professionally run pharmacy,'' which took ''exceptional care in secure storage of [its] controlled substances inventory.'' *Id.* at 30. The consultant further noted the PIC's complaint that he was ''finding it hard to fill some of the prescriptions presented because of the limitation placed on the quantities he can purchase.'' *Id.* at 30–31. The consultant also obtained a copy of the pharmacy's most recent state inspection report, which showed no violations. *Id.* at 32.

On or about August 14, 2008, Respondent approved an increase in The Drug Shoppe's oxycodone purchasing limit from 25,000 to 50,000 du.[38] *Id.* at 115. Notes on a form entitled ''Limit Increase Request Conclusion'' state: ''Previously raised to 25k. Clean license. Satisfactory visit by L. Fisher,'' who was Respondent's consultant. *Id.*

In April 2009, Respondent shipped to The Drug Shoppe 43,000 du of oxycodone 30; 10,800 oxycodone 15; 600 du of Endocet 10/650; 600 du of oxycodone/apap 10/325; and 200 du of oxycodone/apap 5/325, for a total of 55,200 du. GX 10F, at 29–33. Notwithstanding that The Drug Shoppe's purchasing limit was still set at 50,000 du for all oxycodone products, Respondent's records contain no documentation as to why it was allowed to exceed its purchasing limit.

While in both May and June 2009, Respondent's shipments of oxycodone to The Drug Shoppe did not exceed the 50,000 du purchasing limit, in July it shipped 60,000 du of oxycodone 30; 1,000 du of Endocet 10; and 1,000 du of Endocet 5 for a total of 62,000 du. *See id.* The Drug Shoppe's due diligence file contains no explanation for why it was allowed to exceed the purported purchasing limit.

On or about July 14, 2009, Respondent obtained a new UR from The Drug Shoppe, which covered the period of May 14 through July 14, 2009. *Id.* at 148–204. Oxycodone 30 mg was the number one drug dispensed. *Id.* at 148. Indeed, the UR showed that The Drug Shoppe had dispensed 595 prescriptions of oxycodone 30 totaling 105,570 du, for an average of 52,785 du per month and an average prescription size of 177 du. *Id.* at 148 & 161. While The Drug Shoppe dispensed only 54 oxycodone 15 prescriptions totaling 9,360 du (an average of 4,680 per month), the average prescription size was 173 du. *Id.* at 149–50. Including all formulations of oxycodone, Respondent dispensed more than 136,400 du or 68,200 du per month.[39]

A Ship to Memo note dated July 28, 2009 states: ''increase accepted from 50k to 62k on oxy.'' GX 16, at 221. There is, however, no further documentation explaining the justification for the increase. During the month of July 2009, Respondent shipped 60,000 du of oxycodone 30 as well as 2,000 du of combination oxycodone products to The Drug Shoppe. GX 10F, at 29, 31–33.

During August 2009, Respondent shipped to The Drug Shoppe a total of 60,500 du of oxycodone 30, as well as 1,000 du of Endocet 10/325 and 500 du of oxycodone/apap 5 mg. *See id.* However, while the total monthly shipments did not exceed the recently approved 62,000 du limit, the SOMS had gone into effect on August 1 and on several occasions during the month, The Drug Shoppe's orders exceeded the CSL on a rolling 30-day basis.

For example, on August 13, Respondent filled an order for 1,000 du of Endocet 10/325, thus placing The Drug Shoppe's total of filled orders at 62,500 du on a rolling 30-day basis.[40] Although the SOMS was supposed to place an order on hold even if it exceeded the CSL by a single dosage unit and thus trigger the requirements that the Compliance Department obtain an explanation for the order, which was independently verified, as well as that it obtain a new UR, the only notation in Respondent's file states: ''ok to ship within current limit.'' GX 16, at 234.

An entry dated August 20, 2009 in the Memo for Records notes: ''order deleted over current limit compliance review[.] Hold for review.'' RX 2B, at 4. A subsequent entry for the same day states: ''Requested Review of Disc Docs and File.'' *Id.*

The next day, Respondent shipped 19,500 du of oxycodone 30 to the Drug Shoppe. GX 10F, at 29. Of note, on a rolling 30-day basis, The Drug Shoppe's orders totaled 74,000 du of oxycodone, with 72,500 du being for 30 mg tablets.[41]

An MFR entry of the same date states: ''Request Update Survey,'' ''U/R Looks Strong + Voluminous,'' ''OK TO 62,000—oxy family,'' ''HIV,'' ''Large # RX's For HIV Disease State,'' ''Methadone Ok'd @10k.'' RX 2B, at 4. Unexplained is how it was ''ok to 62,000'' when, with this order, The Drug Shoppe was over its CSL by more than 12,000 du. Also, notwithstanding Respondents' representation (to the DI only days before) that its policy required it to independently verify the information it obtained from its customers, there is no evidence that Respondent did so with respect to The Drug Shoppe's claim that a large number of the prescriptions were for HIV patients.[42]

In September 2009, Respondent shipped an additional 62,000 dosage units of oxycodone 30 mg. However, on each occasion on which the orders were shipped, The Drug Shoppe's orders exceeded the 62,000 CSL by a wide

[38] The document also indicates that Respondent set The Drug Shoppe's purchasing limit for hydrocodone and alprazolam at 25,000 du for each drug. RX 2B, at 115.

[39] As for other formulations, the UR showed that The Drug Shoppe dispensed 2,843 du of OxyContin 80; 600 du of OxyContin 60; 3,394 du of OxyContin 40; and 480 du of OxyContin 20. RX 2B, at 148–205. It also dispensed 8,886 du of oxycodone/acetaminophen (apap) 10/325; 2,320 du of oxycodone/apap 10/650; 2,031 du of oxycodone/apap 5/325; and 950 du of oxycodone 5 mg. *Id.*

[40] The total includes orders for oxycodone 30 in the following amounts and on the following dates: 8,000 du on July 16; 12,000 du on July 28; 20,000 du on Aug. 3; 20,000 du on Aug. 7; 1,000 du on Aug. 10; it also includes orders for 500 du of Endocet 5 on Aug. 6; and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[41] The total includes orders for oxycodone 30 in the following amounts: 12,000 du on July 28; 20,000 du on Aug. 3; 20,000 du on Aug. 7; 1,000 du on Aug. 10; 19,500 on Aug. 21; it also includes orders for 500 du of Endocet 5 on August 6 and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[42] The file includes a due diligence survey of the same date. According to the survey, The Drug Shoppe reported that it filled 160 prescriptions per day, of which 60 percent were controlled and 40 percent were schedule II drugs. RX 2B, at 6. The Drug Shoppe asserted that it declined 20 prescriptions a day, and that in ensuring that the doctors were exercising proper standards of care, it looked at the age of its patients, talked to the doctor, and asked about the kind of pain and reason. *Id.* The Drug Shoppe also asserted that it had stopped filling prescriptions for a certain physician because the doctor was ''writing too much pain med or staff gives run around.'' *Id.* However, the size of the oxycodone 30 prescriptions that The Drug Shoppe was fillings begs the question of what quantity was ''too much.''

margin. Specifically, on September 1, Respondent filled an order for 17,500 du of oxycodone 30, bringing the total of the filled orders to 79,500 du.[43] GX 10F, at 29; 32–33. The only note pertaining to the order is a SOMS note indicating that Ms. Seiple released the order, the reason being: ''shipping under current limit of 175 bottles.'' GX 16, at 234. Despite the representations Respondent made to DEA regarding its policy for reviewing those orders held by the SOMS, there is no evidence that it contacted The Drug Shoppe and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

Two days later, Respondent shipped 15,000 du of oxycodone 30; with this shipment, The Drug Shoppe's filled orders totaled 74,500 du on a rolling 30-day basis.[44] GX 10F, at 29, 32–33. There are SOMS notes corresponding to two orders on this date: The first, entered by Ms. Seiple, states: ''shipping with reservation review with wayne''; the second, entered by Mr. Schulze, states: ''ok to ship under current size limit.'' GX 16, at 234. However, here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

On September 8, Respondent shipped another 15,000 du of oxycodone 30; with this shipment, The Drug Shoppe's filled orders totaled 69,000 du on a rolling 30-day basis.[45] GX 10F, at 29, 32. A SOMS note corresponding to this date indicates that Ms. Seiple approved an order and states: ''ok to ship see UR on miox.'' [46] GX 16, at 234. Here again, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

On September 16, Respondent shipped another 14,500 du of oxycodone 30; with this shipment, The Drug Shoppe's filled orders totaled 81,500 du on a rolling 30-day basis.[47] A SOMS note of this date states: ''ok to ship at current limit this order is 62k.'' GX 16, at 235. Unexplained is how The Drug Shoppe's order placed it at its current limit when its orders exceeded the CSL by 19,500 du. And here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

In October, Respondent shipped to The Drug Shoppe 55,200 du of oxycodone 30 mg; 3,600 du of oxycodone 15 mg; 600 oxycodone 20 mg; and 2,600 du of combination oxycodone products for a total of 62,000 du. GX 10F, at 29, 31–33. None of the orders placed The Drug Shoppe over its CSL.

On November 9, Respondent shipped to The Drug Shoppe 14,400 du of oxycodone 30 and 1,000 du of oxycodone 10/325. Thus, on a rolling 30-day basis, Respondent had filled orders totaling 74,700 du.[48]

An MFR entry dated November 9 states: ''update UR last on file w 5/09'' and ''called to get updated UR.'' Further notes state: ''Per Jen ship w/reservation'' and ''still need UR for future orders.'' RX 2B, at 4; *see also* GX 16, at 236 (SOMS note: ''Ship update reservation getting an updated ur'').

The next day, Respondent obtained a UR for the month of October 2009. *Id.; see also id.* at 72–80, 140–146. However, the UR listed the drugs in alphabetical order (rather than the drugs by the quantity dispensed) and did not provide a figure for the pharmacy's total dispensings. *See id.* Moreover, there is no evidence that Respondent obtained an explanation for the order from The Drug Shoppe.

As for the UR, it showed that The Drug Shoppe had dispensed 357 prescriptions totaling 66,271 du of oxycodone 30 (for an average of 186 du per prescription) and 33 prescriptions totaling 4,997 du of oxycodone 15 (for an average of 151 du per prescriptions). *Id.* at 141–42. The UR also showed that The Drug Shoppe had dispensed 4,208 du of various formulations of OxyContin and extended release oxycodone,[49] as well as 480 du of oxycodone 5mg and 4,650 du of combination oxycodone drugs (including Endocet), for a total of 80,606 du of oxycodone products. *Id.* at 77, 142.

On November 16, Respondent filled an order for 2,400 du of oxycodone 30; upon filling the order, Respondent had shipped 63,900 du of oxycodone on a rolling 30-day basis, thus placing The Drug Shoppe's orders over the CSL.[50] GX 10F, at 29. The corresponding SOMS note states: ''ok to ship w/reservation oxy within size for period. Current site visit needed.'' GX 16, at 237. There is, however, no evidence that Respondent contacted the pharmacy and obtained an explanation for the order.

The next day, Respondent filled orders for 2,400 du of oxycodone 30; 2,400 du of oxycodone 15; 1,200 du of oxycodone 10/325; and 500 du of oxycodone 5/325. GX 10F, at 29, 32–33. Upon filling the orders, Respondent had shipped 70,400 du of oxycodone to The Drug Shoppe on a rolling 30-day basis, again placing its orders over the CSL.[51]

A SOMS note for this date states: ''ok to ship oxy within size for period see mfr.'' GX 16, at 237; *see also* RX 2B, at 4. (MFR note: ''ok to ship under current limit''). Here again, it is unexplained how this order could be deemed to be ''within size for period'' or ''under [the] current limit'' given Respondent's representation that the orders were reviewed on a rolling 30-day basis. Moreover, here again, there is no evidence that Respondent obtained an explanation for these orders from The Drug Shoppe. Nor did it report the orders as suspicious.

Yet, the next day (Nov. 18), Respondent shipped an additional 3,000 du of oxycodone 30 to The Drug Shoppe, thus bringing its rolling 30-day total to 73,400 du. GX 10F, at 30. The

[43] This total includes orders for oxycodone 30 in the following amounts: 20,000 du on Aug. 3; 20,000 du on Aug. 7; 1,000 du on Aug. 10; 19,500 du on Aug. 21; it also includes 500 du of Endocet 5 on Aug. 6 and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[44] This total includes orders for oxycodone 30 in the following amounts: 20,000 du on Aug. 7; 1,000 du on Aug. 10; 19,500 du on Aug. 21; and 17,500 du on Sept. 1; it also includes 500 du of Endocet 5 on Aug. 6 and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[45] This total includes orders for oxycodone 30 in the following amounts: 1,000 du on Aug. 10; 19,500 du on Aug. 21; 17,500 du on Sept. 1; and 15,000 du on Sept. 3; it also includes 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[46] The last four letters of this entry could also be ''mlox.'' GX 16, at 234. Regardless, Respondent's records contain no explanation for what either miox or mlox means.

[47] This total includes orders for oxycodone 30 in the following amounts: 19,500 du on Aug. 21; 17,500 du on Sept. 1; 15,000 du on Sept. 3; and 15,000 du on Sept. 8.

[48] This total includes orders for oxycodone 30 in the following amounts: 18,000 du on Oct. 12; 14,400 du on Oct. 20; 7,200 du on Oct. 23; and 14,400 du on Nov. 2; it also includes an order for 600 du of oxycodone 20 on Oct. 22; an order for 3,600 du of oxycodone 15 on Oct. 20; and orders for 300 and 800 du of Endocet 10 on Oct. 20 and 26. GX 10F, at 29, 33–33.

[49] This included 21 prescriptions totaling 2,078 du of OxyContin 80 mg (for an average quantity of 99 du per Rx), as well as 26 prescriptions totaling 1,590 du of OxyContin (and oxycodone er) 40 mg.

[50] This total includes orders for oxycodone 30 in the following amounts: 14,400 du on Oct. 20; 7,200 du on Oct. 23; 14,400 du on Nov. 2; 14,400 du on Nov. 9; 2,400 du on Nov. 12; and 2,400 du on Nov. 13. It also includes an order for 600 du of oxycodone 20 on Oct. 22; an order for 3,600 du of oxycodone 15 on Oct. 20; orders for 300 and 800 du of Endocet 10 on Oct. 20 and 26; and an order for 1,000 du of oxycodone/apap 10/325 on Nov. 9. GX 10F, at 29, 32–33.

[51] This total includes orders for oxycodone 30 in the following amounts: 14,400 du on Oct. 20; 7,200 du on Oct. 23; 14,400 du on Nov. 2; 14,400 du on Nov. 9; 2,400 du on Nov. 12; 2,400 du on Nov.13; and 2,400 du on Nov. 16. It also includes an order for 600 du of oxycodone 20 on Oct. 22; an order for 3,600 du of oxycodone 15 on Oct. 20; orders for 300 and 800 du of Endocet 10 on Oct. 20 and 26; and an order for 1,000 du of oxycodone/apap 10/325. GX 10F, at 29, 33–33.

corresponding SOMS note states: ''ok to ship, at 43,500 for this month, this order of 3,000 OXY puts them at their limit for the month.'' GX 16, at 237.

MFR notes state that on November 17, 2009, the committee reduced The Drug Shoppe's oxycodone CSL by 25 percent to 46,500 du. *Id.* at 3; GX 16, at 221 (Ship to Memo). However, here again, there is no explanation as to why Respondent ignored that The Drug Shoppe's orders exceeded the CSL on rolling 30-day basis by nearly 27,000 du and failed to obtain an explanation for the orders.

While during November 2009, Respondent limited its shipments of oxycodone to 46,500 du,[52] in December it shipped 58,600 du of oxycodone 30 mg, as well as 1,200 du of Endocet 10/325 and 200 du of oxycodone/apap 7.5/325, for a total of 60,000 du. GX 10F, at 30, 32–33. Indeed, as early as December 16, The Drug Shoppe's orders exceeded the new CSL on a rolling 30-day basis when Respondent filled an order for 12,000 du of oxycodone 30, thus bringing the total filled orders to 51,700 du.[53] GX 10F, at 29–33. The SOMS note for this order states: ''ok to ship-file current-oxy @42200 w/this order.'' GX 16, at 238. Here again, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. Nor did it obtain a UR for the month of November. And it did not report the order as suspicious.

An MFR note for Dec. 23 states: ''Order for 15,500 Oxy 30, already at their . . . CSL 46,500[.] Called to let customer know order will be deleted, customer said that Rep said their allotment was at 62,000[.] Said that they will call their sales rep. Spoke to Laurie.'' RX 2B, at 3.[54] This order placed The Drug Shoppe's oxycodone orders at 62,000 on a rolling 30-day basis (as well as on a calendar-month basis) and thus exceeded the CSL.[55] Yet Respondent did not obtain a new UR.

Moreover, the next day, Respondent shipped 13,500 du of oxycodone 30 to The Drug Shoppe. GX 10F, at 30. On filling this order, Respondent had shipped 60,000 du of oxycodone since December 3, with the 30 mg dosage accounting for 58,600 du, and The Drug Shoppe had again exceeded the CSL. GX 10F, at 30, 32–33. The only SOMS note for December 24 does not even appear to pertain to the order as it states: ''ok to ship-hydro @7,700. for period with this order.'' GX 16, at 238. Consistent with the SOMS note, the Government's evidence shows that Respondent filled orders for 2,000 du of combination hydrocodone drugs on this date.[56] GX 10F, at 35.

Even assuming that Respondent relied on the explanation it had obtained the day before, the record is devoid of an explanation as to why the CSL was ignored and the order was shipped. And here again, Respondent did not obtain a new UR.

On nine occasions during January 2010, Respondent filled orders for oxycodone products, which repeatedly placed The Drug Shoppe's orders above the CSL of 46,500. Indeed, several of these orders even placed The Drug Shoppe above the previous CSL of 62,000 du. And as explained below, while on or about January 25, The Drug Shoppe's oxycodone CSL was raised to 60,000 du, GX 16, at 221; four days later, Respondent filled an order for 15,000 du of oxycodone, notwithstanding that the order placed its total shipments on a rolling 30-day basis at 75,000 du.

More specifically, on January 4, Respondent filled an order for 6,000 du of oxycodone 30, thus placing The Drug Shoppe's filled orders on a rolling 30-day basis at 61,200 DU. GX 10F, at 30. Yet the corresponding SOMS note merely states ''ok to ship—oxycodone @ 6k with this order.'' GX 16, at 238.

The next day, Respondent filled an order for 9,600 du of oxycodone 30, thus placing The Drug Shoppe's filled orders at 70,800 du on a rolling 30-day basis. GX 10F, at 30. While there are SOMS notes on this date for two orders, one stating ''ok to ship, under the CSL,'' the other ''ok to ship, frequency not excessive,'' what is clear[57] is that there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On January 7, Respondent filled another order for 9,600 du of oxycodone 30 (and 100 du of Endodan 4.8/325), thus placing The Drug Shoppe's filled orders at 69,500 du on a rolling 30-day basis. GX 10F, at 30, 34. Here again, there are SOMS notes for two orders on this date, both of which refer to oxycodone. The first states: ''ok to ship file current this order for Oxy puts them @25,200 for Jan.'' GX 16, at 239. The second note states: ''ok to ship-file current-oxycodone @15,700. w/this order for Jan-frequency @29/31.'' *Id.*

Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On January 12, Respondent filled orders for 500 du of oxycodone 5 and 100 du of oxycodone 7.5/500, thus placing The Drug Shoppe's filled orders at 55,700 du on a rolling 30-day basis and above the 46,500 du CSL. GX 10F, at 33. A SOMS note dated Jan. 13, which appears to discuss the order, states: ''ok to ship under csl for oxy 25,900 as of 1/13/10.'' [58] Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On January 13, 2010, Jeffrey Chase, an employee of Respondent, conducted a site visit at The Drug Shoppe. In multiple places on his reports, Mr. Chase noted that the pharmacy's dispensing ratio of controlled to non-controlled drugs was 40 percent for controlled drugs and that this was ''a little high.'' RX 2B, at 21, 24. While Mr. Chase noted that The Drug Shoppe ''appears to be a well run pharmacy,'' he recommended that ''we need a utilization report to compare to site visit.'' *Id.* at 21.

On January 20, Mr. Corona reviewed Mr. Chase's recommendation. *Id.* However, as the evidence shows, Respondent did not obtain a new UR for another five months. Nor did it compare the utilization report it had last obtained with The Drug Shoppe's representation as to its dispensing ratio, as recommended by Mr. Chase.

The day after the site visit, Respondent filled orders for 9,600 du of oxycodone and 1,000 du of oxycodone

[52] The shipments included 41,400 du of oxycodone 30; 2,400 du of oxycodone 15; 2,200 of oxycodone/apap 10/325; and 500 du of oxycodone/apap 5/325. GX 10F, at 29–33.

[53] The total includes orders for oxycodone 30 of 2,400 du on Nov. 17; 3,000 du on Nov. 18; 4,800 du on Dec. 3; 9,600 du on Dec. 8; 7,200 du on Dec. 10; 7,200 du on Dec. 11; and 12,000 du on Dec. 16. It also includes orders filled on Nov. 17 for 2,400 du of oxycodone 15; 500 du of oxycodone 5; and 1,200 du of oxycodone 10/325; and orders filled on Dec. 7 for 1,200 du of oxycodone 10/325 and 200 du of oxycodone 7.5/325. GX 10F, at 29–33.

[54] A later MFR entry of the same date states: ''Shipped w/reservation W OK. See email from Diane per Wayne.'' RX 2B, at 3. The due diligence file does not, however, contain the email and it is unclear whether this entry applies to this order or the order for 13,500 du of oxycodone 30 that shipped the following day.

[55] The total includes orders for oxycodone 30 of 4,800 du on Dec. 3; 9,600 du on Dec. 8; 7,200 du on Dec. 10; 7,200 du on Dec. 11; 12,000 du on Dec. 16; and 4,300 du on Dec. 17; it also includes orders filled on Dec. 7 for 1,200 du of oxycodone 10/325 and 200 du of oxycodone 7.5/325. GX 10F, at 29–33.

[56] There is a SOMS note for December 23, 2009 by Ms. Seiple, which states: ''shipping with reservation see mfr.'' GX 16, at 238.

[57] Neither of the notes identifies the drug that was ordered. *See* GX 16, at 238.

[58] While the dates of the order and the SOMS note do not match, this was not unusual. Moreover, The Drug Shoppe did not order any oxycodone on January 13, *see* GX 16, at 252 (showing that only non-controlled drugs ordered on this date); and the total referred to in the SOMS note of 25,900 equals the total of The Drug Shoppe's January oxycodone orders through that date.

10/325, thus bringing The Drug Shoppe's total of filled orders to 66,300 du on a rolling 30-day basis. GX 10F, at 30, 32. The SOMS note for the transaction states: ''ok to ship under csl for Oxy 36500 with this order frequency not excessive.'' GX 16, at 239. Of course, the order was not under the CSL, and here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order or a new UR.

On January 18, Respondent filled an order for 9,600 du of oxycodone 30, and on January 19, it filled orders for 9,600 du of oxycodone 30, 900 du of oxycodone 10/325, and 500 du of oxycodone 5. GX 10F, at 30, 32–33. Upon Respondent's filling of the January 18 order, The Drug Shoppe's filled orders totaled 59,600 du, and upon its filling of the January 19 orders, The Drug Shoppe's filled orders totaled 70,600 du. Yet the SOMS note for the January 18 order states: ''ok to ship, under the CSL of 46,500 on Oxy, this order puts them at 46,100 for the month.'' GX 16, at 239. As for the January 19 orders, only one of the three SOMS entries contains a note and the name of a reviewing employee. The note states: ''ok to ship order reviewed by Jen.'' *Id.*

Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for either the January 18 or 19 orders. Nor did it obtain a new UR.

On January 23, The Drug Shoppe placed an order for 2,900 du of oxycodone 30 and on January 25, Respondent filled the order, thus placing The Drug Shoppe's total filled oxycodone orders at 60,000 du on a rolling 30-day basis.[59] GX 16, at 239; GX 10F, at 30. The SOMS note for the order states: ''ok to ship-oxycodone @60k for current period.'' GX 16, at 239.[60] A January 25 MFR entry notes that the ''oxycodone @57,100—requesting 2,900—more would place @60 k for period'' and that ''Per Jen Oxy @60k.'' RX 2B, at 3; *see also* GX 16, at 221 (Ship to Memo dated 1/25/10 with subject of ''oxycodone limit''; memo states ''currently set @60k for a period'').

Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR. Of further note, none of these documents contain any explanation for why Ms. Seiple approved the increase in the oxycodone CSL.

Notwithstanding the purportedly new oxycodone limit of 60,000 du, on January 29, Respondent shipped an additional 15,000 du of oxycodone 30 mg. Upon Respondent's filling of the order, The Drug Shoppe's filled orders totaled 75,000 du on a rolling 30-day (and monthly) basis. GX 10F, at 30–33.

An MFR note (date Jan. 29) acknowledged that The Drug Shoppe was ''already at 60 k this month need to review w/Jen.'' RX 2B, at 3. A note in the Ship to Memos (which is actually dated two days before the above note) states: ''OK to ship controls requested up to current UR if supported.'' GX 16, at 221. SOMS notes for two orders (which are dated January 29) and made by Ms. Seiple state: ''rele3ase [sic] order supported by ur plus 10% committee ok'' and ''release order supported by ur.'' GX 16, at 240. And an MFR note dated five days later (February 3), which bears Ms. Seiple's initials, states: ''Ship to UR per committee review per company policy.'' RX 2B, at 3. Here again, even though the order clearly placed The Drug Shoppe's orders over the new increased CSL, there is no evidence that Respondent contacted the pharmacy to obtain an explanation for why it needed still more oxycodone and to obtain a new UR.

On February 1, Respondent shipped 9,600 du of oxycodone to The Drug Shoppe. GX 10F, at 30. On filling the order, Respondent had shipped 84,600 du of oxycodone to The Drug Shoppe on a rolling 30-day basis and had thus exceeded the CSL, whether it was set at 60,000 du as per the January 25 note or based on the highest monthly total within the last six months, this being the January total of 75,000 du.

Yet the SOMS note for the order merely states: ''ok to ship jen reviewed 30 day rolling for oxy.'' GX 16, at 240. Here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR. Nor did Respondent report the order as suspicious.

The next day, Respondent shipped 2,400 du of oxycodone 15 to The Drug Shoppe, thus bringing the rolling 30-day total of the filled orders to 87,000 du. GX 10F, at 31. There are two SOMS notes which are potentially applicable to the order: One, by Ms. Seiple, stating ''release order within the csl,'' and the second, by Mr. Schultze, stating ''ok to ship frequency not excessive.'' GX 16, at 240. In any event, here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order and a new UR.

On February 13 (a Saturday), The Drug Shoppe placed an order for 12,000 du of oxycodone 30 and 600 du of oxycodone 10/325. GX 16, at 240; GX 10F, at 30, 32. On filling these orders (on February 15), Respondent had shipped 63,100 du of oxycodone to The Drug Shoppe on a rolling 30-day basis.

While it is unclear whether The Drug Shoppe's CSL was 60,000 du or 75,000 du, the orders were nonetheless held for review by the SOMS for some reason. GX 16, at 240. Two SOMS notes dated February 13, state: ''ok to ship oxy and methadone [sic] under csl'' and ''ok to ship with reservations.'' *Id.* As explained previously, Respondent's Policy 6.2 imposed the same obligations of obtaining an explanation for the order, which was then independently verified, and obtaining a new UR, regardless of the reason the order was held. *See* RX 78, at 32. Yet none of these steps were taken during the review of this order.

On February 18, Respondent shipped 9,600 du of oxycodone 30; 2,400 du of oxycodone 15; and 1,000 du of oxycodone 10/325. GX 10F, at 30–32. According to the SOMS notes, the order was held but subsequently released, the reason documented being: ''ok to ship oxy under csl and frequency not excessive.'' GX 16, at 240. Again, there is no evidence that Respondent contacted The Drug Shoppe and obtained a reason for the order. Nor did it obtain a new UR.

So too, on February 25, Respondent filled an order for 3,600 du of oxycodone 15. GX 10F, at 31. While the order was held by the SOMS, it was released with the following reasons provided: ''ok to ship frequency not excessive-oxycodone within csl for period.'' GX 16, at 241. Again, there is no evidence that Respondent contacted The Drug Shoppe and obtained a reason for the order. Nor did it obtain a new UR.

Likewise, through the ensuing months, The Drug Shoppe placed multiple orders for oxycodone products that were held by the SOMS. *See* GX 16, at 241. Even if these orders did not place The Drug Shoppe's orders over the CSL but were held because they were of either unusual frequency or unusual pattern, the evidence still shows that Respondent released numerous orders without having contacted The Drug Shoppe to obtain an explanation for the orders, which it then verified, and that it rarely obtained a new UR. *See* GX 16, at 241–42, 222–32.

In March, Respondent shipped 55,200 du of oxycodone 30 mg; 2,400 du of

[59] The order was apparently placed on a Saturday and not shipped until the following Monday.

[60] Through the first 25 days of January 2010, Respondent shipped orders totaling 56,900 du of oxycodone 30; 1,900 du of oxycodone/apap 10/325; 100 du of both Endocet 7.5/500 and Endodan; and 1,000 du of Endocet 5 mg, thus bringing its total shipments of oxycodone to The Drug Shoppe to 60,000 du. *See* GX 10F, at 30, 32–33.

oxycodone 15 mg; and 4,500 du of various oxycodone combination products, for a total of 62,100 du. GX 10F, at 30–34. Of note, a SOMS note dated March 22 (which corresponds to an order for 600 du of oxycodone 10/325) states: ''ok to ship, size not excessive on OXY, CSL is 46,500, this order is for 600. Putting them at 44700 for the month.'' GX 16, at 242.

And on March 30, Respondent filled an order for 16,800 du of oxycodone 30. GX 10F, at 30. On filling this order, Respondent had shipped 62,700 du of oxycodone on a rolling 30-day basis and thus The Drug Shoppe's orders exceeded both the CSL referred to in the March 22nd SOMS note and the CSL referred to in the January 25 Ship to Memos and MFR notes.[61] A SOMS note for the order states that it was released because ''ur on file supports oxy order.'' GX 16, at 222. However, the most recent UR was from October 2009. Moreover, once again, Respondent failed to contact The Drug Shoppe and inquire as to why it was ordering in excess of its CSL and obtain a new UR.

On four occasions in April, The Drug Shoppe's filled oxycodone orders exceeded 60,000 du on a rolling 30-day basis including April 2 (rolling total of 60,600 du); April 5 (rolling total 70,200 du); April 7 (rolling total 70,400 du); and April 9 (rolling total 67,500 du). SOMS notes indicate that several of these orders were held for review. GX 16, at 222. However, each order was released, with the reasons provided being that the order was ''within csl for period'' and/or ''frequency was not excessive.'' *Id.* Notably, notwithstanding that the orders were held, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR.

Likewise, in May, The Drug Shoppe's filled oxycodone orders totaled 63,300 du (on May 7); 64,900 du (on May 18); 73,000 du (May 19); and 60,600 du (May 26) on a rolling 30-day basis. The MFRs contain a note dated May 7, 2010, after The Drug Shoppe had placed 4 orders, each for 9,600 du of oxycodone 30, within the first seven days of the month, apparently because this was an unusual pattern. *See* GX 10F, at 30. While Respondent contacted The Drug Shoppe and documented that it had not ordered for a week and a half because an employee named Laurie had been out for two weeks and was ''stocking back up,'' RX 2B, at 2; once again, Respondent did not obtain a UR. Yet the SOMS note for the order states: ''ok to ship UR supports Oxy order puts thm [sic] @39,500—5/7.''[62] GX 16, at 223. In total, during May 2010, Respondent shipped to The Drug Shoppe 57,600 du of oxycodone 30 mg; 1,200 du of oxycodone 15 mg; and 1,800 du of oxycodone combination products, for a total of 60,600 du. GX 10 F, at 30–33.

In June 2010, The Drug Shoppe placed orders for 9,600 du of oxycodone 30 mg on June 1, 3, 8, 14, and 15. GX 10, at 30; RX 2B, at 2. According to the MFR and SOMS notes, on June 15, 2010, an order for 96 bottles of oxycodone 30 mg was edited to 54 bottles and the ''difference of 42 bottles can be place[d] for review after June 20th.'' GX 16, at 225; *see also* RX 2B, at 2. As a result, The Drug Shoppe's oxycodone orders on a rolling 30-day basis totaled 67,600 du.[63] However, Respondent contacted The Drug Shoppe and obtained a UR for the month of May 2010. RX 2B, at 2.

The UR shows that during May 2010, The Drug Shoppe dispensed 316 prescriptions totaling 64,250 du of oxycodone 30 mg, an average of 203 du per prescription. RX 2B, at 66. As for oxycodone 15 mg, the UR showed that The Drug Shoppe dispensed 29 prescriptions totaling 3,524 du, an average of 121.5 du per prescription. *Id.* It also showed that The Drug Shoppe dispensed 18 prescriptions of oxycodone/apap 10/325 mg totaling 2,851 du, an average of 158 du per prescription. *Id.* at 60 & 66.

On June 25, Respondent shipped an additional 6,000 du of oxycodone 30 mg to The Drug Shoppe. GX 10F, at 30. Yet a SOMS note of the same date attributed to Ms. Seiple states: ''oxy edited to zero per csl and policy.'' GX 16, at 225. Respondent offered no evidence to explain this inconsistency.

Moreover, SOMS notes and an MFR note dated June 28 show that The Drug Shoppe placed an order for 3,600 du of oxycodone but that the order was deleted. *Id.; see also* RX 2B, at 2. A further entry in the MFR notes of the same date states: ''can place another order after 6/30/10.'' RX 2B, at 2. However, the order was not reported as suspicious. During the month of June 2010, Respondent shipped a total of 49,800 du of oxycodone 30 mg, 1,200 du of oxycodone 15 mg, and 1,500 du of combination oxycodone products, for a total 52,500 du. GX 10 F, at 30, 32–33.

In July 2010, Respondent shipped to The Drug Shoppe 9,600 du of oxycodone 30 mg on the 1st, 6th, 12th and 19th of the month, as well as 2,400 and 1,600 du of the same dosage on July 15th and July 26th. *Id.* at 30. According to a SOMS note dated July 19, The Drug Shoppe's oxycodone CSL was 42,420 du. GX 16, at 226. Yet as of July 19, Respondent had filled orders totaling 46,800 du of oxycodone 30 on a rolling 30-day basis, placing it over the CSL.[64] A further SOMS note dated July 26 states: ''rwr oxy edited to meet CSL for July.'' *Id.* Here again, there is no evidence that Respondent contacted The Drug Shoppe regarding either the July 19 or 26 orders or obtained a new UR. Nor did it report either order to DEA as suspicious.

In August 2010, Respondent shipped 40,000 du of oxycodone 30 mg, 2,400 oxycodone 15 mg, and 700 du of combination oxycodone products, totaling 43,100 du. Here again, on multiple occasions, The Drug Shoppe's oxycodone exceeded the CSL as referred to in the July 19 SOMS note. Specifically, on August 4, Respondent filed an order for 1,200 du of oxycodone 30, placing The Drug Shoppe's orders at 43,600 du on a rolling 30-day basis.[65] GX 10F, at 31. Yet a SOMS note of the same date establishes that the order was approved, the reason noted as ''oxy under csl.'' GX 16, at 227. Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

So too, on August 9, Respondent filled an order for 9,600 du, bringing The Drug Shoppe's total orders to

[61] There were several other instances in which The Drug Shoppe's orders on a rolling 30-day basis may have placed it over the CSL, including on March 11, 15, and 19, when the orders totaled 60,600 du, 60,900 du and 61,100 du. However, it remains unclear whether The Drug Shoppe's oxycodone CSL was set at 60,000 du, 75,000 du, or 46,500 du.

[62] As for the May 18 order (9,600 du of oxycodone 30 and 1,200 du of oxycodone 15, *see* GX 10F, at 30–31), there are three entries in the SOMS notes for this date, two of which contain the name of a reviewer and a notation. These notations simply state: ''Ok to ship under CSL'' and ''RELEASE ORDER SUPPORTED BY UR.'' GX 16, at 223. However, it is unclear which of the three entries pertain to this order.

There are two SOMS notes dated May 19, which correspond to shipments of 9,000 du of oxycodone 30 and 300 du of oxycodone 10/325. *See* GX 10F, at 30, 33. However, only one includes the name of the reviewer (J. Seiple); it states ''rwr.'' GX 16, at 224. So too, there are two entries dated May 26, but only one contains the name of a reviewer; it states ''ok to ship under CSL UR on File is from OCT.'' *Id.*

[63] This total includes orders for 9,600 du of oxycodone 30 on May 18 and 19, June 1, 3, 8, and 14, as well as orders for 9,000 du on May 19 and 600 du on May 26. GX 10F, at 30, 32–33. The total also includes orders for 1,200 du of oxycodone 15 on May 18 and June 1; orders for 400 and 600 Endocet 10/625 on May 17 and June 10; orders for 300 and 600 oxycodone/apap 10/325 on May 19 and June 1, and an order for 300 oxycodone 5/325 on June 10. *Id.*

[64] This includes the June 25 order for 6,000 du.

[65] On August 2, Respondent had filled an order for 9,600 du of oxycodone 30, which when added to the orders filled on July 6, 12, 15, 19, and 26, totaled 42,400 du. GX 10F, at 30–31. Thus, the Aug. 4 order placed The Drug Shoppe at 43,600 du on a rolling 30-day basis.

44,800 on a rolling 30-day basis.[66] GX 10F, at 31. The SOMS note for the order states: ''rwr Oxy within buying pattern leaves 20820.'' GX 16, at 227. Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On August 23, Respondent filled orders for 8,400 du of oxycodone 30; 1,200 du of oxycodone 15; and 200 du of Endocet 7.5/500; the next day, it filled orders for 300 du of oxycodone 10/325 and 200 du of Endocet 7.5/500. GX 10F, at 31–33. On their respective dates, the orders placed The Drug Shoppe's orders at 44,200 and 44,700 du on a rolling 30-day basis.[67] A SOMS note for August 23 states: ''oxy at 42,400 as of 8/20/10—at csl, need reviewed [sic] if order [sic] again'' and ''ok to ship, size not excessive on 2 ENDO 7.5/500 under CSL of 42420 this order puts them at 33000 for the month.'' GX 16, at 227.

A note in the MFR of the same date states: ''The UR Supports—Qty 60 Endo 7.5–500, Endo 10/325 = 2371, Oxy 15mg 3404, Oxy 30 61285 mal + Oxy 30mg Act—2965 totaling 70,085.'' RX 2B, at 1. A further note in the same entry states: ''CSL is already @42,600.'' However, as found above, The Drug Shoppe's August 23 orders placed it at 44,200 du, 1,800 du over its CSL, and its orders for the month were already nearly 10,000 du more than the 33,000 du figure used to justify shipping the orders.

As for the August 24 orders, the SOMS notes show that Ms. Seiple released the order. As for Ms. Seiple's reason, the SOMS note merely states: ''rwr.'' GX 16, at 227.[68] Yet for both days' orders, Respondent made no inquiry as to why The Drug Shoppe was ordering in excess of the CSL and a new UR (the UR in the file being three months old) was not obtained.

In September 2010, Respondent filled orders for 43,200 du of oxycodone 30 mg and 1,800 du of three oxycodone combination products, for a total of 45,000 du. GX 10F, at 31–33. Moreover, on each date during the month that Respondent filled The Drug Shoppe's oxycodone orders, The Drug Shoppe exceeded the CSL of 42,400 du that was documented in the SOMS and MFRs.

On September 1, Respondent filled orders for 9,600 du of oxycodone 30 and 300 du of oxycodone 10/325, placing The Drug Shoppe's orders on a rolling 30-day basis at 43,400 du. The next day, Respondent filled an order for 300 du of oxycodone 5, placing The Drug Shoppe's orders on a rolling 30-day basis at 43,700 du.[69] Both orders were released with reservation because the orders were ''within [the] monthly buying pattern.'' GX 16, at 228. However, in neither case did Respondent contact The Drug Shoppe and obtain an explanation for the order and a new UR.

On September 7, Respondent filled orders for 9,600 du of oxycodone 30; 600 du of oxycodone 10/325; and 200 du of oxycodone 7.5/325; bringing The Drug Shoppe's rolling 30-day total to 51,700 du. GX 10F, at 31, 33. Two SOMS notes of the same date made by Ms. Seiple state: ''rwr over 30 days under csl supported by u r dd complete'' and ''rwr.'' GX 16, at 228. However, with the order, The Drug Shoppe was more than 9,000 du over the CSL as documented in Respondent's records.[70] Moreover, Respondent had not obtained a new UR in three months, and there is no evidence that it contacted The Drug Shoppe and obtained an explanation for its order.

On September 13, Respondent filled another order for 9,600 du of oxycodone 30; this order brought The Drug Shoppe's rolling 30-day total to 52,100 du.[71] GX 10F, at 31. While the SOMS notes show that three orders were placed that day, only one of the orders lists the name of a reviewer, Ms. Seiple, who simply wrote ''rwr.'' GX 16, at 228. Again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

So too, on September 20, Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's rolling 30-day total to 50,500 du, and on September 23, it filled an order for 4,800 du of oxycodone 30, bring The Drug Shoppe's rolling 30-day total to 55,300 du. GX 10F, at 31. While the SOMS notes include two entries for Sept. 20, only one of them lists the name of a reviewer, again Ms. Seiple, who wrote: ''rwr under csl.'' GX 16, at 228. Likewise, the SOMS entry for the September 23 order again lists Ms. Seiple as the reviewer and provides the reason as: ''rwr.'' [72] *Id.* Again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for either order and a new UR.[73] Nor did it report the orders as suspicious.

In October 2010, Respondent filled orders from The Drug Shoppe totaling 39,600 du of oxycodone 30 and 1,700 du of three oxycodone combination products, for a total of 41,300 du. GX 10F, at 31, 33–34. Here again, on four occasions, Respondent filled orders that placed The Drug Shoppe over the 42,420 du CSL.

Specifically, on October 4, Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's rolling 30-day total to 44,400 du. GX 10F, at 31, 33. While a SOMS note lists the name of the reviewer, it then merely states: ''oxy at 9600 10/4/10,'' ignoring that the order placed The Drug Shoppe over its CSL. GX 16, at 229.

On October 7, Respondent filled an order for 600 du of oxycodone 5, bringing The Drug Shoppe's rolling 30-day total to 45,000 du. GX 10 F, at 33. Here again, while the SOMS note shows that the order was reviewed, it then states: ''rwr Oxy within monthly buying pattern,'' ignoring that the order placed The Drug Shoppe over its CSL. GX 16, at 229.

On October 11 Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's rolling 30-day total to 43,800 du. GX 10F, at 31. While the SOMS notes show that the order was reviewed, it was released with the reviewer noting only that: ''oxy at 19800 as of 10/11/10,'' again ignoring that the order placed The Drug Shoppe over its CSL. GX 16, at 229.

On October 18, Respondent filled orders for 9,600 du of oxycodone 30 and 200 du of Endocet 10/650, bringing The Drug Shoppe's rolling 30-day total to 44,300 du and over the CSL. GX 10F, a 31–33. While both orders were reviewed, the reviewer simply noted ''oxy at 29700 10/18/10'' (upon review of the oxycodone 30 order) and ''oxy at 29900 2nd order today 10/18/10'' (upon

[66] This total includes the orders from July 12 forward, including an order for 1,200 du of oxycodone 30 placed on August 5.

[67] These totals include orders on August 16 for 9,600 du of oxycodone 30, and orders on August 18 for 400 du of oxycodone 30 and 1,200 du of oxycodone 15. GX 10F, at 31–32.

[68] According to Mr. Corona, if an order placed a customer even one pill over its CSL, the SOMS placed the order on hold and subjected it to review. Tr. 1000–01.

[69] These totals include orders for 1,200 du on Aug. 4 and 5; 9,600 du on Aug. 9 and 16; 400 du on Aug. 18; and 8,400 du on Aug. 23; it also includes orders for 1,200 du of oxycodone 15 on Aug. 18 and 23; 300 du of oxycodone 10/325 on Aug. 24; and 200 du of oxycodone 7.5/500 on Aug. 23 and 24. GX 10F, at 31–34. The total of the orders as of Sept. 2 includes the 9,600 du of oxycodone 30 and 300 du of oxycodone 10/325. *Id.*

[70] In addition to the previous references that the CSL had been set at 42,420 du, a SOMS entry for October 26 also states that the CSL was set at 42,420. GX 16, at 230.

[71] This total includes a Sept. 8 order for 400 du of oxycodone 10/325. GX 10F, at 33.

[72] While there is a second SOMS entry dated Sept. 23, the accompanying note shows that it was for ''[h]ydro'' and not oxycodone. GX 16, at 228.

[73] Of further note, there are no entries in either the Ship to Memos or the MFRs for any of September orders. *See* GX 16, at 221; RX 2B, at 1–2.

review of the Endocet order). GX 16, at 229.

Of note, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for any of these orders, let alone that it independently verified any such explanation. Nor, in reviewing these orders, did Respondent obtain a new UR.

During November, Respondent filled orders from The Drug Shoppe totaling 10,800 du of oxycodone 30 and 1,300 du of combination oxycodone products.[74] GX 10F, at 31, 33. To be sure, this marked a substantial decrease in the amount of oxycodone Respondent shipped to The Drug Shoppe.

However, on November 1, Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's total of filled orders to 50,900 du on a rolling 30-day basis.[75] GX 10F, at 31. While the SOMS note indicates that the order was reviewed, the reviewer released the order noting: ''ok to ship 96 OXY 30mg, order os within roling [sic] 30 day.'' GX 16, at 230. Here again, while the order exceeded the CSL, there is no evidence that Respondent obtained an explanation for the order and a new UR.

Likewise, on November 9, Respondent filled an order for 1,200 du of oxycodone 30, bringing The Drug Shoppe's total filled orders to 42,500 du on a rolling 30-day basis.[76] The order was released with the reviewer providing the following reason in the SOMS note: ''rwr Oxy order under last monthly purchse[sic] pattern leaves 29,900—11/9/10.'' GX 16, at 230. Here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR.

On November 18, 2010, Respondent conducted another site visit. RX 2B, at 12. During the visit, Respondent's inspector was told by a pharmacy technician that The Drug Shoppe's PIC would be changing the following week. RX 2B, at 12. The inspector was also told that controlled drugs comprised 40 percent of the prescriptions the pharmacy filled and that 10 percent of its prescriptions were for any schedule II drug. *Id.* at 13. The inspector was further told that 85 percent of the controlled substance prescriptions were paid for with cash. *Id.*[77] Respondent did not, however, obtain a new UR (and had not obtained a new UR since June (for the month of May)) and would not obtain a new UR until December 15. RX 2B, at 1, 52. According to a note in the Ship to Memos, Respondent requested that The Drug Shoppe provide a UR for the month of October because of ''allocation issues in November for Oxy.'' GX 16, at 221.

The UR shows that during October, The Drug Shoppe dispensed 262 prescriptions totaling 49,637 du of oxycodone 30 mg, for an average of 189 du per prescription. RX 2B, at 46. Yet The Drug Shoppe's total dispensings of all drugs (including non-controlled) were 184,679 du. *Id.* at 51. Thus, oxycodone 30 mg alone comprised 27 percent of The Drug Shoppe's dispensings.

With respect to oxycodone 15 mg, the UR showed that The Drug Shoppe dispensed 21 prescriptions totaling 3,140 du of oxycodone (and Roxicodone) 15 mg, for an average of 149.5 du per prescription. *Id.* at 46, 48. In addition, the UR showed that The Drug Shoppe also dispensed 1,653 du of continuous release oxycodone products (*e.g.,* OxyContin), 3,171 du of combination oxycodone drugs, and 560 du of oxycodone 5 mg, for a total of 58,161 du, or more than 31 percent of its total dispensings.[78] RX 2B, at 39, 46.

Notwithstanding this information, during December 2010, Respondent shipped 24,400 du of oxycodone 30 and 2,000 du of oxycodone 15 mg, for a total of 26,400 du. GX 10F, at 31. Notably most of the orders were shipped on or after December 15, the date it received the UR. *Id.;* RX 2B, at 52.

In January 2011, Respondent shipped 17,000 du of oxycodone 30 mg, 2,700 du of oxycodone 15 mg, and 2,100 du of five combination oxycodone products. GX 10F, at 31–34. While an MFR note dated January 10, 2011, which is of marginal legibility, suggests that The Drug Shoppe was on CR (compliance review) ''for re-review,'' another note in the ''sign off'' column states ''RWR [release with reservation] until file reviewed [unintelligible].'' RX 2B, at 1.[79] Moreover, after January 11, Respondent filled orders for 12,000 du of oxycodone 30 and 1,200 du of oxycodone 15.

On February 8, 2011, Respondent filled orders from The Drug Shoppe for 3,000 du of oxycodone 30 mg; 900 du of oxycodone 15 mg; 200 du of oxycodone 5mg; and 800 du and 1,100 du of various oxycodone combination products. GX 10F, at 31–34. The same day, several DEA Diversion Investigators went to Respondent's Kemper Springs facility and requested The Drug Shoppe's file. RX 2B, at 1. While it is unclear whether the Investigators discussed with Respondent's staff that The Drug Shoppe had been issued an Order to Show Cause based on allegations that its owner and PIC (Bhupendra Agravat) had engaged in the unlawful distribution of controlled substances,[80] or that Mr. Agravat had recently agreed to settle the matter on the pharmacy's behalf by, in part, having no management, operational, or ownership interest in it, an MFR note states that ''file was reviewed/requested by DEA on 2/8/11'' and that ''the account was placed on NC [non-controlled] for review.'' RX 2B, at 1. A further MFR note states that during a phone call on February 10, Mr. Agravat admitted that during 2004–05, he was involved in distributing hydrocodone and Xanax over the internet but ''did not know [he] was being prosecuted by DEA.'' *Id.* Thereafter, Respondent finally terminated The Drug Shoppe as a controlled substance customer. *Id.*

On February 23, 2011, The Drug Shoppe placed an order for 500 du of alprazolam 2mg. GX 40, at 14. Respondent reported the order to DEA as suspicious. *Id.*

In her declaration, Ms. Seiple asserted that because The Drug Shoppe's PIC provided a written description of its policies and procedures to prevent diversion, Respondent's ''Compliance

[74] Evidence in the record suggests that the reduction in the orders Respondent filled during this month was ''due to allocation issues.'' GX 16, at 221. There is some evidence that late in a year, there could be a supply shortage of oxycodone.

[75] The total includes orders for 9,600 du of oxycodone 30 on Oct. 4, 11, 18, and 25, and an order for 1,200 du on Oct. 26; it also includes orders for 600 oxycodone 5 on Oct. 7; 200 du of Endocet 10/650 on Oct. 18; 600 du of oxycodone 10/325 on Oct. 25; and 300 du of oxycodone 5/325 on Oct. 13. GX 10F, at 31,33.

[76] The total included orders for 9,600 du of oxycodone 30 on Oct. 11, 18, 25, and Nov. 1, and 1,200 du of oxycodone 30 on Oct. 26. It also includes orders for 200 du and 300 du of Endocet 10/650 on Oct. 8 and Nov. 3 respectively; 600 du and 300 of oxycodone 10/325 on Oct. 25 and Nov. 3; and 300 du of oxycodone 5/325 on Oct. 13.

[77] Immediately following the inspector's report in the due diligence file is a page with the following handwritten notations: ''Assumption-,'' ''Comparisons of Business Norms,'' ''Patterns of Distribution,'' and ''compare like Nationally.'' RX 2B, at 15. However, the record does not establish who wrote the notations and his/her purpose in doing so.

[78] The October 2010 UR also showed that The Drug Shoppe had dispensed 9,697 tablets of methadone 10 mg, another schedule II drug. RX 2B, at 44.

[79] There is no corresponding entry in the SOMS notes for the same date. GX 16, at 232.

[80] The Show Cause Order issued to The Drug Shoppe alleged that: 1) Mr. Agravat had engaged in an unlawful internet distribution scheme by filling controlled substances prescriptions which violated 21 CFR 1306.04(a) because the physicians, who were located in different States than their patients, did not establish a valid doctor-patient relationship; 2) on May 22, 2009, Agravat had pled guilty in Arizona Superior Court to facilitation to commit the sale of narcotic drugs; and 3) Agravat had distributed 480 du of OxyContin to a single individual, by filling four prescriptions written in four different names, in exchange for $5,350. GX 17, at 10.

Department believed that Drug Shoppe understood its obligations to prevent diversion . . . and was taking affirmative steps to meet those obligations.'' RX 103, at 42–43. She further asserted that because its PIC told Respondent's consultant that its ''business model included filling prescriptions for a number of patients suffering from . . . HIV/AIDS[,] [t]his accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* at 43. Yet Respondent simply accepted this assertion without any further inquiry into how many HIV/AIDS patients The Drug Shoppe was dispensing to, let alone how many of these patients were being prescribed oxycodone 30. Nor did she identify the other drugs which the HIV/AIDS patients, who filled their oxycodone prescriptions at The Drug Shoppe, were presumably taking, and compare the number of prescriptions for these drugs with the number of the oxycodone prescriptions.

Next, Ms. Seiple asserted that both a sales manager and sales representative ''were personally acquainted with Mr. Agravat (they referred to him as 'Boo') and vouched for his character and that of the pharmacy.'' *Id.* However, the fact that these two employees referred to Agravat by his nickname hardly establishes that they had sufficient personal knowledge to vouch for his character.

Ms. Seiple also asserted that ''[a]fter Drug Shoppe's account was approved, [Respondent's] SOMS . . . identified and held any order for controlled substances placed by Drug Shoppe that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' *Id.* at 43–44. However, as found above, this statement is misleading as the SOMS did not become operational until August 2009, and during the period from April 1, 2009 through the date on which the SOMS became operational, Respondent shipped to The Drug Shoppe quantities that placed the pharmacy over its oxycodone purchasing limit and failed to document why it did so; it also did not report the orders as suspicious. Moreover, as found above, even after the SOMS became operational, on numerous occasions Respondent shipped oxycodone in quantities that placed The Drug Shoppe over the CSL and yet failed to obtain an explanation for the order from the pharmacy, which it then independently verified, and only rarely obtained URs, even though its Policy 6.2 required doing so on the review of each held order.

In her declaration, Ms. Seiple failed to specifically address the numerous instances in which the Compliance Department released orders which placed The Drug Shoppe over its CSL without obtaining an explanation (which was independently verified), as well as its repeated failure to obtain new URs. Instead, she offered only conclusory assertions to the effect that Respondent ''was aware of the volume of oxycodone and other controlled drugs being dispensed by Drug Shoppe, and the percentage of controlled drugs dispensed relative to other drugs,'' that it ''specifically investigated the reasons why Drug Shoppe's ordering and dispensing patterns were as indicated on the URs,'' and that ''[t]he URs and other information provided by Drug Shoppe were consistent with the pharmacy's business model as explained by Mr. Agravat and confirmed in the April 2008 site inspection.'' *Id.* at 44.

Addressing the January 2010 site visit, after which Mr. Chase noted that The Drug Shoppe's dispensing ratio of controlled to non-controlled drugs seemed ''a little high'' and recommended that a new UR be obtained, Ms. Seiple offered the unresponsive assertion that Respondent's policies and procedures ''do not specify any particular percentage of controlled . . . to non-controlled drugs that the Company considers 'high' or 'a little high.' '' *Id.* at 45. She then maintained that ''Mr. Chase did not recommend that [Respondent] stop selling controlled drugs to Drug Shoppe following his inspection,'' *Id.*, while entirely failing to address why Respondent ignored his recommendation to obtain a new UR and did not obtain a new UR until five months later. *Id.* at 46.

As for the circumstances surrounding the eventual termination of The Drug Shoppe, Ms. Seiple asserted that Respondent was unaware that Mr. Agravat had ''any drug-related criminal issues'' and believed that he left the country because he had a visa problem. *Id.* at 46–47. She stated that while Mr. Agravat had admitted (in 2008) that in 2006, he had been disciplined by the Florida Board of Pharmacy, he did not inform Respondent ''of any other criminal, regulatory, or disciplinary actions [including any action by DEA] taken against him or [The] Drug Shoppe,'' and that it was only in February 2011 that Agravat told Respondent ''that he was under investigation for issues relating to pharmaceutical sales on the internet that occurred in 2004 or 2005.'' *Id.* at 47. She further asserted that DEA does not publish information to the pharmaceutical industry regarding the issuance of Show Cause Orders. *Id.*

Even accepting that Respondent was unaware of the criminal case against Mr. Agravat until February 2011 and that the record does not establish the date on which he was charged by the State of Arizona, it is notable that, with the exception of the May 2008 site visit report, the various forms used by Respondent's employees and consultants in performing due diligence did not even contain a question as to whether the pharmacists had ever been criminally charged with offenses related to controlled substances. *See generally* RX 2B. Moreover, while the form used for the May 2008 site visit included a question which asked if ''any of the staff pharmacists'' had ever ''been criminally prosecuted[] or subjected to civil fines relative to the sale or dispensing of controlled substances,'' Respondent's consultant did not document an answer. *Id.* at 28. Yet there is no evidence that Respondent ever followed up on this omission.

Englewood Specialty Pharmacy

Englewood Specialty Pharmacy, which did business as Gulf Coast Pharmacy and was located in Port Charlotte, Florida, first became a customer of Respondent on January 29, 2008. RX 2C, at 71, 74. According to the due diligence file, the pharmacy, which had opened three years earlier, had begun ''as almost all compounding'' but had since become ''more of a retail pharmacy.'' *Id.* at 81. Printouts (dated March 14 & 17, 2008) in the due diligence file establish that Respondent verified the license and registration status of the pharmacy, as well as the license status of a pharmacist named Kevin Parkosewich. *Id.* at 86, 91–92. Of note, however, Respondent's ''DEA Schedule Orders—Due Diligence Report Form,'' which indicates that a review was done on March 17, 2008, lists one Dan Farris as the pharmacist and owner but there is no license verification for him in the due diligence file.[81] *Id.* at 81.

According to the Due Diligence Report Form, Englewood had requested an increase in its purchasing limits for hydrocodone and oxycodone. *Id.; see also id.* at 89. On the form, Englewood disclosed that its daily prescription average was 190, that 30 percent of the

[81] There is a license verification dated Sept. 8, 2008 for a Michael A. Farris, who was listed as the pharmacy ''prescription department manager'' on a Florida Department of Health Inspection Report dated August 30, 2007. RX 2C, at 74. The Report was signed, however, by ''D. Farris.'' *Id.*

prescriptions were for controlled drugs, and that 15 percent of the prescriptions were for schedule II drugs. *Id.* It also reported that 60 percent of its prescriptions were paid for by insurance and that they had a ''good relationship'' with a pain clinic doctor who was located ''across the street.'' *Id.* Englewood represented that to prevent doctor shopping it made ''sure the RX is valid''; that if a doctor was from outside the area, it called the doctor; and that it validated the doctors' DEA numbers. *Id.* at 82.

Respondent also obtained a UR showing Englewood's dispensings during the month of January 2008. RX 2C, at 129–162. The UR shows that Englewood had dispensed a total of 342,760 dosage units for all prescription drugs; this included 161,729 du of schedule II drugs; 19,953 du of schedule III drugs; 45,817 of schedule IV drugs; 2,518 du of schedule V drugs; and 112,743 du of non-controlled legend drugs. *See id.* at 131, 134, 137–38, 162. By dosage units, Englewood's controlled substance dispensings constituted 67 percent of its dispensings, and schedule II drugs comprised 47 percent of its total dispensings.[82]

The UR also showed the total number of prescriptions for each scheduled and legend drug. Specifically, it showed that the pharmacy had filled 1,286 schedule II Rxs, 208 schedule III Rxs, 513 schedule IV Rxs (after subtracting out carisoprodol), 11 schedule V Rxs, and 1,952 legend drug Rxs (including carisoprodol). Thus, the schedule II prescriptions actually comprised more than 32 percent, and all controlled substances comprised 51 percent of the total prescriptions dispensed, both figures being substantially larger than the figure reported by the PIC. Respondent nonetheless approved Englewood to purchase oxycodone, with documents suggesting that the amount was initially set at 250 bottles or 25,000 du per month. *Id.* at 87, 89.

A ''Schedule Drug Limit Increase Request'' form states that on September 3, 2008, Englewood requested that its oxycodone limit ''be bumped up to the next level.'' *Id.* According to the form, Englewood now reported that its monthly usage of oxycodone was 95,000 du. *Id.* According to a Due Diligence Report Form (dated September 8) which noted that Englewood had requested an increase for oxycodone, the pharmacy reported that it filled 220 prescriptions per day, of which 30 percent were controlled drugs and 20 percent were schedule II drugs. *Id.* at 71. Respondent again asked Englewood for information regarding its policies and procedures; in the words of Respondent's account manager, its owner/pharmacist ''basically sa[id] the same answers as before.'' *Id.* at 73. While Respondent re-verified Englewood's pharmacy license and DEA registration, as well as the pharmacists' licenses of Michael Farris and Kevin Parkosewich, it again failed to verify the license of Dan Farris, its owner and pharmacist-in-charge. *See generally* RX 2C.

On September 22, Respondent obtained a new UR from Englewood which listed the pharmacy's dispensings of all prescription products from March 1 through that morning. RX 2C, at 114–28. The report showed that during that period, Englewood dispensed 345,175 du of oxycodone 30, an average of 51,355 du per month, and 154,008 du of oxycodone 15, an average of 22,947 du per month.[83] The report also showed that Englewood dispensed 185,426 du of various dosage strengths of oxycodone continuous release drugs (including OxyContin), an average of 27,268 du per month. Finally, the report showed that Englewood dispensed 118,420 du of combination oxycodone products, an average of 17,645 du per month, as well as 27,768 du of oxycodone 10 mg and 5 mg, an average of 4,137 du per month. In total, Englewood dispensed 830,797 du of oxycodone during the period of the report, an average of 123,789 du per month. By contrast, even including Englewood's dispensings of carisoprodol (99,222 du) (which was then controlled in the State of Florida but not under the CSA) in calculating its dispensing of non-controlled prescription drugs, Englewood's dispensings of these drugs totaled only 556,938 du.

In total, Englewood's UR showed that it dispensed more than 1,280,332 du of schedule II drugs;[84] 400,581 du of schedule III through V drugs (excluding carisoprodol); and 2,238,571 du of all prescription drugs. Thus, schedule II drugs comprised a total of 57 percent of Englewood's total dispensings, and all controlled substances comprised 75 percent of its dispensings.

The UR also showed the number of prescriptions Englewood filled for each drug and provided a separate total for all schedule IIs (9,928 Rxs), all schedule III through V (6,724 Rxs), and Legend drugs (5,663 Rxs), for a total of 22,315 prescriptions. *Id.* at 122, 127, 128. Thus, schedule II prescriptions comprised 44.5 percent of all prescriptions, nearly three times what the PIC had reported during the initial due diligence survey. Moreover, even after subtracting out the 1,129 prescriptions for carisoprodol from the total for schedules III through V, *id.* at 114, 117; controlled substance prescriptions totaled 15,523 prescriptions and nearly 70 percent of all prescriptions, more than double the figure reported by the PIC.

On November 3, 2008, Respondent's consultant performed a site visit at Englewood. RX 2C, at 75. On his report, the consultant listed Dan Farris as the Pharmacist-in-Charge. *Id.* He also noted that the pharmacy filled 220 prescriptions per day, but did not service nursing homes, hospice programs or inpatient facilities. *Id.* at 77. He also noted that 25 percent of the prescriptions were for controlled substances, and that the pharmacy filled prescriptions for pain management clinics and listed the names of six pain management physicians. *Id.* at 77–78. While the consultant then wrote that Englewood was ''[a]djacent to 2 large hospitals and several buildings with doctors offices in them,'' and ''appears to be a busy prescription store,'' he further noted that ''*[h]e [the PIC] appears to be doing a larger narcotic business than he admits to.*'' *Id.* at 78 (emphasis added).

The due diligence file contains no evidence that Respondent did anything to address the consultant's observation, even though it had the UR. Nor does it contain any evidence that Respondent compared the prescription percentage reported by the consultant with the most recent UR. Instead, a notation on the Schedule Drug Limit Increase Request form from two months earlier indicates that on November 25, 2008, Respondent approved Englewood to purchase 50,000 du per month of oxycodone. *Id.* at 87. The due diligence

[82] On a Schedule Drug Limit Increase Request Form dated March 13, 2008, an account manager for Respondent noted that Englewood used 70,000 du of solid dose oxycodone per month. RX 2C, at 89. However, the data in the January 2008 UR show that the pharmacy was actually dispensing more than 102,000 du of all formulations of oxycodone, which included 39,469 du of oxycodone (and Roxicodone) 30; 17,303 du of oxycodone 15; 13,040 du of OxyContin 80 and 450 du of oxycodone 80 CR; 10,254 du of OxyContin 40; 2,725 du of oxycodone 5; 1,678 of oxycodone 20 CR; 880 du of OxyContin (and oxycodone CR) 10; 1,170 du of Endocet 10/650; 11,675 du of Endocet 10/325; 350 du of Endocet 7.5/500; 860 du of Endocet 7.5/325; and 2,447 du of Endocet 5/325, for a total of 102,301 du. RX 2C, at 129–31.

[83] The monthly averages were calculated by dividing 30.5 by the total number of days from March 1 through and including September 21 (205), and then multiplying this figure (.149) by the total dispensings.

[84] The UR for Englewood's schedule II dispensings lists the number of units dispensed as 128,033. RX 2C, at 122. As the first entry on the UR indicates that Englewood dispensed 183,154 du of methadone, *see id.* at 119, it is apparent that the total figure is in error and that the last digit was cut off.

file contains no documentation that Englewood's oxycodone purchasing limit was raised between this date and April 1, 2009.

However, in April 2009, Respondent filled multiple orders placed by Englewood for 71,900 du of oxycodone 30 and 8,400 du of oxycodone 15, for a total of 80,300 du of oxycodone. GX 10F, at 16–17. Notwithstanding that these orders (and in particular the April 29 order for 30,300 du) exceeded the purported oxycodone purchasing limit by more than 30,000 du, the due diligence file contains no explanation for why this order was approved. Moreover, the order was not reported as suspicious.

In May 2009, Respondent filled orders totaling for 50,000 du of oxycodone 30. GX 10F, at 16–17. However, on June 1, it filled an order for 50,000 du of oxycodone 30, and on June 11, it filled orders for 52,000 du of oxycodone 30, for a monthly total of 102,000 du. *Id.* at 17. Here again, notwithstanding that Englewood's June 11 orders placed it more than 50,000 du over (and at more than double) its oxycodone purchasing limit, the due diligence file contains no explanation as to why the June 11 orders were approved. And here again, the orders were not reported as suspicious.

On July 1, 2009, Respondent filled orders for 100,000 du of oxycodone 30, and 2,000 du of oxycodone 15, for a total of 102,000 du. *Id.* at 17. Again, Englewood's due diligence file contains no documentation explaining why these orders, which were more than double the oxycodone purchasing limit, were approved. And here again, the orders were not reported as suspicious.

On August 3, Respondent filled orders for 90,000 du of oxycodone 30 and 12,000 du of oxycodone 15, for a total of 102,000 du. *Id.* And on September 28, Respondent filled orders totaling 90,000 du of oxycodone 30 mg, as well as for 10,000 du of oxycodone 15, for a total of 100,000 du. *Id.* The SOMS notes indicate that neither set of orders were held for review. *See* GX 18, at 163.

An MFR note dated October 1, states: ''need updated UR report. [P]urchased 1000 pills in two days on CH. [Talked To] Michele K.[85] Will be purchasing Oct. 26th.'' RX 2C, at 4. And an MFR note dated October 5 states that Respondent contacted Englewood to request a UR, spoke with Dan (the PIC), and received a UR for the month of September later that day. *Id.*

The UR showed that during that month, Englewood dispensed a total of 302,459 du of schedule II drugs; 20,608 du of schedule III drugs; 52,283 du of schedule IV drugs (excluding carisoprodol); 1,480 du of schedule V drugs; and 112,947 du of non-controlled prescription drugs (including carisoprodol). RX 2C, at 43, 45, 48–49, 69. Of Englewood's total dispensings of 489,777 du, schedule II drugs comprised 62 percent and all controlled substances were 77 percent.

The UR further showed that during that month, Englewood dispensed a total of 123,476 du of oxycodone 30 mg; 26,097 du of oxycodone 15 mg; 41,619 du of various strengths of oxycodone extended release and OxyContin; and 21,485 du of other oxycodone drugs including oxycodone 5 mg (2,930 du) and combination drugs. *Id.* at 40, 42–43. Englewood's dispensings of oxycodone alone totaled 212,677 du, more than 43 percent of all dispensings.

As for the number of prescriptions, the UR showed that Englewood had dispensed 2,392 sch. II Rxs, 218 sch. III Rxs, 870 sch. IV Rxs (excluding carisoprodol), 9 sch.V Rxs, and 1,804 legend drug Rxs (including carisoprodol). Thus, the schedule II prescriptions alone accounted for 45 percent and all controlled substances were 66 percent of all prescriptions dispensed.

On October 8, Ms. Seiple spoke with Englewood's PIC who now claimed that his pharmacy was filling 250 to 300 prescriptions per day. GX 18, at 166. The PIC also claimed that his pharmacy was located ''in close proximity'' to two hospitals and that it got ''most of [its] business from pain clinics in the area,'' including a clinic which was ''lacated [sic] across the street.'' [86] *Id.* The PIC further stated that his methadone prescriptions ''range from 60–1000 pills per script'' and they averaged ''480–600 pills per script.'' *Id.*

Ms. Seiple also noted that ''[t]he account is showing usage of 150k oxy in month of September'' and that Englewood was also purchasing controlled substances from Amerisource Bergen. *Id.* Continuing, Ms. Seiple noted that her ''recommendation is to review [the] account and reduce limits . . . on these two products until committee review to 12k on methadone and 50k on oxy to contain purchasing.'' *Id.* Ms. Seiple also noted that Englewood's PIC had ''indicate[d] [that] he will be doin[sic] the bulk of his purchasing now at the end of the month to take advantage of the full 45 days.'' *Id.*

A handwritten MFR note by Ms. Seiple of the same date states: ''we need to override limits @ 12k methadone 500 on Oxy'' and ''very concerned w/ quantity dispensed per ur.'' RX 2C, at 4. Indeed, while Englewood's pharmacist had previously stated that the methadone prescriptions averaged 480–600 pills per script, the September UR showed that Englewood had dispensed 194 prescriptions totaling 50,004 du, an average of 258 du per prescription.

Yet there is no evidence that Respondent compared the PIC's statement with what the UR actually showed. This was just one of multiple times when Englewood's PIC had made false statements to Respondent's employees regarding his controlled substance dispensings, which could have been easily verified but were not.

According to the SOMS notes, on October 27, 2009, Englewood ordered 100,000 du of oxycodone 30 and 20,000 du of oxycodone 15; however, the order was held for review by the SOMS. GX 18, at 163. Notes in the MFR and Ship to Memos showed that the committee reviewed Englewood's account and approved the limits of 50,000 du of oxycodone and 12,000 du of methadone, which Ms. Seiple had previously imposed pending the review. *Id.; see also* RX 2C, at 4. A note in the MFR further shows that Respondent contacted Englewood's PIC and was made ''aware'' that his ''order was edited'' and ''[r]educed from 100k to 50k.'' RX 2C, at 4; *see also* GX 18, at 163 (SOMS note: ''order revised shipped 50k on oxy for the month edited order from 100k on oxy 30 and 15 mg edit from 20 to 0''). Respondent did not, however, report the order as suspicious.

On October 29, Respondent filled an order for 50,000 du of oxycodone 30. GX 10F, at 17. Respondent did not, however, report the order as suspicious.

In November, the compliance committee further reduced Englewood's oxycodone CSL from 50,000 to 37,500 du.[87] GX 18, at 166. Consistent with the new limit, on November 30, Respondent filled Englewood's order for 37,500 du of oxycodone 30. GX 10F, at 17; RX 2C, at 3.

[85] Various documents in the due diligence file list a Michelle Kostoff as Respondent's account manager for Englewood. RX 2C, at 84–85, 89.

[86] While at the Nov. 2008 site visit, Respondent's consultant had noted that Englewood was located ''adjacent'' to ''several buildings with doctors offices in them,'' he did not specify that there was a pain clinic across the street. RX 2C, at 78. Moreover, while Englewood's PIC attempted to justify the pharmacy's orders for narcotics by claiming that a pain clinic—which he named—was located across the street, there is no evidence that Respondent did anything to verify this statement.

[87] Entries in the MFR dated December 17 suggests that this reduction was not motivated by concern that Englewood was diverting the drugs but by Respondent's decision to ''allocate'' its supply of oxycodone because it had a reduced inventory. *See* RX 2C, at 3.

However, just three days later, Englewood placed an order for 50,000 du of oxycodone 30 and 24,000 du of methadone. RX 2C, at 3. An MFR note states that the oxycodone order was deleted because Englewood had ''just purchased'' on November 30 with the further notation of ''rolling 30.'' *Id.* The MFR notes further show that Ms. Seiple called the PIC and told him that the ''order was deleted'' and that orders for the account would not be filled until there was a review by the committee. *Id.*

Of further note, the MFR contains no reference as to the PIC's explanation for the order and a new UR was not obtained. Here again, the order was not reported as suspicious, even though the order placed Englewood's oxycodone orders on a rolling 30-day basis at 87,500 du, more than double its CSL.

On December 17, Englewood placed another order for 50,000 du of oxycodone and 24,000 du of methadone. RX 2C, at 3. While Wayne Corona directed that the orders not be filled because they exceeded Englewood's CSLs on a ''rolling 30'' day basis, the note further indicated that the committee would review the account after 12–21–09 and that Respondent ''only will allocate 37,500 oxy [and] 12k meth[adone] per committee review.'' *Id.* Continuing, the note states: ''get w/ Wayne to see if he wants to ship 37,500 or decrease,'' as well as ''see email to wayne'' and ''correspondence on account.'' *Id.* However, neither the email nor any ''correspondence on account'' is in the due diligence file submitted by Respondent.

A second entry for December 17 indicates that Ms. Seiple called Englewood's PIC and ''advised [that] order is not shipping'' and ''referred to'' their conversation of two weeks earlier. RX 2C, at 3. The PIC asked Ms. Seiple if an order placed on December 21 would be shipped and if he was ''guaranteed product this month.'' *Id.* Seiple noted that she referred to Respondent's ''script and reasoning on allocation in industry per training,'' and that after assuring the PIC that the decision ''was not personal,'' she told him that she would ''advise Michele [the account manager] to place [the] order on 12–21–09 for review.'' *Id.* A further note in the margin adjacent to this entry states: ''will be resubmitting if approved to ship only can have 375 of oxy 120 of meth.'' *Id.*

While the order clearly placed Englewood above its CSL, here again there is no evidence that Ms. Seiple asked its PIC why his pharmacy needed so much oxycodone 30. Nor did she obtain a new UR. Moreover, Respondent did not report the order as suspicious.

On December 28, 2009, the compliance committee conducted a new review and approved Englewood for an order of 50,000 oxycodone 30 and 24,000 methadone, which was shipped. RX 2C, at 2; *see also* GX 10F, at 17. The MFR note further states that Englewood was on the site visit list. RX 2C, at 2.

On January 12, 2010, Jeff Chase conducted a site visit at Englewood. *Id.* at 34–38. Mr. Chase noted that Dan Farris was the owner/PIC. *Id.* at 35. The form included the question: ''Has the Pharmacy, the PIC, or the owner ever had their DEA license, or any other license in any State, suspended, revoked, or disciplined?'' *Id.* Mr. Chase checked ''No.'' *Id.* However, once again, there is no evidence that Chase or anyone else at Respondent verified this information even though this could have been easily done by accessing the Florida Department of Health's Web page and had never been done with respect to the PIC.

Mr. Chase noted that Englewood filled an average of 265 prescriptions per day. *Id.* at 36. He then noted that ''40%'' were for any controlled substances—adding the comment ''A little high!''—and that ''25% were for schedule II drugs.'' *Id.*

In contrast to the PIC's representation in October that a pain management practice was located across the street, Mr. Chase noted that a ''G.P. Doctor [was] next door and a couple [of] pain clinics [were] in the area.'' *Id.* at 37. He also noted that there were ''two hospitals down the street.'' *Id.* However, no further information was documented as to how many controlled substance prescriptions issued by physicians at the hospitals were being filled at Englewood, nor the types of drugs involved in those prescriptions. While Mr. Chase further noted that pharmacy appeared to have a full selection of pharmaceuticals available, he also noted that it had a ''small selection of OTCs.'' *Id.*

As part of his visit, Mr. Chase also prepared a ''Site Visit Recommendation'' form. *Id.* at 34. While Mr. Chase indicated that the site visit was acceptable, he recommended that a new UR be requested. *Id.* Mr. Chase checked three reasons for his recommendation, noting that the pharmacy had ''Minimal OTCs,'' that controlled drugs were ''40%'' which was ''*a little high,*'' a point he reiterated under ''Other'' reasons. *Id.* (underlining in original). As to the latter, Mr. Chase wrote: ''This pharmacy appears to be a well ran [sic] pharmacy but is a *little high on CII–Vs!!* We need to get a Utilization Report & compare it to what was reported to site visit.'' *Id.* (underlining in original). The form bears the circled initial of ''W'' and the date ''1/20/10,'' *id.,* and an MFR note, which discusses the site visit, states that it was ''signed by Wayne.'' RX 2C, at 2.

However, here again, Mr. Chase's recommendation was disregarded. Instead, a new UR was not obtained until August 12, 2010. *See id.* at 2, 13.

On January 26, Respondent filled Englewood's order for 47,600 du of oxycodone 30 and 2,400 du of oxycodone 15. GX 10F, at 17. This order placed Englewood's total oxycodone orders at 100,000 du on a rolling 30-day basis and again exceeded the CSL (which, according to a Jan. 27 note by Ms. Seiple, was still set at 37,500 du). GX 18, at 163. Moreover, it was more than double the amount approved by the compliance committee in December. As for why the order was approved, an MFR note of the same date states: ''Ship per UR per Committee signed by Wayne.'' RX 2C, at 2.

The next day, Respondent filled Englewood's orders for an additional 20,000 du of oxycodone 30. GX 10F, at 17. Thus, with the order, Englewood's oxycodone orders on a rolling 30-day basis totaled 70,000 and again exceeded the CSL.

While the order was held, a SOMS note made by Ms. Seiple states: ''releasing order supported by ur csl 37500 on oxy committee ok 50k in dec and to ur in jan.'' GX 18, at 163. And a note in the Ship to Memos by Ms. Seiple states: ''per committee 50k in dec and ship to ur on 1/26/10. Order for 20k releasing on 1/27/10 month to date on oxy 70k.'' *Id.* at 167. *See also* RX 2C, at 2 (MFR note: ''Order for 20,000 Oxy 30 mg,'' ''Release order @50k w/order,'' and ''70k on the month for oxy'').

Here again, there is no evidence that Respondent contacted Englewood to obtain an explanation for the January 26 and 27 orders. And notwithstanding that: (1) It had not obtained a new UR in four months; (2) its inspector had recommended that it obtain a new UR; and (3) its policy required that it obtain a new UR whenever it reviewed an order held by the SOMS; Respondent still failed to obtain a new UR.

On February 25, Respondent filled Englewood's order for 50,000 du of oxycodone 30; the order placed Englewood's oxycodone orders at 70,000 du on a rolling 30-day basis. GX 10F, at 17. There are two SOMS notes of the same date, but neither specifically refers to oxycodone. The first establishes that an order was reviewed by Ms. Seiple, who released the order, because it was ''supported by ur.'' GX 18, at 164. The second shows that an order was reviewed by another

employee, who wrote: ''ok to ship all controls within csl for period.'' *Id.* However, as found above, the February 25 oxycodone order placed Englewood over its CSL.

The next day, Respondent filled Englewood's orders for another 14,000 du of oxycodone 30 and 6,000 du of oxycodone 15, again totaling 70,000 du on a rolling 30-day basis (as well as for the month). *Id.* A SOMS note dated Feb. 26, 2010 shows that Ms. Seiple released the order because it was ''supported by UR.'' GX 18, at 164.

Here again, there is no evidence that Respondent obtained an explanation from Englewood for either the Feb. 26 or 27 orders. Moreover, the last UR Respondent obtained was five months old.

In March, Respondent filled even larger orders for Englewood. Specifically, on March 17, it filled an order for 50,000 du of oxycodone 30, and on March 26, it filled an order for another 30,000 du of oxycodone 30. GX 10F, at 17. The March 17 order placed Englewood's oxycodone orders at 120,000 du on a rolling 30-day basis, and the March 26 order placed Englewood's oxycodone orders at 150,000 du on a rolling 30-day basis. *Id.*

A SOMS note shows that the March 17 order was released by Mr. Schulze, who noted: ''oxy supported by ur.'' GX 18, at 164. Likewise, Ms. Seiple released the March 26 order noting that it was ''supported by ur.'' *Id.* Notwithstanding that Englewood's orders exceeded the previously set CSL by a factor of three to four (and 82,500 and 112,500 du), Respondent did not contact the pharmacy and obtain an explanation for the orders. Nor did it obtain a new UR. And it did not report either order as suspicious.

On March 29, Respondent filled an order for 9,600 du of oxycodone 15, thus totaling 89,600 du for the month and again exceeding the CSL by more than 50,000 du.[88] GX 10F, at 17. *Id.* According to a SOMS note, the March 29 order was ''ok to ship-oxycodone ur supported increase for period.'' GX 18, at 164. Here again, Respondent failed to obtain an explanation for the order and a new UR. It also failed to report the order as suspicious.

On April 15, Respondent filled an order for 50,000 du of oxycodone 30, which according to the SOMS was approved because it was ''under [the] CSL.'' GX 18, at 164. Yet on placing the order, Englewood's oxycodone orders totaled 139,600 du on a rolling 30-day basis and thus clearly exceeded the CSL. Here again, there is no evidence that Respondent obtained an explanation for the order from the pharmacy and it did not report the order as suspicious.

Thereafter, on April 26, Englewood ordered an additional 30,000 du of oxycodone 30 and 10,000 du of oxycodone 15, placing its total orders at 99,600 du on a rolling 30-day basis. GX 10F, at 17; RX 2C, at 2. According to an MFR note, the order was released with ''reservation per committee'' as it was ''supported by [the] UR.'' RX 2C, at 2; *see also* GX 18, at 164 (SOMS note: ''order supported by ur per committee order is released see mfr''). Here again, there is no evidence that Respondent obtained an explanation for the order from the pharmacy and it did not report the order as suspicious.

On May 17, Englewood ordered 70,000 du (700 bottles) of oxycodone 30 mg. RX 2C, at 2; GX 18, at 164. The order (before it was edited) placed Englewood's oxycodone orders at 110,000 du on a rolling 30-day basis and well over its CSL. GX 10F, at 17. According to notes in the SOMS and MFRs, the order was edited from 700 bottles to 500 bottles ''due to [its] pattern and size.'' RX 2C, at 2; GX 18, at 164. While the MFR states ''[s]till only using Masters & ABC,'' it further states ''pattern & size was always 500 in middle of month.'' RX 2C, at 2. However, here again, even inferring that Respondent contacted Englewood to determine what distributors it was using, it did not obtain a new UR and failed to report the order as suspicious.

In addition to filling the above order at 50,000 du, on May 26, Respondent filled an order for an additional 30,000 du of oxycodone 30, and on May 28, it filled an order for an additional 10,000 du of oxycodone 30. GX 10F. These orders placed Englewood's oxycodone orders at 80,000 and 90,000 du on a rolling 30-day basis. Moreover, during the month, Respondent again shipped a total of 90,000 du of oxycodone to Englewood.

While there is a SOMS note dated May 26 by Ms. Seiple, which states ''release order under csl,'' it is unclear what Englewood's oxycodone CSL was at this point, and notes pertaining to the following month suggest that the CSL was considerably lower than 90,000 du. GX 18, at 164.

On June 25, Respondent shipped an order for 50,000 du of oxycodone 30, and on June 28, it shipped an additional 13,000 du of oxycodone 30 to Englewood. GX 10F, at 17. A SOMS note dated June 28, states: ''order edited from 400 bottles of oxy to 130 per csl.'' GX 18, at 164. Given that as of the June 28 order, the only other order that had been filled on a rolling 30-day basis was the June 25 order for 50,000 du, the SOMS note establishes that Englewood's oxycodone CSL was then set at 63,000 du. Yet this order was not reported as suspicious. Moreover, here again there is no evidence that Respondent obtained an explanation for the order and a new UR.

Moreover, a note made by Ms. Seiple in the Ship to Memos dated June 30 suggests that Englewood made an additional order for oxycodone two days later as it states: ''left a message for pharmacy recieved [sic] vm again orders for 96 each on oxy deleted at csl per policy[.] have been unable to get a hold of dan,'' the Owner/PIC. GX 18, at 167. Notwithstanding that Englewood had again ordered in excess of its CSL, Respondent again failed to report the order as suspicious.

On July 13, Respondent shipped an order for 50,000 du of oxycodone 30. GX 10F, at 17. This order brought the rolling 30-day total of Englewood's oxycodone orders to 113,000 du, nearly double its CSL.[89] A SOMS note of the same date shows that Ms. Seiple released the order, explaining that ''dan [the PIC] is not ordering allotment anymore at the end of the month was only doing so for 60 day billing.'' GX 18, at 164. It is unclear what to make of this given that the PIC had ordered large quantities of oxycodone (typically 50,000 du) on multiple occasions in the middle of the months of March, April, and May. *See* GX 10F, at 17. Moreover, the PIC subsequently continued to order substantial quantities (13,000 du) of oxycodone 30 towards the end of subsequent months, including on July 27. *See id.* And in any event, Ms. Seiple did not obtain a new UR and had not done so in nine months.

As for the latter order, a SOMS note dated July 26, which is the only order noted in the SOMS between July 16 and August 10, shows that Ms. Seiple reviewed the order. The note then states: ''rwr edit order 300 to 130.'' GX 18, at 164. As found above, Respondent had filled oxycodone 30 orders on June 28 for 13,000 du and on July 13 for 50,000 du. Thus, on placing the order, Englewood's orders totaled 93,000 du on a rolling 30-day basis.

Here again, even though the order clearly placed Englewood over its oxycodone CSL, Respondent did not obtain an explanation for the order or a

[88] Moreover, even on a calendar-month basis, Englewood's March orders were nearly 20,000 du greater than its February orders.

[89] As previously explained, this total does not include the 370 bottles (37,000 du) that were deleted from the June 28 order or the June 30 order for 96 bottles which was entirely deleted.

new UR. And it did not report the order as suspicious.

On August 10, Respondent shipped an order for 50,000 du of oxycodone 30. On a rolling 30-day basis, Englewood's orders (not counting what was deleted) totaled 113,000 du. A SOMS note by Ms. Seiple states: ''rwr pending updated ur.'' GX 18, at 164. Unexplained is why the order was released given that it: (1) Was now seven months since Mr. Chase had conducted his site visit, after which he warned that Englewood seemed ''a little high'' on its controlled substance dispensings, and recommended that a new UR be obtained, and (2) it was also ten months since Respondent had obtained the last UR. Moreover, the order was not reported as suspicious.

An MFR note made the next day states: ''compliance hold until ur updated provided.'' RX 2C, at 2. On August 11, Englewood provided Respondent with a UR for the month of July 2010. *Id.* at 13.

The UR showed that Englewood had dispensed 204,291 du of oxycodone 30 (including 80 du of Roxicodone 30) and 15,210 du of oxycodone 15 (including 60 du of Roxicodone 15) during the month. *Id.* at 13, 28–29. It also showed significant dispensings of other oxycodone products, as well as other schedule II drugs and schedule IV benzodiazepines.[90] Notably, Englewood's total dispensings of all prescriptions drugs totaled 519,071 du. *Id.* at 32. Moreover, with the exception of carisoprodol, each of the top ten drugs dispensed by quantity was an oxycodone product, methadone, or alprazolam, and of the top 20 drugs dispensed, the only other non-controlled drug was albuterol. *Id.* at 13.

Notwithstanding the information provided by the UR, on August 23, Respondent filled an additional order for 13,000 du of oxycodone 30. GX 10F, at 17. MFR notes of the same date state: ''250 oxy 30 mg currently at 50k[.] CSL is 63k,'' and ''Edited oxy from 250 to 130.'' RX 2C, at 1; *see also* GX 18, at 165 (SOMS notes entry dated Aug 23: ''order edited per mfr''). On a rolling 30-day basis, Englewood's orders totaled 88,000 du (25,000 du more than its CSL), and even after Ms. Seiple edited the order, Englewood's orders still exceeded its CSL by 13,000 du.

On September 10, Respondent filled an order for 50,000 du of oxycodone 30. GX 10F, at 17. While this order did not place Englewood over its CSL, a SOMS note establishes that on September 27, 2010, Englewood ordered an additional 18,000 du of oxycodone 30. GX 18, at 165. Ms. Seiple edited the order ''from 180 to 130 for csl on oxy,'' *id.,* and Respondent shipped 13,000 du to Englewood. GX 10F, at 17.

However, once again, Englewood had placed an order that exceeded its CSL, and once again, Respondent failed to obtain an explanation for the order and to report the order as suspicious.

The next day, Respondent filled orders for 1,200 du of oxycodone 20 mg and 600 du of oxycodone 10 mg, bringing its rolling 30-day total to 64,800 du and over its CSL. GX 10F, at 17. While the orders were held for review, the orders were released with the SOMS note stating: ''ok to ship with reservations [sic] first time purchase on Oxy since 2009.'' GX 18, at 165. Yet, as found above, Englewood had repeatedly purchased oxycodone from Respondent throughout 2010. Once again, Respondent did not obtain an explanation for the order and failed to report it as suspicious.

On October 6, 2010, Respondent performed another site visit at Englewood. RX 2C, at 5–7. According to the inspector's report, the PIC stated that he did not fill for out-of-state or out-of-area patients. *Id.* at 6. He also stated that 40 percent of the prescriptions it filled were for controlled substances, and 20 percent were for schedule II drugs. *Id.* at 6. After noting that the pharmacy had a ''small selection of OTCs,'' the inspector wrote the following:

> When I arrived I observed a man appearing to be in his mid 20's waiting in a KY licensed car in front of the store. While waiting I observed other men appearing to be in their late 20's to early 30's taking large trash bags out from the pharmacy to a dumpster. The men spoke to and went into the KY licensed vehicle. When leaving, I observed other men in their mid 30's in the pharmacy waiting area. A TN temporary licensed car was in the parking lot. There were no other businesses open near the pharmacy and open at that time. Front of store was designed more as a waiting room rather than a store front. Owner reported filling for patients from local Pain Clinic.

Id. at 7.

An MFR note of October 7 states that the ''site visit [was] questionable,'' that the account needed to be reviewed, and that it was placed on compliance hold based on ''suspicious activity outside of pharmacy.'' RX 2C, at 1. The noted further stated that the account was terminated, and that when the decision was communicated, Respondent PIC ''was upset'' and ''felt that [Respondent was] being a little harsh.'' *Id.*

Regarding Respondent's sales to Englewood, Ms. Seiple offered testimony similar to that which she offered with respect to the pharmacies previously discussed. For example, she asserted that because the PIC had provided copies of its policies and procedures for preventing diversion and described them to Respondent, the ''Compliance Department believed that Englewood understood its obligations to prevent . . . diversion . . . and was taking affirmative steps to meet those obligations.'' RX 103, at 48–49. She further asserted that ''before shipping any pharmaceutical products to Englewood, [Respondent] verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.'' *Id.* at 49. Yet Ms. Seiple made no claim that Respondent had verified the status of the PIC's license and there is no evidence that it ever did so.

Next, Ms. Seiple asserted that because during the 2008 site visit, the PIC ''explained that Englewood's business model included servicing patients from two large hospitals and a number of [nearby] physician offices,'' as well as ''patients from several nearby pain clinics[,] . . . this accounted for the volume of pain medications and other controlled substances, including oxycodone, being dispensed relative to other drugs.'' *Id.* at 49. However, hospitals usually have their own pharmacies and, in any event, a pharmacy's mere proximity to a hospital does not explain why the quantity of oxycodone 30 prescriptions being dispensed at Englewood dwarfed the quantity of the most commonly prescribed non-controlled prescription drugs, such as those used to treat high cholesterol, hypertension, or hypothyroidism. *See* RX 81 (showing top five prescription drugs from 2006 through 2010, which did not include oxycodone).[91] So too, a pharmacy's mere proximity to buildings with doctors' offices falls well short of what is necessary to explain why a pharmacy's dispensings of oxycodone

[90] As for other oxycodone products, Englewood dispensed 13,436 du of OxyContin 80; 7,266 du of OxyContin 40; 2,025 du of OxyContin 60; 800 du of OxyContin 30; 644 du of OxyContin 20; 70 du of OxyContin 10. *See* RX 2C, at 13–15, 28. It also dispensed 12,183 du of Endocet 10/325; 2,250 du of oxycodone 20; 710 du of Endocet 10/650; 594 du of oxycodone 5/325; 402 du of oxycodone 5; 140 du of oxycodone 7.5/500; 90 du of oxycodone 7.5/325; and 120 du of Endodan (oxycodone and aspirin). *See id.* at 13, 15–16, 18–19, 22, 24–25. Its total dispensings of oxycodone came to nearly 258,000 du.

It also dispensed 53,583 du of methadone 10 mg; 20,407 du of alprazolam 2 mg; and 9,899 of alprazolam1 mg. *See id.* at 13.

[91] As Respondent's Exhibit 81 shows, while combination hydrocodone drugs were the most frequently prescribed drugs during 2008 through 2010, the next most frequently prescribed drugs were non-controlled drugs including Lipitor (a statin), Simvastatin, Lisinopril, Levothyroxine, and Azithromycin.

30 prescriptions dwarf its dispensings of non-controlled prescription drugs.

While it is true that Respondent's consultant also obtained the names of six pain clinic doctors, two of these doctors were located in Sarasota, which is more than 47 miles from Port Charlotte.[92] *See http://maps.randmcnally.com/mileage-calcualtor.do.* Moreover, there is no evidence that Respondent verified the licensure and registration status of any of these doctors, let alone whether they had any specialty training or board certification in pain management.

Ms. Seiple further asserted that ''[a]fter Englewood's account was approved, [the] SOMS . . . identified and held any order for controlled substances placed by Englewood that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 49. As explained previously, this statement is misleading because the SOMS was not even operational until August 2009. Moreover, notably absent from this paragraph of Ms. Seiple's declaration is any claim that the Compliance Department's employees followed the policies and procedures which required contacting the pharmacy and obtaining a reason for why a held order exceeded the SOMS parameters, followed by independently verifying that reason. As found above, Respondent's Compliance Department repeatedly failed to comply with its policies and procedures.

While it is true that ''[o]n some occasions, the Compliance Department would request . . . a UR as part of its review of orders that had been held by the SOMS,'' the evidence shows that it obtained a new UR infrequently. As the evidence shows, after April 1, 2009, it did not obtain a new UR until October 5, 2009, at which point it had not obtained a new UR in more than a year, and it did not obtain the next UR until August 11, 2010, ten months later. Yet Respondent's policy required that it obtain a new UR whenever an order was held for review.

As for Ms. Seiple's assertions that Respondent ''specifically investigated the reasons why Englewood's ordering and dispensings patterns were as indicated on the URs'' and that ''[b]ased on [its] extensive investigation, it determined that the orders it shipped to Englewood were not suspicious,'' *id.* at 50–51, it did no such thing. As an example, during the initial site visit, Respondent's consultant wrote that ''[h]e [the PIC] appears to be doing a larger narcotic business than he admits to.'' RX 2C, at 78. In her declaration, Ms. Seiple offered no explanation as to what was done in response to this observation, and her assertion that ''the URs and other information provided by Englewood were consistent with the pharmacy's business model as explained by Mr. Farris and confirmed in the November 2008 site inspection'' is just one example as to how Respondent's Compliance Department simply accepted the inadequate explanations provided by its consultant and employees to support its continued selling of controlled substances to Englewood, while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensings of controlled substances.

Ms. Seiple provided still another example of this in her discussion of the Compliance Department's response to the January 2010 site visit by Mr. Chase. As found above, following the visit, Mr. Chase recommended that Respondent obtain a new UR and compare it with Englewood's claim that 40 percent of the prescriptions it dispensed were for control substances, which in Mr. Chase's view, was ''a little high.'' Respondent did not, however, obtain a new UR in response to his recommendation and failed to obtain a new UR until August 11, some seven months later.

As with the pharmacies previously discussed, Ms. Seiple's explanation of this was that Respondent's policies and procedures did ''not specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers 'high' or 'a little high,' '' and that ''Mr. Chase did not recommend that [Respondent] stop selling controlled drugs to Englewood following his inspection in January 2010.'' RX 103, at 51. Ms. Seiple's testimony fails to explain why the Compliance Department ignored Mr. Chase's recommendation to obtain a new UR and did not do so until seven months later.

While Ms. Seiple acknowledged that Respondent was aware of the volume of oxycodone and other controlled substances being dispensed and the percentage of controlled drugs being dispensed relative to other drugs, *id.* at 50, there is no evidence in the Englewood file that Respondent ever actually calculated the ratio of its dispensings of oxycodone and controlled substances to other drugs. *See generally* RX 2C. Indeed, throughout the course of its dealings with Englewood, its PIC repeatedly understated the level of its controlled substance (including its schedule II) dispensings and did so by a wide margin and Respondent was put on notice of this as early as the November 2008 site visit. RX 2C, at 78. The PIC's false statements as to the percentage levels of his controlled substances dispensings were another red flag that he was engaged in the diversion of controlled substances and the falsity of his representations could have been easily determined because the URs calculated the total number of prescriptions for each schedule of controlled substances and the non-controlled prescription drugs the pharmacy dispensed. Instead, Respondent's Compliance Department ignored available information (and failed to request information) which would have shown that the PIC was providing false information.

It is true that after the October 6, 2010 inspection, during which Respondent's inspector observed that Englewood's clientele included persons who were driving vehicles with Kentucky and Tennessee license plates and who were engaged in suspicious activity (and yet was told by the PIC that he did not fill for out-of-state patients), Respondent finally made the decision to terminate Englewood. However, Englewood had been purchasing controlled substances (including oxycodone) from Respondent for at least two years at this point and yet, only in the face of the above, did it finally stop selling controlled substances to Englewood. The evidence thus suggests that Respondent's Compliance Department was primarily concerned with justifying the continued sale of controlled substances and not with identifying those entities that were engaged in diversion. Moreover, Respondent did not file a single suspicious order report during the course of its dealings with Englewood.

City View Pharmacy

City View Pharmacy, a retail community pharmacy located in Orlando, Florida, opened in January 2005. RX 2D, at 74. While it is unclear when City View first became a controlled substance customer of Respondent, a Schedule Drug Limit Increase Request Form dated March 17, 2008, indicates that City View was seeking an increase in its purchasing limit for both alprazolam and solid dose oxycodone. *Id.* at 73. According to the form, City View was using 200 100-count bottles or 20,000 du of oxycodone per month. *Id.*

[92] Pursuant to 5 U.S.C. 556(e), I take official notice of the distance between Port Charlotte and Sarasota as determined by using the online Rand McNally mileage calculator. Pursuant to 21 CFR 1316.59(e), Respondent may dispute this finding by filing a properly supported motion no later than 10 days from the date of this Order.

After verifying that City View held a DEA registration and state license, on March 25, Respondent contacted City View and prepared a DEA Schedule Order-Due Diligence Report Form; it also obtained from City View a State Inspection Report and a UR. According to the Due Diligence Report Form, City View reported that it filled 80 prescriptions per day, that 60 percent of the prescriptions were for controlled drugs, and 40 percent were for schedule II drugs. *Id.* at 74. City View also reported that it accepted insurance and well as Medicare and Medicaid and that 80 percent of the prescriptions were paid for by insurance. *Id.* As for its policies and procedures, City View's pharmacist represented that to prevent doctor shopping, it worked ''mainly'' ''with three doctors,'' and that it ''call[ed] any new doctors.'' *Id.* As for how it ensured that doctors exercised proper standards of care, City View's pharmacist stated that he called a pain management clinic. *Id.* As for whether he had ever refused to fill a prescription, City View's pharmacist represented that he did so ''all the time'' as he required the patients to present a driver's license and would refuse to fill the prescriptions ''if they don't supply it.'' *Id.* at 75. Finally, City View's pharmacist represented that he refused prescriptions written by physicians who had problems with their DEA registrations or other disciplinary actions. *Id.*

The UR provided by City View covered the month of February 2008, and showed that the pharmacy had dispensed a total of 101,908 du of all prescription products. *Id.* at 100. The UR further showed that during the month, City View dispensed 150 prescriptions totaling 24,928 du of oxycodone 30, an average of 166 du per prescription. *Id.* at 97. It also showed that City View dispensed 20 prescriptions for 2,300 du of oxycodone 15, as well as 32 prescriptions totaling 3,525 du of Endocet 10/325.[93] *Id.* at 92, 97. In total, City View dispensed more than 36,000 du of oxycodone products (35.5 percent of all its dispensings), and its dispensings of oxycodone 30 alone accounted for more than 24 percent of its dispensings. Indeed, the UR showed that the next largest drugs dispensed were two other highly abused drugs: Alprazolam 2 mg (6,940 du), a schedule IV controlled substance, and carisoprodol 350 mg (5,609 du dispensed), a drug which was then controlled under Florida law and which has since been controlled under the CSA. *See id.* at 89, 91.

As found above, City View also provided Respondent with a copy of a Florida Department of Health inspection report dated November 29, 2006. *Id.* at 76. The Report identified multiple deficiencies, including that City View did not maintain ''[c]omplete pharmacy prescription records'' and the ''[p]rescription records did not identify the responsible dispensing pharmacist''; the pharmacist was not initialing the controlled substance prescriptions (as well as the refills) that were filled; DEA Schedule II order forms were not being properly completed; and several controlled substance prescriptions were missing required information such as the prescriber's name, address and DEA number as well as the patient's name and address. *Id.* at 76.

On June 25, Respondent's consultant conducted an onsite inspection of City View. *Id.* at 104. According to the consultant's report, City View represented that it had purchased drugs from five different distributors including Respondent during the past 24 months. *Id.* at 105. It also represented that it filled an average of 100 to 120 prescriptions per day, that 35–40 percent of the prescriptions were for controlled substances, and that only 20 percent of the prescriptions were paid for with cash. *Id.* at 106. It also acknowledged that it filled for pain management clinics and identified six physicians and their DEA numbers.[94] The consultant also reported that City View was located next door to the Police Department and that this ''does tend to keep some of the drug abusers away according to the pharmacist.'' *Id.* at 108.

Finally, the consultant noted that the pharmacy was willing to provide a copy of its most recent state inspection report, and a report dated May 1, 2008 is in the due diligence file. *Id.* at 105, 109. Notably, while the report showed that several of the deficiencies identified at the previous inspection had been corrected, City View's pharmacist was still not properly completing the Schedule II order forms. *Id.* at 109. Several weeks later, on July 1, 2008, Respondent approved City View to purchase 25,000 du of oxycodone per month. *Id.* at 73.[95]

In April 2009, Respondent filled orders placed by City View for 18,500 du of oxycodone 30 and 1,200 du of oxycodone 15, and in May, it filled orders for 24,000 du of oxycodone 30 and 1,000 du of oxycodone 15. GX 10F, at 3–4. In June, Respondent filled orders for 28,000 du of oxycodone 30 and 2,000 du of oxycodone 15 (as well as 200 oxycodone 80), followed by orders in July for 26,000 du of oxycodone 30; 3,000 du of oxycodone 15; 1,000 du of Endocet 10/325; and 300 du of oxycodone 80 mg. *Id.* at 3–5.

On August 3, 2009, Respondent filled orders placed by City View for 20,000 du of oxycodone 30, as well as 2,400 du of oxycodone 15. *Id.* at 3. A note in the Ship to Memos added by Ms. Seiple on August 5 states: ''8/3/09 please keep on hold until UR is received per file.'' GX 19, at 111. Of note, Respondent had not obtained a new UR since February 2008 and would not do so until October 5. RX 2D, at 5–6. Yet, on August 25—a week after it had presented its Policies and Procedures to the DIs—Respondent filled City View's order for an additional 7,600 oxycodone 30, GX 10F, at 3, bringing its total filled orders on a rolling 30-day basis to 33,000 du, even though it had not received a new UR.[96] According to a SOMS note for this order, the order was ''ok to ship'' because it was at City View's ''oxy limit for the month.'' GX 19, at 118.

Yet on September 1, 8, and 14, Respondent filled three separate orders by City View for 10,000 du of oxycodone 30, notwithstanding that Respondent had yet to receive a UR and the account was supposedly on hold. GX 10F, at 3. As for the September 1 order, it placed City View's oxycodone orders at 40,000 du on a rolling 30-day basis and thus over the previously noted limit. Yet the order was released by Ms. Seiple, who noted in the SOMS that it was ''under current limit.'' GX 19, at 118. And while it is clear that the order was held for review, there is no evidence that Respondent contacted City View and obtained an explanation for the order.

The September 8 order did not place City View over the CSL. However, with the September 14 order, City View's oxycodone orders totaled 37,600 du on

[93] As for other oxycodone products, the UR showed that City View dispensed 1,310 du of OxyContin (and generic OxyContin) 40 mg, 990 du of OxyContin (and generic OxyContin) 80 mg, 906 du of oxycodone 5 mg, 1,035 du of Endocet 5/325, 300 du of Endocet 10/650 mg, 240 du of OxyContin 20 mg, 210 du of Endocet 7.5/325 mg, 200 du of Endocet and generic oxycodone 7.5/500 mg, and 38 du of oxycodone/apap 5/500. RX 2D, at 92, 97.

[94] With respect to whether the pharmacy serviced nursing homes, hospices, and inpatient facilities, the consultant wrote the word ''pending'' next to each of these categories and did not identify a single such facility which City View actually serviced. RX 2D, at 106.

[95] A note on the Schedule Drug Limit Increase Request Form indicates that Respondent did not approve City View's request to purchase alprazolam because it was ''too new'' a customer. RX 2C, at 73. Unexplained is why City View was not too new a customer to purchase oxycodone.

[96] City View had placed an order for 3,000 du of oxycodone 30 on July 28, thus bringing the rolling 30-day total to 33,000 du. GX 10F, at 3.

a rolling 30-day basis. A SOMS note establishes that Ms. Seiple released the order and provided the following reason: ''ok to ship puts them at their current limit.'' GX 19, at 119. Here again, notwithstanding Respondent's purported policies and procedures, there is no indication that City View was contacted to provide an explanation for the order, which was then independently verified, and Respondent still had not obtained a new UR.

Moreover, according to an MFR noted dated September 23, City View placed an additional order for 10,000 du of oxycodone 30 mg which Respondent deleted. RX 2D, at 6. The note further states that City View's ''calendar limit [was] 30,000'' and that it had ''already received 37,600 within 30 days.'' *Id.*

A second MFR note of the same date shows that Ms. Seiple called City View's pharmacist a second time that day and that the pharmacist stated that he ''did not want the 100 bottles only [the] hydromorphone 8mg.'' *Id.* Ms. Seiple further documented that she ''tried to get info'' but the pharmacist said he had to go, and that after she ''asked him to call [her] back,'' the pharmacist said he would ''and hung up.'' *Id.* Ms. Seiple then documented that she had talked to Mr. Corona about the situation and was told to place City View ''on compliance hold.'' *Id.* The same day, Ms. Seiple also made a note in the Ship to Memos for the account, which states: ''Need to have an updated survey and UR before ordering any CONTROLS.'' GX 19, at 111. Yet the order was not reported as suspicious.

An MFR note dated September 28 made by Ms. Seiple again acknowledged that Respondent did not have a current UR on file. RX 2D, at 6. The note further states: ''put 1k pills for oxy back in today'' and refers to Ms. Seiple's having called another employee of Respondent, and that the employee was ''getting'' with City's View pharmacist. *Id.* According to a note made the next day, this order was placed on hold. *Id.* However, notwithstanding that City View was on compliance hold, on October 1—and before City View provided a new UR—Respondent filled an order for 2,000 tablets of hydrocodone/apap 10/500 mg. GX 10F, at 5. Moreover, there is no evidence that Respondent did a new due diligence survey.

The evidence also suggests that on or about October 1, City View placed an order for 10,000 du of oxycodone 30. Specifically, a Ship to Memo dated October 2, 2009 by Ms. Seiple states: ''TIL ur IS RECEIVED THE ORDER WAS DELETED FOR OXY 30 100 BOTTLES.'' GX 19, at 111; *see also* RX 2D, at 5 (MFR note dated October 1 noting that message was left for pharmacist ''to call me back need UR or order will not ship & will be deleted'').

On October 5, Respondent finally obtained a new UR from City View. RX 2D, at 5–6. The UR showed that during the month of September, City View dispensed 324 prescriptions totaling 47,472 du of oxycodone 30, an average of 146.5 du per prescription, as well as 30 prescriptions totaling 3,505 du of oxycodone 15, an average of 124 du per prescription. RX 2D, at 62–71. City View's dispensings of all prescription products totaled 116,180 du. Thus, oxycodone 30 alone comprised nearly 41 percent of City View's total dispensings. Moreover, the top ten drugs dispensed were comprised entirely of three oxycodone products (oxycodone 30, oxycodone 15, and 2,340 du of Endocet 10/325), four alprazolam products (9,722 du of four different manufacturers' version of 2 mg dosage and 1,230 du of one manufacturer's 1 mg tablet), carisoprodol 350 mg (5,124 tablets), and hydrocodone/apap 10/500 (2,423 tablets). *See id.*

A second MFR note dated October 5 states that Respondent was ''shipping 100 bottles'' and that the order had been put in the same day. RX 2D, at 5. The note further states: ''however, his limit is 30,000 current limit No.'' *Id.* A Ship to Memo note of the same date states: ''Released oxy order for 100 bottles based on UR and clean file.'' GX 19, at 111. Thereafter, Respondent filled additional orders by City View for 10,000 du of oxycodone 30 on both October 12 and 20. GX 10F, at 3.

On October 29, City View placed still another order for oxycodone 30 mg. GX 19, at 111; RX 2D, at 5. According to both the Ship to Memos and MFRs, City View's oxycodone order was edited off the order. *See id.* Ms. Seiple further noted that City View's oxycodone limit needed ''to be reviewed'' because the pharmacy ''only buys 30 mg Mall,'' [97] that the ''UR is 46k as of September,'' and added, ''decrease limit to 20k see Wayne.'' *See id.* However, the same entry then contains an additional note (in different color ink) that: ''No limit is 30k—please call,'' and further noted that an employee had spoken with City View's pharmacist and that oxycodone had been ''cut from order.'' RX 2D, at 5.

While it is unclear what the size of the order was, it is clear that the order would have placed City View's oxycodone orders over its 30,000 du CSL on a rolling 30-day basis. Yet Respondent did not report the order as suspicious.

On November 2 and 6, Respondent filled orders totaling 10,000 du of oxycodone 30 on each date. GX 10F at 3. Even ignoring the deleted order of Oct. 29, each of the orders placed City View's orders at 40,000 du on a rolling 30-day basis.

As for the November 2 order, a SOMS note made by Ms. Seiple states: ''ok to ship is provided non control business per committee limit 22500.'' GX 19, at 119. Entries in the MFRs and Ship to Memos show that on either November 3 or 4, the compliance committed had conducted a review and reduced City View's oxycodone limit by 25 percent to 22,500 du. RX 2D, at 5; GX 19, at 112. As for the November 6 order, the corresponding SOMS notes states: ''ok to ship oxycodone @20k with this order—within size for current period.'' GX 19, at 120. However, whether City View's oxycodone CSL was 22,500 du or 30,000 du, the orders clearly exceeded the CSL and yet there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the November 2 and 6 orders and a new UR. Nor did it report the orders as suspicious.

On November 16, City View placed an order for 10,000 du of oxycodone 30. *See* RX 2D, at 4 (MFR note: ''release 25 Qty. requested 100.0—limit of oxy @ 22,500''). While Respondent edited the order and only shipped 2,500 du, *id.,* the order still placed City View's orders at 40,000 du on a rolling 30-day basis. GX 10F, 3; *see also* GX 19, at 120. (SOMS note: ''ok to ship—oxy revised to 25.0 to met [sic] current size allotment'').

Here again, City View had placed orders which, on a rolling 30-day basis, exceeded the CSL. Yet there is no evidence that Respondent obtained an explanation for the order from the pharmacy and a new UR. Nor was the order reported to DEA as suspicious.

Moreover, on December 1, 2009, Respondent filled two orders totaling 20,000 du of oxycodone 30. GX 10F, at 3. With these orders, Respondent had filled orders totaling 42,500 du on a rolling 30-day basis. A SOMS note of the same date states: ''ok to ship-oxy within size for period @10K with this order.'' GX 19, at 120. The same reviewer made a second SOMS note, which, while bearing the date of ''11/24/09,'' is interspersed between the above note and another note of ''12/1/09'' which states: ''ok to ship oxy @20K with this order for period 12–1–09.'' *Id.* Notwithstanding that City View had

[97] This is likely an abbreviation for Mallinckrodt, a manufacturer of controlled substances. Other evidence establishes that Respondent distributed oxycodone manufactured by Mallinckrodt.

again clearly exceeded its CSL, there is no evidence that Respondent contacted City View to obtain a reason for the orders and a new UR. Nor did it report the orders as suspicious.

On December 14, Respondent filled an additional order for 2,500 du of oxycodone 30. GX 10F, at 3. Thereafter, on January 4 and 11, 2010, it filled orders for 10,000 du of oxycodone 30 on each date, followed on January 19 by an additional order for 2,500 du of oxycodone 30, for a monthly total of 22,500 du. *Id.*

On February 1, 8, and 18, Respondent filled three separate orders for 10,000 du of oxycodone 30. *Id.* Upon filling both the Feb. 1 and 8 orders, Respondent had shipped 32,500 du on a rolling 30-day basis and thus exceeded the CSL whether it was set at 22,500 or 30,000 du.[98] However, the SOMS note for the Feb. 1 and 8 orders respectively state: ''ok to ship, under the CSL'' and ''ok to ship oxy under csl.'' GX 19, at 113.

Of note, on February 17, 2010, Mr. Chase conducted a site visit at City View. According to his report, City View filled an average of 100 prescriptions per day, with controlled substances comprising 30 percent of the prescriptions. RX 2D, at 43. Mr. Chase reported that schedule II controlled substances comprised 15 percent of all prescriptions. *Id.* While Mr. Chase reported that City View appeared to be a full service pharmacy with a ''good selection'' of front store items, he did not document that City View serviced any pain clinics. *Id.* at 40, 45.

While on the Site Visit Recommendation Form, Mr. Chase checked that the site visit was acceptable, he also recommended that a new utilization report be obtained, noting that controlled substances were 30 percent of City View's dispensings. *Id.* at 40. And on the Recommendation Form, Mr. Chase further wrote: ''We Need A Utilization Report & Compare it to Site Visit.'' *Id.*

As for the Feb. 18 order, an MFR entry dated February 18 states: ''Order for 10,000 Oxy 30 mg CSL Is 22,500, already at 20,000 this month—last order on Oxy 30 was 2/8/10 + 2/1/10.'' RX 2D, at 4. An additional entry below the above states: ''limit approved on 10/09 for 30k'' and ''order would be 2500 over thus releasing w/reservation.'' *Id.* And a separate MFR note of the same date states: ''shipped 10k w/reservation CSL @32500'' and ''Must be reviewed w/ committee along w/[illegible].'' RX 2D, at 5. Additional notes in the same entry state: ''30k on oxy'' and ''CSL for month @[ ] 15k.'' *Id.*

As for the February 1 and 8 orders, while they clearly exceeded the CSL—indeed, during this period, Respondent's records repeatedly indicate that the CSL was 22,500 du and do so even in notes made after the Feb. 18 MFR entry—there is no evidence that Respondent complied with its policies and procedures by contacting the pharmacy and obtaining an explanation for the increase in its orders, which was then independently verified. Nor did Respondent obtain a new UR. Moreover, Respondent provided no explanation at the hearing as to why the SOMS notes state that the CSL was 22,500 but then was suddenly increased to 32,500 du on February 18. As these notes indicate, Respondent simply ignored the CSL and manipulated it to justify the distributions.

There is also no evidence that Mr. Chase's site visit and recommendation were reviewed before the February 18 order was shipped. Indeed, a SOMS note of February 23 clearly suggests that the site visit report and recommendation were not reviewed until that date. GX 19, at 112. Significantly, this note also states: ''CR [compliance review]—CH [compliance hold] UR on file needs to be reviewed with site visit.'' *Id.*

Here again, there is no indication that the previous UR was reviewed and compared with the information Mr. Chase had reported as to the percentage of City View's dispensings comprised by controlled substances and the percentage comprised by schedule II drugs. As for the recommendation that a new UR be obtained, Respondent did not obtain a new UR until late April, more than two months later.

On March 3, Respondent filled an order for 10,000 du of oxycodone 30, which according to the SOMS was released, with the reason being that it was ''under csl.'' GX 10F, at 3; GX 19, at 114.

On March 12, Respondent filled an additional order for 10,000 du of oxycodone 30. GX 10F, at 3. The SOMS note of this date states: ''ok to ship, under the CSL of 22,500, this is their 2nd order for 10k OXY 30mg this month.'' GX 19, at 114. *See also* RX 2D, at 3 (MFR note: ''Order for 10,000 Oxy 30 mg—this order is under CSL of 22,500 they purchased 30k last month.''). However, the March 12 order placed City View's orders at 30,000 du on a rolling 30-day basis, and thus the order actually placed City View above the CSL level referred to in the SOMS note. A March 15 MFR note by Ms. Seiple justified the shipment stating: ''order above supported by UR and last month of 30k supported by UR per committee.'' RX 2D, at 3. Notably, Ms. Seiple did not state that Respondent had contacted the pharmacy and obtained an explanation for the order as well as a new UR.

On March 18, Respondent shipped a new order for 10,000 du of oxycodone 30. GX 10F, at 3. A SOMS note of this date states: ''ok to ship, order supported by UR on the OXY, this order for 10k puts them at 30K for the month.'' GX 19, at 114. However, when added to the previous orders Respondent shipped to City View on February 18, as well as March 3 and 12, each of which was for 10,000 du, Respondent had shipped 40,000 du on a rolling 30-day basis, and thus again exceeded the CSL, whether it was set at 22,500 or 30,000 du. Once again, there is no evidence Respondent contacted City View and obtained an explanation for the order and a new UR.

On March 22, Respondent filled an order for 1,200 du of oxycodone 30, thus bringing City View's rolling 30-day total to 31,200 du. GX 10F, at 3. Various notes explain that the order was released because it was supported by the UR, even though Respondent still had not followed the recommendation of its inspector to obtain a new UR and the previous UR was nearly six months old. RX 2D, at 3; GX 19, at 114.

Two days later, Respondent filled an order for an additional 10,000 du of oxycodone 30. GX 10F, at 3. The corresponding notes states: ''ok to ship, CSL is 22,500, they have already purchased 31,200 this month, this order is for 10K, putting them at 41200 for the month, UR supports order see file.'' GX 19, at 114. Here again, there is no evidence that Respondent obtained an explanation from City View's pharmacist regarding the increase in its orders (which it independently verified) and obtained a new UR. Nor did it report the order as suspicious even though the order placed City View's orders at nearly double its CSL.

Moreover, on March 27 (a Saturday), City View placed two orders, each being for 10,000 du of oxycodone 30. GX 19, at 114; RX 2D, at 3. City View's orders thus totaled 61,200 du on a rolling 30-day (as well as on a calendar month) basis, and were nearly three times the CSL and more than double the previous highest month's shipments. While on March 29 Respondent shipped only 10,000 du, it again justified the

[98] Both SOMS notes and an MFR note indicate that City View also placed an order for 2,000 du of oxycodone on February 16. *See* GX 19, at 113 (''ok to ship, under the CSL of 22,500 on OXY, this order puts them at 22,000 for the month''); RX 2D, at 4 (''Order for 2000 oxy CSL 22,500 already ordered 20,000 this month. This order puts them at 22,000 for the month.''). The ARCOS report does not, however, list an order on either this date or of this size as having been filled by Respondent. GX 10F, at 3–5.

shipment on the ground that the ''UR supports release—places CSL @51,200 for current period.'' RX 2D, at 3; GX 10F, at 3.

An MFR note corresponding to the second March 29 order states that Respondent called City View's pharmacist, who ''said that he placed this order to be released on April 1, 2010, please hold order until 4/1/10.'' RX 2D, at 3. While that may be, Respondent did not document that it questioned the pharmacist about the order it did fill that day, notwithstanding that the orders it filled during March represented a more than 70 percent increase from the previous month's orders, and it also failed to obtain a new UR. Nor did Respondent report the orders as suspicious. Yet here again, City View's CSL was increased even though Respondent repeatedly failed to follow its own policies and procedures for verifying the legitimacy of the pharmacy's orders.

In April, Respondent continued its practice of failing to follow its policies and procedures when City View's oxycodone orders clearly exceeded the CSL. On April 1, Respondent filled the order for 10,000 du of oxy 30 which City View had previously submitted. GX 10F, at 4. Even assuming that Respondent had a valid basis for resetting City View's oxycodone CSL to 51,200 du based on the March shipments, upon filling this order, Respondent had shipped 61,200 du of oxycodone 30 on a rolling 30-day basis. GX 10F, at 3–4. Yet the MFR note corresponding to the order states only that ''order was released from 3/29'' and the SOMS note states: ''ok to ship-oxycodone within csl for period.'' RX 2D, at 3; GX 19, at 114.

On April 5, Respondent filled another order by City View for 10,000 du of oxycodone 30. GX 10F, at 4. Here again, upon filling the order, Respondent had shipped 61,200 du to City View on a rolling 30-day basis and City View's orders exceeded the CSL. *Id.* Yet Respondent's records contain no documentation to explain why it shipped the order. *See generally* RX 2D, at 1–6 (MFRs); GX 19, at 111–12 (Ship to Memos); *id.* at 114 (SOMS notes during relevant time period). Indeed, there is no SOMS entry for April 5 and the next SOMS entry (April 8) does not contain the name of a reviewer and a reason, thus indicating that the order (whether it was for oxycodone or some other drug) was not reviewed.

So too, on April 12, Respondent filled a further order by City View for 10,000 du of oxycodone 30. GX 10F, at 4. Here again, upon filling the order, Respondent had shipped 61,200 du of oxycodone 30 to City View on a rolling 30-day basis. *Id.* The SOMS note for the transaction states: ''ok to ship, OXY 30mg, already purchased 20K this month this order is for 10K putting them at 30K for the month UR supports order (4/12/10) (last month they were at 51200).'' GX 19, at 114. Here again, while the order exceeded the CSL, there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order and a new UR.

On April 19, Respondent filled a further order by City View for 10,000 du of oxycodone 30. GX 10F, at 4. Here again, upon filling the order, Respondent had shipped 61,200 du of oxycodone 30 to City View on a rolling 30-day basis. *Id.* The MFR note pertaining to the order states: ''released order for 10k Oxy 30mg, with this order they are at 40k for the month,'' RX 2D, at 3; and the SOMS note states: ''puts them at 40k for the month, UR soppurts [sic] order (4/19/10).'' GX 19, at 114. Again, there is no evidence that Respondent obtained an explanation for the order and a new UR from City View.

On April 21, Respondent filled an order by City View for 2,000 du of oxycodone 15 mg, and on April 22, it filled an order for 2,000 du of oxycodone 30. GX 10F, at 4. Upon filling the April 21 order, Respondent had shipped 62,000 du within the rolling 30-day period, and on filling the April 22 order, it had shipped 64,000 du within the rolling 30-day period. GX 10F, at 3–4. A SOMS note dated April 21 simply says ''ok to ship,'' [99] and two SOMS notes dated April 22 state: ''ok to ship-oxycodone increase released off ur support'' and ''ok to ship-oxycodone increase-current ur supports.'' GX 19, at 114.

However, at this point, the most recent UR was more than six months old, and neither note acknowledges that City View's orders were more than 10,000 du over the purported CSL. And once again, there is no evidence that Respondent obtained an explanation for the order and a new UR from City View.

On April 26, Respondent filled an order by City View for 10,000 du of oxycodone 30, thus again resulting in the rolling 30-day total of orders (and shipments) of 64,000 du. GX 10F, at 3–4. An MFR note discussing the order explains: ''Order for 100—Oxy 30mg already at 44,000 this month[.] [T]his order will put them at 54,000[,] most they have gotten was 51,200 (last month)[.] [C]alled to get an updated UR[.] TT [pharmacist] he will fax it over today.'' RX 2D, at 1. An additional MFR note of the same dates states: ''UR received—supports Oxy increase CSL @ 54k for current Period.'' *Id.*

The UR covered March 1–30, 2010. RX 2D, at 26–34. However, the UR was clearly incomplete as it did not list the total number of prescriptions and dosage units which were dispensed during the period. *Compare id.* at 34, *with id.* at 71 (last page of March 09 UR providing this information) and *id.* at 100 (last page of Feb. 08 UR providing this information). However, a Diversion Investigator calculated the total dispensings listed on the UR at 178,458 du. GX 49B, at 53.

The UR showed that City View had dispensed 586 prescriptions totaling 93,943 du of oxycodone 30 during the period as well as 98 prescriptions totaling 10,746 du of oxycodone 15.[100] *Id.* at 32–33. Of consequence, City View's dispensings of oxycodone 30 had nearly doubled from the amount on the previous UR (47,472 du) and comprised more than 52.5 percent of its total dispensings. The UR also showed that City View's dispensings of oxycodone 15 had more than tripled from the amount on the previous UR (3,715 du). And the UR further showed that City View's dispensings of alprazolam 2 mg, another controlled substance highly sought after by narcotic abusers for use as part of a drug cocktail, now totaled 19,738 du, more than double the amount on the previous UR (9,722). *Id.* at 26.

However, here again, notwithstanding that its policies and procedures required Respondent to obtain a reason for why City View's order exceeded the CSL, and also required a review of its file to determine whether the order was ''consistent with legitimate business practices,'' RX 78, at 32–33; Respondent ignored this information and shipped the order. It also failed to report the order as suspicious.

On May 5, Respondent filled an order for 10,000 du of oxycodone 30; on May 10, it filled two orders totaling 20,000 du of oxycodone 30 as well as an order for 1,000 du of Endocet 10/325; and on May 18, it filled a further order for 10,000 du of oxycodone. GX 10F. at 4–5. Here again, even if the CSL had been raised to 54,000 du based on the April orders, upon filling the May 10 orders, City View's oxycodone orders totaled 65,000 du on a rolling 30-day basis and thus exceeded the CSL. Incredibly, a SOMS note of the same dates states: ''Ok

[99] While this note does not refer to a specific drug, it is the only SOMS note dated April 21, 2010. GX 19, at 114.

[100] In contrast to the previous UR which ranked City View's dispensing by the quantity dispensed for each drug by NDC, this UR listed the drugs in alphabetical order. *Compare* RX 2D, at 26–34, *with id.* at 62–71.

to ship-oxy within csl for period.'' GX 19, at 115.

So too, upon filling the May 18 order, Respondent had shipped 65,000 du of oxycodone to City View on a rolling 30-day basis and thus exceeded the CSL. Yet the corresponding SOMS note states: ''ok to ship undr [sic] CSL leave 10,200 for May on 5/18.'' *Id.* at 115. And a note in the Ship to Memos states: ''PER COMMITTEE CSL IS 51200 WHICH IS THE MARCH CSL. PLEASE DO NOT SHIP OVER 51200 WITHOUT REVIEWS.'' *Id.* at 111. *See also* RX 2D, at 1.[101] While Respondent conducted a due diligence survey by telephone, even assuming that it considered the various statements discussed in the footnote to be the explanation for the order (such as that it was servicing two small nursing homes), there is no evidence that it independently verified any of these statements. Nor did it obtain a new UR. And it did not report the order as suspicious.

On June 1, 7, and 14, Respondent filled three separate orders for 10,000 du of oxycodone 30 mg, for a total of 30,000 du for the month. GX 10F, at 4. A SOMS note of June 1 states that this order was ''flagged for frequency'' but was released because the order was ''not excessive.'' GX 19, at 115. A subsequent MFR note states that Respondent decreased City View's allocation of oxycodone per policy. RX 2D, at 1. The note, however, does not state what City View's new oxycodone CSL was.

On June 28, Respondent performed a new site inspection of City View. *See id.* at 35–37. During the inspection, City View asserted that it filled ''only in town RX,'' that it filled an average of 100 prescriptions per day, that 30 percent of the prescriptions were for controlled substances, and that 20 percent were for schedule II drugs. *Id.* at 36. The inspector reported that City View was located two blocks from a hospital and that there were pain clinics in the area. *Id.* at 37. He also reported that City View appeared to have a full selection of pharmaceuticals available and that it had a limited supply of front store items. *Id.* Finally, he reported that business was ''slow while [he] was there'' and that he observed ''nothing untoward.'' *Id.*

On July 1, Respondent filled an order for 10,000 du of oxycodone 30, and on July 6, it filled orders for 5,000 more du of oxycodone 30 and 2,000 du of oxycodone 15. GX 10F, at 4. An MFR note dated July 7 states that the site visit was reviewed and that the account was placed on compliance hold pending the receipt of an updated UR and that the CSL was set at 28,700. RX 2D, at 1; *see also* GX 19, at 111 (noting compliance hold and that ''full ur for june is needed'').

Notwithstanding this entry, Respondent did not obtain a new UR from City View until on or about December 2, nearly five months later. RX 2D, at 7. According to the Ship to Memos, on July 13, Respondent conducted an account review using the previous UR and the recent site visit, after which it took City View off of the compliance hold and apparently maintained its CSL at 28,700 du. GX 19, at 111.

Yet on July 13, Respondent also filled an order for 10,000 du for oxycodone 30, bringing City View's total filled orders to 37,000 du on a rolling 30-day basis. GX 10F, at 4. Respondent's records contain no explanation for why the order was shipped given that it placed City View's orders at more than 8,000 du above the new CSL and that City View had not provided a new UR.[102] Nor was the order reported as suspicious.

Next, on July 28, Respondent filled an order for 1,700 more du of oxycodone 30. GX 10F, at 4. While City View's filled orders totaled 28,700 du, a SOMS note of the same date states: ''rwr Oxy edited to meet CSL for July.'' GX 19, at 116. Here again, City View's oxycodone orders exceeded the CSL, and yet there is no evidence that Respondent obtained an explanation for the order as well as a new UR. Nor did it report the order as suspicious.

In August, Respondent filled orders totaling 20,300 du, including 15,000 du of oxycodone 30, and 3,000 du of oxycodone 15. GX 10F, at 4–5. In September, Respondent filled orders totaling 28,700 du, including orders for 20,000 du of oxycodone 30; 7,600 du of oxycodone 15; and 1,100 du of Endocet products. However, a SOMS note dated September 28 (which corresponds to orders for 5,000 du of oxycodone 30 and 1,600 du of oxycodone 15) states that City View's order was ''edited to meet CSL,'' GX 19, at 117; and on a rolling 30-day basis, City View's oxycodone orders actually totaled 34,700 du.[103] GX 10F, at 4–5. Here again, while the September 28 orders clearly placed City View over its CSL, there is no evidence that Respondent obtained an explanation for the orders and a new UR. And it also failed to report the orders as suspicious.

In October, Respondent filled orders placed on five different days totaling 29,300 du, including 20,000 du of oxycodone 30; 8,000 du of oxycodone 15; and 1,300 du of Endocet. GX 10F, at 4–5. Moreover, on each date, upon filling the orders, City View exceeded the CSL of 28,700 du on a rolling 30-day basis.

Specifically, on October 5, Respondent filled orders for 7000 du (5,000 oxycodone 30 and 2,000 oxycodone 15), bringing City View's rolling 30-day total to 35,300 du.[104] *Id.* A SOMS note of this date simply states: ''ok to ship order for 20 OXY 15mg & 50 OXY 30mg is under CSL.'' GX 19, at 117.

On October 12, Respondent again filled orders for 7000 du (5,000 oxycodone 30 + 2,000 oxycodone 15), bringing City View's rolling 30-day total to 35,200 du.[105] GX 10F, at 4–5. The corresponding SOMS notes states: ''rwr Oxy under CSL leaves 14,400 as of 10/12.'' GX 19, at 117.

On October 20, Respondent again filled orders for 7,000 du (5,000 oxycodone 30 + 2,000 oxycodone 15), bringing City View's rolling 30-day total to 35,200.[106] GX 10F, at 4–5. Here again, a SOMS note simply states ''oxy under csl.'' GX 19, at 117.

On October 26, Respondent again filled orders for 7,000 du (5,000

[101] On May 18, 2010, Respondent conducted an updated due diligence survey, apparently by telephone. RX 2D, at 38. According to the survey, City View reported that its daily prescription average was 100–120, that the ratio of controls to non-controls was 30–70 percent, that it was near a medical center, and that it was now servicing two small nursing homes. *Id.* Here again, there is no evidence that Respondent attempted to verify City View's claims regarding the ratio of controlled to non-controlled drugs dispensed which was clearly inconsistent with the March 2010 UR. Nor did it inquire as to the names of the nursing homes City View was servicing, how many residents the homes had, and the types and quantities of prescriptions it filled for their residents.

[102] A Ship to Memo of the same date made by Ms. Seiple merely states: ''accoutn [sic] review using ur on file for 3/10 new site visit complete 6/28/10 maintaining soms csl.'' GX 19, at 111. A July 12, 2010 SOMS note (there being no SOMS note for July 13) made by Ms. Seiple states: ''rwr order sitevisit [sic] and ur on fiel [sic].'' *Id.* at 116.

[103] In addition to the September orders, this total includes orders filled on August 30 for 5,000 du of oxycodone 30 and 1,000 du of oxycodone 15. GX 10F, at 4; GX 19, at 116.

[104] The total includes Sept. 9 orders for 7,400 du (5,000 oxycodone 30; 2,000 oxycodone 15; and 400 Endocet 10/650); Sept. 16, orders for 7,000 du (5,000 oxycodone 30 and 2,000 oxycodone 15); Sept. 23 orders for 7,300 du (5000 oxycodone 30; 2,000 oxycodone 15; and 300 Endocet 5); and Sept. 28 order for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15). GX 10F, at 4–5.

[105] The total includes Sept. 16 orders for 7,000 du (5,000 oxycodone 30 and 2,000 oxycodone 15); Sept. 23 orders for 7,300 du (5000 oxycodone 30; 2,000 oxycodone 15; and 300 Endocet 5); and Sept. 28 order for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15), and the October 5 orders for 7,000 du. GX 10F, at 4–5.

[106] The total includes the Sept. 23 orders for 7,300 du (5000 oxycodone 30; 2,000 oxycodone 15; and 300 Endocet 5); the Sept. 28 orders for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15), and the October 5 and 12 orders for 7,000 and 7,300 du. GX 10F, at 4–5.

oxycodone 30 + 2,000 oxycodone 15), bringing City View's rolling 30-day total to 34,900 du.[107] GX 10F, at 4–5. A SOMS note of this date states: ''ok to ship, size not excessive on a total of 70 OXY this order puts them at 28300 for the month, CSL is 28700.'' GX 19, at 117.

Finally, on October 27, Respondent filled an order for 1,000 du of Endocet 10, bringing City View's rolling 30-day total to 35,900 du. GX 10F, at 4–5. A SOMS note merely states: ''rwr under 30 on csl of oxy.'' GX 19, at 117.

With respect to each of these dates, Respondent filled orders which clearly placed City View's orders over the oxycodone CSL on a rolling 30-day basis. Yet, there is no evidence that Respondent ever obtained an explanation for the order, which it then independently verified, and a new UR. And it did not report any of the orders as suspicious.

Similarly, Respondent filled orders totaling 28,700 du for the month of November. This included orders for 5,000 du of oxycodone 30 and 2,000 du of oxycodone 15 on November 2; orders for 6,500 du of oxycodone 30 on and 500 Endocet on November 9; 8,000 du of oxycodone 30 on November 18, and 6,700 du of oxycodone 30 on November 29. GX 10F, at 4–5. Here again, on each occasion, City View's orders placed its oxycodone orders over 28,700 du CSL on a rolling 30-day basis.

Specifically, City View's filled orders from October 5 through November 2 totaled 36,300 du; its filled orders from October 12 through November 9 also totaled 36,300; and its filled orders from October 20 through November 18 totaled 37,000 du. GX 10F, at 4–5. SOMS notes for both November 2 and 18 show that Ms. Seiple released the orders; as for the reason, Ms. Seiple wrote ''rwr'' for both orders. GX 19, at 117–18.

As for the November 9 order, the SOMS note states: ''rwr Oxy within buying pattern under CSL leaves 14,700 as of 11/09/10 @947am.'' GX 19, at 118. As for the November 29 order, the SOMS note states: ''order edit to 67 bottles from 70,'' *id.,* thus once again establishing that City View's actual orders totaled 29,000 du and again exceeded the CSL.

Here again, notwithstanding that each of City View's November orders placed it over the oxycodone CSL, Respondent failed to obtain an explanation for the orders, which it then verified, as well as new URs. And again, it did not report any of the orders as suspicious. On December 2, Respondent filled an order for 700 du of two Endocet products. GX 10F, at 5. According to MFR notes, the same day, an employee of Respondent requested that City View provide a new UR; City View provided a UR for the month of November. However, the UR was incomplete, a fact which Ms. Seiple herself noted in an MFR dated December 17. RX 2D, at 1. Indeed, this UR clearly did not list City View's total dispensings of all prescription products.[108] *Id.* at 14.

Notwithstanding that City View had provided an incomplete UR, and that this was the first UR it had obtained since the March 2010 UR, on December 6, Respondent filled orders for 8,000 du of oxycodone 30 and 1,000 du of oxycodone 15.[109] GX 10F, at 4–5. While there are three entries in the SOMS notes for this date, only one lists the name of a reviewer (Ms. Seiple) with the following explanation: ''rwr under csl and last 30 days not excessive due to allocation of market producet [sic].'' GX 19, at 118.

A note in the Ship to Memos (made on Jan. 8, 2011) states that City View's account was placed on compliance hold on December 9 ''due to updated information [being] needed'' and that the account was terminated on December 16 ''due to business model of insurance ratio.'' GX 19, at 111; *see also* RX 2D, at 1.

Additional notes which are dated December 2, but which may have been added after the fact,[110] state that City View's November 2010 UR ''will be low due to allocation in market.'' RX 2D, at 2. Other notes for the entry list figures of 35,530 and 5,400; these figures correspond to line entries on the UR for City View's dispensings of oxycodone 30 (with the NDC for product manufactured by Mallinckrodt) and alprazolam 2 mg. *Compare id. with id.* at 7 (UR line entries #s 1 & 5). Additional notes state: ''11/10 25200 Malinkrodt [sic] purchased'' and ''1000 KVK.'' *Id.* at 2. As found above, these numbers correspond to Respondent's total shipments of 26,200 du of oxycodone 30 during the month of November 2010. Still more notes appear to compare the number of oxycodone 15 and alprazolam 2 mg dispensed by City View with the quantities Respondent distributed to it, with the notes indicating that City View's Xanax CSL was being reduced to 3,800 du or 70 percent of the November UR. *Id.*

Thereafter, the notes state ''hold order until review complete'' and ''*concerns regarding # of doses dispensed as opposed to noncontrols*'' and then refer to a phone call made to City View's pharmacist on December 15. *Id.* (emphasis added). According to the note, during the call Respondent told its pharmacist that its ''order will hold.'' *Id.* Further notes state ''only purchases from Cardinal & Masters'' and ''insurance how does he make profit??'' *Id.*

A note dated December 16 recounts that City View's file was ''reviewed in length.'' *Id.* Therein, Ms. Seiple further wrote that she ''spoke to customer on phone multiple times regarding ratio of controls & noncontrols,'' as well as ''in regards to ratio cash vs. insurance,'' and that per Respondent's policy, City View was ''placed in noncontrolled status due to customer indicating cash in OXY.'' *Id.*[111]

On December 17, City View requested a review of its status. GX 19, at 111. Respondent requested that City View provide a UR for the month of October, which it did. RX 2D, at 1. The UR showed that during October 2010, City View had dispensed a total of 310 prescriptions totaling 51,725 du of oxycodone 30 and 148 prescriptions totaling 11,259 du of oxycodone 15. RX 2D, at 16–17. According to the UR, City View's total dispensings for the month were 122,626 du.[112] *Id.* at 25. Thus, City View's dispensings of oxycodone 30 alone amounted to 42 percent of its total dispensings, and its dispensings of both oxycodone 30 and 15 amounted to 51 percent of its total dispensings.

Thereafter, Respondent did not re-instate City View as a controlled substance customer. However, there was

[107] The total includes the Sept. 28 orders for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15), and the prior October orders. GX 10F, at 4–5.

[108] The UR also listed substantially fewer drugs than other URs. *Compare* RX2D, at 14 (listing 272 drugs), *with id.* at 34 (Mar. 2010 UR listing 396 drugs although also missing total dispensings); *id. at* 71 (Sept. 2009 UR listing 401 drugs); *id.* at 100 (Feb. 2008 UR listing 495 drugs).

[109] A SOMS note dated Dec. 4, 2010 states: ''oxy edited off order mallinkrodt [sic].'' GX 19, at 118.

[110] This note is written on a blank sheet following the lined MFR page which contains notes dated Dec. 16 and 17, but not Dec. 2. *See* RX 2D, at 1–2.

[111] This entry includes an additional statement which suggests that Respondent was ''not clear on [City View's] business model.'' RX 2D, at 2. However, because of legibility issues, the meaning of the rest of the sentence cannot be determined.

[112] This included three prescriptions for Gavilyte-N Solution, which according to the UR totaled 12,000 units. RX 2D, at 17. Gavilyte-N Solution is a product which is mixed with water to create a solution with a volume of four liters; it is used to clean a patient's bowels before undergoing procedures such as a colonoscopy. *See http://www.drugs.com/pro/gavilyte-n.html.* Thus, while Gavilyte-N is a prescription product, assigning a quantity of 12,000 du to three prescriptions arguably distorts City View's total dispensings of all drugs, as well as its dispensing ratio of controlled to non-controlled drugs. However, the total quantity of dispensings as listed on the UR was used in calculating the dispensing percentages for oxycodone 30 and oxycodone 15 and 30.

really nothing new in the information Respondent had developed on City View.

In her declaration, Ms. Seiple asserted that because City View's PIC had ''provided an explanation of the policies and procedures [it] used to prevent diversion,'' the ''Compliance Department believed that City View understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.'' RX 103, at 53. The answers provided by City View's PIC reflected only that when confronted with a suspicious prescription, he would call the prescriber; more, however, is required under federal law. *See United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979) (''Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification.''). Significantly, when asked whether he ever refused to fill prescriptions, the PIC responded that he did so only if a patient would not present his driver's license or if the physician had a problem with his/her DEA registration or other disciplinary action.

However, a pharmacist has a duty to fill only those prescriptions which are issued for a legitimate medical purpose by a practitioner acting within the usual course of professional practice, *see* 21 CFR 1306.04(a), which requires that a pharmacist must ''pay[] attention to the 'number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment,' the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse.'' *Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409, 412 (6th Cir. 2008). Moreover, during the June 25, 2008 site visit, Respondent's consultant simply drew a dash in the place for answering the question whether the pharmacy could supply a copy of any written policies and procedures it ''might have in place to prevent drug diversion and doctor shopping,'' thus suggesting that there were no written policies, a fact confirmed during the June 2010 site visit. RX 2D, at 36, 105. Thus, I find that the explanation City View provided as to its policies and procedures to prevent diversion was clearly inadequate to support the conclusion that the pharmacy ''understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.'' RX 103, at 53.

In her declaration, Ms. Seiple also asserted that City View's PIC had explained that the pharmacy's ''business model included marketing to 'closed door' facilities such as nursing homes, hospice programs, and in-patient medical facilities.'' *Id.* Yet, there is no indication that this explanation was provided during the initial due diligence survey, RX 2d, at 73–75; and during the June 2008 site visit, the consultant had noted only that City View's servicing of each of these types of facilities was ''pending.'' *Id.* at 106. Significantly, nearly two years later, City View reported only that it serviced two small nursing homes, with 20–30 beds. *Id.* at 38.

Ms. Seiple also asserted that the pharmacy was located within two blocks of two hospitals. RX 103, at 53. Yet this was not noted by either the consultant following the June 2008 site visit or by Mr. Chase after the February 2010 inspection. While it was noted in the report for a third site visit (June 28, 2010), the names of the hospitals were not identified, and in any event, the mere proximity of a pharmacy to a hospital does not justify dispensing levels of oxycodone 30 which are grossly disproportionate to the dispensings of the most commonly prescribed drugs. Indeed, in City View's case, its URs consistently showed that highly abused controlled substances (including other strengths of oxycodone and alprazolam) were predominant among the pharmacy's dispensings.

Ms. Seiple stated that City View had informed Respondent ''that it filled prescriptions for patients from several pain clinics, and identified the physicians who wrote the prescriptions for those patients.'' RX 103, at 53–54. While it is undoubtedly true that this ''accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs,'' *id.* at 54, this does not establish that the oxycodone was being dispensed by City View pursuant to prescriptions that were issued by the identified physicians for a legitimate medical purpose. *See* 21 CFR 306.04(a). Nor is there any evidence that Respondent verified the licensure status of the identified physicians and whether they had any specialized training or board certification in pain management.

Next, Ms. Seiple asserted that after City View's account was approved, the SOMS ''identified and held any order for controlled substances . . . that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 54. As found previously, the SOMS did not become operational until August 2009. Moreover, as found above, numerous orders were released even though Respondent's personnel failed to comply with its purported policy which required that it contact the pharmacy and obtain an explanation for the order, which it then independently verified, as well as that it obtain a new UR. Indeed, Respondent rarely obtained new URs, as Ms. Seiple's declaration makes clear. *Id.*

Ms. Seiple further acknowledged that Respondent ''was aware of the volume of oxycodone and other controlled drugs being dispensed by City View, and the percentage of controlled drugs dispensed relative to other drugs.'' *Id.* Unexplained by Ms. Seiple is why she did not find it suspicious that City View's actual dispensings of controlled substances (including its schedule II dispensings) constituted a much greater percentage of its total dispensing than the dispensing ratio identified in the August 2009 Compliance Review. *Compare* RX 2D, at 62–63, 71 (Sept. 2009 UR showing that oxycodone 30 dispensings alone comprised 41 percent of total dispensings) *with* RX 13, at 1 (suggested questions document with notation that typical pharmacy's dispensing ratio of controlled to non-controlled drug as 20 to 80 percent); GX 51B, at 4 ¶ 12 (testimony of Wayne Corona that DEA ''advised us to focus on whether a customer . . . dispensed a high percentage of controlled substances as compare[d] to non-controlled substances'').

Indeed, discussing the February 2010 site visit, Ms. Seiple simply noted that ''Mr. Chase did not note any suspicious activity during his inspection, and determined that the site inspection was acceptable.'' RX 103, at 55. Yet Mr. Chase recommended that a new UR be obtained and compared to the site visit. RX 2D, at 40. Ms. Seiple entirely failed to address why Mr. Chase's recommendation was not followed until more than two months later. *See* RX 103, at 55. Moreover, as found above, while City View's pharmacist had told Mr. Chase that schedule II drugs were 15 percent of all dispensings, the March 2010 UR showed that City View's dispensings of oxycodone 30 had nearly doubled from the level of the previous UR (totaling nearly 94,000 du on the new UR), and its dispensings of this drug alone comprised 52.5 percent of its total dispensings. So too, the UR showed a doubling in City View's dispensings of alprazolam 2 mg, another

controlled substance highly sought after by drug abusers.

As for why Respondent continued to fill City View's orders and failed to report them as suspicious even when they were held by the SOMS, Ms. Seiple offered several inadequate explanations. These included that Respondent ''specifically investigated the reasons why City View's ordering and dispensing patterns were as indicated on the URs,'' that ''it appeared to be a full-line pharmacy that was dispensing a large variety of both controlled and non-controlled drugs, and appeared to be servicing patients of nearby hospitals, closed-door facilities, and pain management physicians,'' RX 103, at 54, and that ''based on [Respondent's] extensive investigation, it determined that the orders it shipped to City View were not suspicious.'' *Id.* at 55.

I find, however, that the reality is far different, as Respondent simply accepted at face value whatever superficial explanation it believed would support its continued selling of controlled substances while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensing of controlled substances. And with respect to those orders which were held by the SOMS, Respondent typically did not investigate the orders as it routinely failed to contact City View to obtain a reason for the order, which it independently verified.

Remarkably, Ms. Seiple explained that City View's account was terminated because Respondent ''developed concerns following its review of URs [it] obtained from City View,'' and that ''[d]uring a discussion of City View's dispensing patterns and volume [she] had with [its PIC] on or about December 6, 2010, [she] became concerned because of discrepancies in the information he provided to [her] and the dispensing history set forth on the UR.'' *Id.* at 55–56. As found above, notes in Respondent's records show that there were concerns as to the number ''of doses dispensed as opposed to noncontrols,'' and the ''ratio of controls & noncontrols.'' RX 2D, at 2. Yet these issues had been present for the entire period in which Respondent distributed controlled substances to City View, and Ms. Seiple offered no credible explanation for why it took Respondent so long to terminate the account.[113]

Medical Plaza Pharmacy

Medical Plaza Pharmacy was a community pharmacy located in Plantation, Florida. RX 2F, at 137. According to Respondent's due diligence file, Medical Plaza became a customer of Respondent in November 2008. *Id.* at 131. However, documents in the due diligence file indicate that the pharmacy was sold the next month and a printout verifying the pharmacy's license states that the new owner's license was issued on December 30, 2008. *Id.* at 131, 137.[114] Respondent also verified the license of its PIC; the verification showed that he had not been subject to discipline. *Id.* at 138.

On March 24, 2009, Respondent conducted an initial due diligence survey for purchasing controlled substances, speaking to the pharmacy's PIC. *Id.* at 131. According to the survey, the PIC reported that Medical Plaza's daily prescription average was 120 and that it filled schedule II prescriptions. *Id.* He further reported that 35 to 40 percent of the prescriptions were for schedule II drugs. *Id.* However, with respect to the percentage of its dispensings comprised by all controlled substances, the PIC stated that he was ''unsure'' and ''didn't want to give [the] wrong answer.'' *Id.*

The PIC also reported that Amerisource was Medical Plaza's primary wholesaler, that he did not fill prescriptions that had been issued ''via the Internet,'' that the pharmacy accepted insurance, and that 70 to 80 percent of the prescriptions were paid for by insurance. *Id.* With respect to its policies and procedures, the PIC stated that he had refused to fill prescriptions if he did not have the ''item in stock'' or if he felt that the prescription was ''not valid.'' *Id.* at 132. He also reported that he did not fill controlled substance prescriptions written by out-of-area or out-of-state doctors. *Id.* As for whether he filled controlled substance prescriptions for out-of-area or out-of-state patients, the PIC reported that he ''normally'' did not for ''CS,'' but did if the patient was ''visiting'' and ''g[o]t hurt or something.'' *Id.* At the bottom of the form, Respondent's employee noted that the PIC had ''answered questions ok.'' *Id.*

On the same day, Respondent also conducted the same survey of the Hillmoor Plaza, d/b/a IV Plus pharmacy. *See id.* at 133–34. On the checklist for the due diligence review on Hillmoor Plaza, Ms. Seiple wrote: ''N/C too new 6 month review.'' *Id.* at 130. Notably, no such note appears on the checklist for Medical Plaza Pharmacy, and while the words ''site visit'' are written on the top of this document, *id.* at 129, the evidence shows that Respondent did not perform a site visit until June 18, 2009. *Id.* at 56. Moreover, Respondent did not obtain a UR from the pharmacy until August 11, 2009, nearly five months after it had approved Medical Plaza to purchase controlled substances.

In April 2009, Respondent filled three orders placed by Medical Plaza totaling 5,000 du of oxycodone 30; on May 1, it filled an order for 4,800 du of oxycodone 30; and on June 2, it filled an order for 5,000 du of oxycodone 30. GX 10F, at 42. Respondent thus shipped to Medical Plaza 14,800 du of the drug before it even conducted a site visit, which took place on June 18. RX 2F, at 56.

During the site visit, Respondent's inspector noted that Medical Plaza was located in a medical center next to a hospital and appeared to be very busy. *Id.* at 61. He also noted that the pharmacy was not a specialty pharmacy, did not engage in mail order business, that it sold front store items and appeared to be a full service pharmacy, that it was not affiliated with any Web sites, and did not fill prescriptions for physicians who were primarily engaged in pain management. *Id.* at 58–60. He also documented that the pharmacy had used at least two other distributors.[115] *Id.* at 59.

Respondent's inspector then noted that the pharmacy filled 100–120 prescriptions per day, that controlled substances comprised 60 percent of the prescriptions, and that schedule II drugs comprised 20 percent of the prescriptions. *Id.* According to the inspector, 25 percent of the prescriptions were paid for with cash. *Id.* at 60. The inspector further noted that Medical Plaza ''want[ed] an increase in Oxy's—Maybe to Next Tier?'' and that this was ''ok by me!'' [116] *Id.* at 58. In his concluding comments, the inspector further wrote: ''Masters needs to meet this pharmacy's needs.'' *Id.* at 61.[117]

[113] While Respondent's records note that there were concerns over the ratio of cash to insurance and the ''business model of insurance ratio,'' in her testimony, Ms. Seiple did not cite these as reasons for the termination of the account.

[114] The due diligence file also includes documents establishing that the owners of Medical Plaza also owned Hillmoor Plaza Pharmacy, Inc., which did business under the name of IV Plus, and was located in Wellington, Florida. RX 2F, at 139–40. However, the Government's evidence focused entirely on Respondent's distributions to the pharmacy located in Plantation. *See* GX 10F, at 41–42.

[115] The form actually lists a fourth distributor; however, the name of the distributor is in a different color and different handwriting than the majority of the notations on the form. RX 2F, at 59.

[116] Next to this is the following notation: ''will be reviewed by committee JS. 8–21–09.'' RX 2F, at 58.

[117] In addition, Respondent's inspector obtained a copy of a December 23, 2008 Florida DOH

Continued

On July 15, 2009, Respondent filled an order by Medical Plaza for 5,000 du of oxycodone 30, and on August 6, it filled an order for 10,000 du of oxycodone 30. GX 10F, at 42.

The due diligence file includes a ''Schedule Drug Limit Increase Request Form.'' RX 2F, at 110. The form, which is dated August 11, appears to have been submitted by Respondent's account manager for the pharmacy. *Id.* A handwritten notation states: ''order on hold'' and ''please see if we can release it—Thanks!'' *Id.* Further notations, which were apparently also made by the account manager, state: ''Please Review customer, In a medical building of 60 doctors, and next to a hospital. Dispenses *many* controls. *Thanks,''* followed by the initials of the account manager. *Id.* The form also includes two additional notes which were handwritten diagonally across the page and initialed by Ms. Seiple. The first states: ''We Donot [sic] Do limit increases''; the second states: Please have UR sent in for review by committee.'' *Id.*

The same day, Respondent finally obtained a UR from Medical Plaza. The UR covered the month of July and showed that the pharmacy had dispensed a total of 201,444.74 du for all prescription products. RX 2F, at 127.

The UR further showed that Medical Plaza had dispensed 369 prescriptions totaling 61,130 du of oxycodone 30 mg and 229 prescriptions totaling 27,122 du of oxycodone 15 mg.[118] *Id.* at 111–12. Thus, Medical Plaza's dispensings of oxycodone 30 mg alone amounted to more than 30 percent of its total dispensings, and its dispensings of both dosage strengths (which totaled 88,252 du) amounted to nearly 44 percent of its total dispensings. Moreover, Medical Plaza's dispensings of all oxycodone products including OxyContin and combination drugs such as Endocet 10/325 and 10/650 totaled 112,401 du, 56 percent of its total dispensings.[119] Yet, during the June inspection, the pharmacy's PIC had represented that schedule II drugs comprised only 20 percent of its prescriptions.

Moreover, while the UR ranked the drugs by the number of prescriptions (per NDC) as opposed to the quantity of dosage units dispensed, with the exception of carisoprodol, controlled substances were predominant by either measure. *Id.* The UR also contained financial information for each drug including the adjudicated amount, the acquisition cost, the profit in dollars, and profit percentage. *See* RX 2F, at 111–17. However, the data for the most dispensed controlled substances were blacked out.[120] *See id.*

The next day (Aug. 12, 2009), Respondent filled Medical Plaza's orders for 5,000 du of oxycodone 15 and 3,600 du of Endocet 10/325. GX 10F, at 42. A SOMS note of the same date states: ''order does not exceed current size limit, ok to ship.'' GX 22, at 143. Moreover, the MFR notes establish that the compliance committee did not conduct its review of the site visit and UR until August 21. RX 2F, at 1. Yet the two orders were shipped nine days earlier.[121]

Respondent did not ship any oxycodone to Medical Plaza during September 2009, and in October, it filled a single order for 10,000 du of oxycodone 30 and two orders totaling 1,000 du of OxyContin 80. GX 10F, at 41–42. An MFR note dated November 11 states that ''UR was received on 8/11 for month of July'' and ''Need survey updated—completed 11/18.'' RX 2F, at 1.

On November 17, Respondent filled Medical Plaza's orders for 1,200 OxyContin 80, 1,200 of Endocet 10/325 and 200 du of Endocet 5/325. GX 10F, at 41–42. An MFR note dated November 17 states: ''order flagged for oxy 15 + 30 order is for 100, CSOS limit is 5000 already order 1400 on 11–17–09'' and ''[c]alled to let customer know order was not shipping today[.] The ph[arma]cy] was closed.'' RX 2F, at 1.

Medical Plaza's orders for 7,000 du of oxycodone 30 and 3,000 du of oxycodone 15 placed its total oxycodone orders at 23,600 du on a rolling 30-day basis; however, its highest monthly total during the previous six months was 18,600 du during August. GX 10F, at 41–42. Thus, the November 17 orders for oxycodone placed Medical Plaza's oxycodone orders at 5,000 du more than its CSL.

On November 18, a member of the compliance department contacted Medical Plaza and conducted a second due diligence survey. *Id.* at 68. According to the form, Respondent's representative asked its owner: ''what is the pharmacy's primary customer base?'' *Id.* Respondent's representative checked the box for ''community,'' leaving blank such boxes as ''Geriatric,'' ''Worker Comp,'' and ''Pain Management.'' *Id.* Respondent's representative also documented that the pharmacy did not do any ''Institutional' or ''Closed Door Business.'' *Id.* According to the form, Medical Plaza reported that McKesson was its primary wholesaler and that it also purchased from Anda. *Id.* It also reported that its daily prescription average was 120, that it filled ''C2s,'' and that its ''daily ratio of controls to non controls'' was ''40/60.'' *Id.* It further reported that it accepted insurance as well as Medicare and Medicaid and that ''70–80%'' of the prescriptions were paid for ''by insurance.'' *Id.*

As for its policies and procedures, Medical Plaza again reported that it filled prescriptions for out-of-state or out-of-area patients visiting the area but that it did not fill prescriptions written by out-of-state or out-of-area physicians. *Id.* at 69. It also denied soliciting practitioners and retirement communities for business. *Id.*

To prevent doctor shopping, Medical Plaza stated that it ''check[ed] profile'' and ''verif[ied] w/doctor.'' *Id.* And to ensure that doctors were exercising proper standards of care, Medical Plaza reported that it ''call[ed] to verify doctor information.'' *Id.* Medical Plaza also advised that it had a refused to fill a prescription because the prescription was not valid. *Id.* However, when asked whether it had ''ever decided to permanently stop filling scripts for a certain physician,'' it answered ''No.'' *Id.*

Notwithstanding that it conducted the due diligence survey, there is no evidence that Respondent's employee obtained an explanation for the November 17 orders or a new UR as required by its Policy 6.2 Yet the same

Inspection Report. RX 2F, at 62. The report noted that it was for ''an OPENING INSPECTION'' and that ''many responses [were] NOT APPLICABLE.'' *Id.*

[118] For each NDC, the report also calculated the average quantity dispensed per prescription. Specifically, the first line entry for oxycodone 30 (34,784 du) showed an average of 157 du per prescription; the second entry for oxycodone 30 (25,356 du) showed an average of 178.5 du per prescription; and the third entry (810 du) showed an average of 162 du per prescription. RX 2F, at 111, 114.

[119] The UR also showed that Medical Plaza had dispensed 75 prescriptions totaling 9,654 du of Endocet 10/325; 59 prescriptions totaling 5,047 du of OxyContin (and oxycodone er) 80 mg; 35 prescriptions totaling 2,487 du of OxyContin (and oxycodone er) 40 mg; 23 prescriptions totaling 2,120 du of oxycodone (and Roxicet) 5/325; 21 prescriptions totaling 1,700 du of oxycodone/apap 5/325; 14 prescriptions totaling 1,656 du of Endocet 10/650; 10 prescriptions totaling 1,140 du of oxycodone 5 mg; 7 prescriptions totaling 840 du of OxyContin (and oxycodone er) 10 mg; 10 prescriptions totaling 720 du of OxyContin (oxycodone er) 20 mg; 4 prescriptions totaling 295 du of Endocet 7.5/325; and 3 prescriptions totaling 190 du of Endocet 7.5/500. RX 2F, at 111–22.

[120] Given that the financial data for particular drugs on URs from other pharmacies were not blacked out, the fair inference is that Medical Plaza blacked out the data.

[121] Another SOMS note dated August 7 made by Ms. Seiple states: ''Or [sic] to ship please see UR and site visit.'' GX 22, at 143. Even if this entry does not correspond to one of the oxycodone orders that were filled the previous day, it should be noted that Respondent had yet to obtain a UR from Medical Plaza.

day (Nov. 18), Respondent filled the aforesaid orders which were for 7,000 du of oxycodone 30 and 3,000 du of oxycodone 15. GX 10F, at 41–42. According to notes in both the SOMS and MFRs, the orders were ''shipped [with] reservation'' and an ''updated UR was requested.'' RX 2F, at 1; GX 22, at 143.

On December 14, Medical Plaza placed an order for 15,000 du of oxycodone 30. RX 2F, at 2. On a rolling 30-day basis, Medical Plaza's oxycodone orders totaled 27,600 du, 9,000 du over the CSL of 18,600 (with August being the highest monthly total). Respondent contacted Medical Plaza to obtain a new UR, and the next day, Medical Plaza provided a UR for the month of November 2009. *Id.; see also id.* at 72–90. While Respondent did not fill the order, apparently because Medical Plaza was not ordering enough non-controlled products, there is no evidence that Respondent obtained an explanation for the order. RX 2F, at 2. (MFR note stating: ''Per Diane Customer need [sic] to order 3800 in non control [sic] products as of 12.15'').[122] Nonetheless, Respondent failed to report the order as suspicious even though it had been placed on hold because of its unusual size.

As for the November 2009 UR, it showed that Medical Plaza had dispensed 479 prescriptions totaling 92,404 du of oxycodone 30 mg [123] (an average of 193 du per Rx) and 348 prescriptions totaling for 44,051 du of oxycodone 15 (an average of 127 du per Rx); [124] it also showed that Medical Plaza's total dispensings of prescription products were 246,255 du. RX 2F, at 72, 74, 83, 90. Thus, since the previous UR, Medical Plaza's dispensings of oxycodone 30 had increased by 31,274 du, an increase of 51 percent, and its dispensings of oxycodone 15 had increased by 16,929 du, an increase of 62.4 percent.[125]

Moreover, Medical Plaza's dispensings of oxycodone 30 comprised 37.5 percent of its total dispensings, and its dispensings of oxycodone 15 comprised 17.9 percent. Thus, these two dosages alone accounted for 55.4 percent of its total dispensings, and its dispensings of all oxycodone products comprised nearly 64 percent of its dispensings. Yet during the previous due diligence survey, Medical Plaza had represented that *all* controlled substances constituted 40 percent of its dispensings. And once again, the financial data pertaining to the most dispensed controlled substances were blacked out. *Id.*

Respondent did not ship any more oxycodone to Medical Plaza until February 24, 2010, when it filled orders for 3,600 du of oxycodone 30 and 6,000 du of oxycodone 15. GX 10F, at 41–42.

In March 2010, Respondent filled orders for Medical Plaza for 49,000 du of oxycodone 30 and 31,500 du of oxycodone 15, for a total of 80,500 du. GX 10F, at 41–42. Notably, during the preceding six months, Medical Plaza's highest monthly total purchase of oxycodone was 12,600 du during the month of November. *Id.* As found above, according to Respondent, the SOMS reset the CSL ''for each control [sic] group . . . on the first of every month'' based on ''[t]he highest monthly total from the preceding six months.'' RX 78, at 60. Thus, the CSL should have been set at 12,600 du.

On March 11, Respondent filled Medical Plaza's orders for 4,000 du of oxycodone 30 and 4,000 du of oxycodone 15. GX 10F, at 41–42. With these orders, Medical Plaza's rolling 30-day total of oxycodone was 17,600 du, 5,000 du more than its CSL. According to a SOMS note, the order was ''ok to ship'' because its ''size was not excessive.'' GX 22, at 144. Here again, there is no evidence that Respondent obtained an explanation for the order and a new UR.

On March 16, Respondent filled Medical Plaza's orders for 10,000 more du of oxycodone 30, raising its total orders on a rolling 30-day basis to 27,600 du, a level more than double the CSL. GX 10F, at 41. The corresponding SOMS notes states: ''oxy 30 supported bu [sic] UR increase due to getting things squared away with AR.'' GX 22, at 144. An MFR note which is dated either March 11 or 16 states: ''Oxy orders have varied due to understanding ratio & problems with AR.'' RX 2F, at 2. While Respondent provided no further explanation as to the meaning of ''problems with AR,'' this order also placed Medical Plaza over its CSL, and even assuming that this explanation was provided by the pharmacy, Respondent did not obtain a new UR.

On March 18, Respondent filled an order for 7,500 du of oxycodone 30. GX 10F, at 41. With this order, Respondent had filled orders for 25,500 du just in March, as well as 9,600 du on February 24, for a total of 35,100 du on a rolling 30-day basis, placing Medical Plaza's filled orders at nearly three times the CSL.

The corresponding SOMS note states: ''ok to ship over 1,763 over UR for Oxy 30.'' GX 22, at 144. Once again, there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order as well as a UR. Of further note, while on numerous occasions Respondent filled orders notwithstanding that the orders exceeded the CSL, it typically justified doing so (even if improperly) because the order was under the dispensing levels showed by the UR. In short, the justification documented in the SOMS makes no sense.

On March 19, Respondent filled Medical Plaza's orders for 7,500 du of oxycodone 30 and 7,500 du of oxycodone 15, thus placing its total orders on a rolling 30-day basis at 50,100, a level more than four times the CSL. GX 10F, at 41–42. A note in the MFR states: ''RWR [Release with

[122] The evidence shows that this policy was not motivated by the concern that a customer that ordered only controlled substances was likely diverting drugs, but rather, out of the sales department's interest in using the availability of controlled substances to increase sales of other products. *See* GX 25, at 19 (email (Feb. 25, 2010) from Diane Garvey, Senior Vice President to Sales Department: ''DO NOT EVER ENTER A C2 ORDER UNLESS THE SYSTEM IS SHOWING 10% . . . . also the second you receive an csos [controlled substances ordering system] email and you see your customer has not reached the 10% that order will be put on hold for one day ONLY to try to secure the 10% then it will be deleted.''); *id.* (email (Feb. 25, 2010) from Jennifer Seiple to Compliance Department: ''Compliance does not hold orders for ratio. Ratio is controlled by sales. It is not factored in when the order is reviewed.''). *See also id.* at 5 (email Dec. 1, 2010 from Diane Garvey to Sales Department: ''When you get a csos order and your customers are NOT at 10% the order will hold no need to email us simply call the customer and get them to 10%. You should be calling them anyway and thanking them for the order and selling the daily specials, syringes, etc.''); Tr. 1276 (testimony of former compliance department employee regarding Ms. Garvey's Dec. 1, 2010 email that it was ''correct'' that Respondent ''did not want its customers to . . . purchase nothing but controlleds. It wanted to maximize its revenue by selling other products, specifically noncontrolleds, to the same customers, correct?'').

[123] Of further note, the first page of the UR contains the following handwritten notations: ''91,804 oxy 30's'' and ''43,991 Oxy 15's.'' RX 2F, at 72. These figures are the sum of the quantities listed in the entries on the first page of the UR for oxycodone 30 and oxycodone 15. However, the UR also includes an entry for 600 tablets of Roxicodone 30 mg (the same drug as oxycodone 30), *see id.* at 74, and an entry for 60 tablets of oxycodone 15 under a different NDC. *See id.* at 83.

[124] The UR also showed that Medical Plaza had dispensed a total of 20,095 du of other oxycodone products including OxyContin (and oxycodone extended release) and oxycodone combination drugs. *See* RX 2F. These included 6,740 du of Endocet and generic oxycodone 10/325; 4,469 du of OxyContin 80; 2,700 du of Percocet and generic oxycodone 5/325; 1,812 du of OxyContin 40; 1,158 du of Endocet 10/650; 984 du of OxyContin 10; 780 du of OxyContin 20; 420 du of Endocet and generic oxycodone 7.5/325; 364 oxycodone 5; 360 OxyContin 60; 150 du of OxyContin 30; and 150 du of Endocet 7.5/500. *See id.*

[125] The UR also showed the quantity per prescription for each drug by NDC code—thus Respondent's employees who reviewed the UR did not even have to calculate this figure; the UR showed that for oxycodone 30 with NDC 00406–8530–01, the average quantity was 195.59, and for NDC code 52152–0215–02, the average quantity was 186.91. RX 2F, at 72.

Reservation]—order supported by UR fluctuation in buying pattern due to credit & sales,'' RX 2F, at 2; and a SOMS note states: ''ok to ship UR supports Oxy order.'' GX 22, at 144.

Regarding the MFR's reference to the fluctuation in Medical Plaza's buying pattern because of credit and sales, the record does contain a February 8, 2010 email from Dennis Smith, Respondent's CEO, to various employees including Ms. Seiple and Mr. Corona which states: ''Sales on these Oxycodone and and [sic] SOMS activity should grow significantly due to reduced prices on these products to the retail trade. Look for KVK Oxycodone sales to increase dramatically.'' RX 20. However, while it would be reasonable for a pharmacy to increase its purchases of a product to take advantage of a discount being offered by a manufacturer or distributor, there is no evidence that any of Respondent's employees who reviewed Medical Plaza's orders contacted the pharmacy and were provided this explanation by it for any order until late April.

On March 24, Respondent filled Medical Plaza's orders for 10,000 du of oxycodone 30 and 10,000 du of oxycodone 15, thus placing its total orders during the rolling 30-day period at 70,100 du, a level nearly six times the CSL. GX 10F, at 41–42. A SOMS note states that the order was ''ok to ship-oxycodone increase ur supported-frequency not excessive.'' GX 22, at 144. Again, there is no evidence that Respondent contacted Medical Plaza to obtain an explanation for the increase in its orders, or that it obtained a new UR even though the UR on file was then four months old.

On March 25, Respondent filled two more orders from Medical Plaza for 10,000 du each of oxycodone 30 and 15, thus placing its total orders during the rolling 30-day period at 90,100 du, a level more than seven times its CSL. GX 10F, at 41–42. A SOMS note by Ms. Seiple states: ''rwr [release with reservation] per committee supported by ur on file please do not exceed quantity on ur for roxy 30 and 15.'' GX 22, at 144. An MFR note by Ms. Seiple further states: ''Ship to UR per committee order released for 20k (10k Oxy 30 10k OX 15) only ship to UR on file Do not ship over UR.'' RX 2F, at 2. Here again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the order and a new UR.

Medical Plaza's March orders marked a more than four-fold increase in its oxycodone purchases over its previous highest month's purchases (18,600 du in August), and a nearly six-fold increase over its highest month's purchases during the previous six months. Yet Respondent failed to report any of the March orders as suspicious.

On April 1, Respondent filled Medical Plaza's order for 10,000 du of oxycodone 30, bringing its total orders on a rolling 30-day basis to 90,500. GX 10F, at 41. Yet a SOMS note on the order states: ''ok to ship-morphine and oxycodone within csl for period.'' GX 22, at 144. However, even assuming that Medical Plaza's oxycodone CSL was automatically increased to 80,500 du based on the March 2010 orders, the April 1 order still placed it 10,000 du over the CSL. Here again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

Thereafter, on April 8, Respondent filled Medical Plaza's orders for 3,700 du of oxycodone 30 and 10,000 du of oxycodone 15, bringing its total orders on a rolling 30-day basis to 104,200 du and nearly 24,000 du over its CSL . GX 10F, at 41–42. Incredibly, a SOMS note for the transactions states: ''ok to ship, size & [f]requency not excessive on OXY CSL is 15k, this order is for (100) OXY 15mg & (37) OXY 30mg already purchased 10k this month.'' GX 22, at 144. Here again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the orders and a new UR. Nor did it report the orders as suspicious.

On April 15, Respondent filled Medical Plaza's orders for 42,000 du of oxycodone 30 and 10,000 du of oxycodone 15, thus bring its total orders on a rolling 30-day basis to 138,200 du, nearly 58,000 du over its CSL. GX 10F, at 41–42. Two SOMS notes of the same date state: ''ok to ship oxy ur supports order'' and ''ok to ship Oxy 15 & 30 ur supprts [sic].'' GX 22, at 144. A note in the Ship to Memos states: ''Oxy 30mg-91,804'' and Oxy 15mg–43,991.'' *Id.* at 141. These numbers correspond to the numbers in the handwritten notation on the first page of the November 2009 UR. *See* RX 2F, at 72; *see also supra* n. 125. And a second note in the Ship to Memos, which was added later that day, states: ''released 10k of Oxy 15mg leaves 23,991 . . . 30k of the Oxy 30mg leaves 14,804 for the month of April.'' GX 22, at 141. Once again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the order and a new UR. Nor did it report the orders as suspicious.

The evidence also shows that on or about April 23, Medical Plaza placed additional orders for 30,000 du of oxycodone 30 and 15,000 du of oxycodone 15. RX 2F, at 2. On a rolling 30-day basis, these orders placed the Medical Plaza's oxycodone orders at 140,700 du, a level more than 60,000 du above the March shipments.[126]

Regarding the April 23 orders, an MFR note states: ''order pending 15k oxy 15 oxy 30, 30 K.'' *Id.* The note then states that the account was ''currently @ 55k on OX 30 mg for month & 20k on Oxy 15 mg'' and that the order was ''not supported [by] the UR.'' *Id.* The note then states: ''get updated UR from March for Review'' and ''let them know order will not ship & will be reviewed in [illegible] days.'' *Id.* A further note in the Ship to Memos states: ''In April shipped 75700 Oxy. The account was reviewed to not ship over this amount[.] An order was deleted for 450 bottles above the 75700 already shipped.'' GX 22, at 141.

Other MFR notes show that Respondent contacted the pharmacy and was told that the order was because of ''price'' and that the pharmacy was ''stocking up.'' RX 2F, at 3. The pharmacist also said he would accept a lower quantity and that ''business [wa]s still about the same.'' *Id.* According to the note, Respondent's employee told the pharmacist that the last UR was from November,[127] to which the pharmacist replied that ''nothing changed.'' *Id.* Respondent's employee told the pharmacist that the order would be reviewed, and in a later phone call, told the pharmacist that the order would not be shipped that day. *Id.* According to the MFR, the pharmacist said ''ok it was for over stock anyway.'' *Id.*

An MFR note of April 26 indicates that Ms. Seiple called Medical Plaza and talked with its pharmacist. *Id.* The additional note states: ''McKesson is wholesaler—Advertise promoting sending out flyers.'' *Id.* A further note states that the account was reviewed with Wayne Corona and that the pharmacy's oxycodone limit was currently at 75k. *Id.* The notes also indicate that Respondent had already shipped 75,700 du in April and that the decision was made to keep the limit at 75k and to not ship ''over 75K.'' *Id.* Further notes establish that Medical Plaza's pending order for 450 bottles of oxycodone (45,000 du) was then deleted and that Respondent contacted the pharmacist and ''explained not able to ship more than the 75,700 Oxy already shipped.'' *Id.*

[126] This total includes the Mar. 25 orders for 10,000 du of oxycodone 30 and 10,000 du of oxycodone 15; the April 1 order for 10,000 du of oxycodone 30; the April 8 orders for 3,700 du of oxycodone 30 and 10,000 du of oxycodone 15; and the April 15 orders for 42,000 du of oxycodone 30 and 10,000 du of oxycodone 15. GX 10F, at 41–42.

[127] According to another note, Respondent's employee had called the pharmacy earlier, spoken to a floater, and asked for a new UR. RX 2F, at 3.

Notably, the April 23 orders were not reported as suspicious, even though Medical Plaza's employees gave inconsistent explanations for the order, with one saying the order was placed because of price, that it ''was for overstock anyway,'' and that the ''business [wa]s still about the same,'' and the other indicating that the order was needed because Medical Plaza was promoting its business. This was so even though the orders placed Medical Plaza's oxycodone orders at more than 60,000 du over its CSL.

Moreover, while the orders had initially prompted Respondent to request a new UR, Medical Plaza did not provide one. Indeed, Respondent did not obtain another UR until August 19, 2010, even though it continued to ship oxycodone to Medical Plaza. *Id.* at 12; GX 10F, at 42.

On May 3, 2010, Medical Plaza placed orders for 30,000 oxycodone 30 mg and 20,000 oxycodone 15 mg. GX 22, at 145. On a rolling 30-day basis, Medical Plaza's orders thus totaled 115,700 du, 40,000 du above the CSL of 75,700 (calculated based on the orders filled in April). GX 10F, at 41–42. A note in the MFR states: ''Called @1.46 p.m. spoke w/Dana Call back @ 2:30 TT—Jeff.'' RX 2F, at 3. Not only is it unclear whether Respondent's employee called back the pharmacy and spoke with Jeff, but even if he/she did, there is no evidence as to what explanation was provided for the order. However, what is clear is that a new UR was not obtained. Moreover, while the evidence shows that Respondent edited the orders to 10,000 du for each dosage strength, it did not report the orders as suspicious. GX 10F, at 42; GX 22, at 145 (SOMS note: ''ok to ship qty was reduced from 200 OXY 15mg to 100 & 300 OXY 30mg to 100'').

Respondent did not fill another oxycodone order for Medical Plaza until June 28, 2010, when it shipped 14,000 du of oxycodone 30 mg to it.[128] GX 10F, at 42. An MFR note for the transaction states that ''Order for 200 bottles of Oxy has been reduced to 140 bottles @CSL for June 14K. Called + spoke w/Jeffery + told him he can reorder after the 30th.'' RX 2F, at 4; *see also* GX 22, at 145 (SOMS note: ''releasing Oxy with reservation reduced to be @CSL for June.''). While the CSL is far closer to the CSL which should have been in place at the time of the March 2010 orders, there is no evidence as to how this new CSL level was set.

On July 1, 2010, Medical Plaza placed an order for 20,000 du of oxycodone 30 mg. GX 22, at 145. However, Respondent shipped only 14,000 du. GX 22, at 145. A SOMS note for the order states: ''ok to ship 140 Oxy 30 mg, order has been edited from 200 to meet CSL of 14000.'' *Id.* Yet, on filling the order, Respondent had actually shipped 28,000 du in the last three days, thus exceeding the CSL on a rolling 30-day basis. However, Respondent did not contact the pharmacy to obtain an explanation for the order and it again failed to obtain a new UR.

According to a July 14 note in the Ship to Memos made by Ms. Seiple, on that date, Respondent placed Medical Plaza's account ''on termination per sales surrounding issues of customer and ratio.'' GX 22, at 141. However, on July 22, Ms. Seiple created a second Ship to Memo which states that Medical Plaza was actually only ''on noncontrol status per sales until further notice'' and that she would ''get [an] update from sales'' four days later. *Id.* at 142. Ms. Seiple noted that she had ''request [an] updated ur'' and placed Medical Plaza on the ''tentative site visit list.'' *Id.*

An initial entry in the MFRs for July 30 states that an order for 10,300 oxycodone 30 was deleted because Medical Plaza was on non-control status. RX 2F, at 4. However, a further entry establishes that the same day, the sales department approved the pharmacy to resume purchasing controlled substances. *Id.* While Ms. Seiple had requested that Medical Plaza provide a new UR eight days earlier, Respondent filled its order for 10,300 du of oxycodone 30 mg without obtaining the UR. GX 10F, at 42. Moreover, the order placed Medical Plaza's orders on a rolling 30-day basis at 24,300 du, more than 10,000 du over its CSL.[129]

However, there is no evidence that Respondent obtained an explanation for the order.

Only four days later on August 3, Respondent filled Medical Plaza's order for 12,200 du of oxycodone 30. GX 10F, at 42. Moreover, while the order clearly placed the pharmacy over the 14,000 du CSL on a rolling 30-day basis,[130] the SOMS notes contain no indication that the order was flagged for additional review.[131]

On August 17, Medical Plaza placed an order for 20,000 du of oxycodone 30. GX 22, at 145. While both the MFRs and SOMS notes state that the order was reduced to 1,800 du to keep Medical Plaza at its CSL of 14,000 du, other notes state that Respondent deleted the order and told its pharmacist that he needed to provide an ''updated UR'' and needed to re-order after the UR was reviewed. RX 2F, at 4; GX 22, at 145.

On August 19, Medical Plaza faxed to Respondent a UR for the month of July 2010. RX 2F, at 12–30. The UR showed that during that month, Medical Plaza had dispensed 118,848 du of oxycodone 30 and 41,160 du of oxycodone 15; its total dispensings of just these two drugs were 160,008 du, out of its total dispensings of 285,977.85 du. RX 2F, at 12–13, 20, 30. Thus, Medical Plaza's dispensings of oxycodone 30 alone comprised 41.6 percent of its total dispensings, and its dispensings of oxycodone 15 comprised 14.4 percent. Moreover, the UR showed that Medical Plaza had also dispensed 21,455 du of other oxycodone products including OxyContin and combination oxycodone drugs.[132] Thus, Medical Plaza's dispensings of oxycodone amounted to 63.5 percent of all drugs it dispensed. These figures were again flatly inconsistent with what the pharmacy had reported during the last due diligence survey. RX 2F, at 68

[128] There are, however, entries in both the SOMS notes and MFRs dated May 10, 2010. The MFR note states ''UR on file Oxy 30 68k 15 mg 23k'' and ''Only purchases 30's & 15's.'' RX 2F, at 4. To be clear, the last UR on file had been obtained on December 15, 2009 and covered the month of November 2009. Further entries in the MFR notes state ''April 75K, March 80K,'' an apparent reference to the pharmacy's oxycodone purchases from Respondent in the two previous months, and then lists the names of its distributors: ''McKesson, Anda[,] Masters.'' *Id.* The final entry in this note states: ''120 scripts a day, currently.'' *Id.*

As for the SOMS note, it states ''rlease [sic] order do nto [sic] ship over 50k without review.'' GX 22, at 145. As stated above, there is no other evidence that Medical Plaza placed any order for oxycodone on or about May 10 and it is unclear to which drug this note pertains.

[129] A Ship to Memo dated July 14 states that the ''last control [sic] purchase'' was ''being returned'' because the ''wrong product'' was ordered. GX 22, at 141. However, according to materials Respondent provided on the SOMS, the monthly totals used in determining whether an order exceeded the CSL ''include product returned when it is calculated'' and ''[t]he rolling 30 day invoice history will include invoices and credit memos from the past 30 days.'' RX 78, at 60. Thus, the fact that Medical Plaza returned the July 1 order should have had no effect on whether subsequent orders exceeded the CSL on a rolling 30-day basis.

[130] Notwithstanding that the SOMS materials state that returned product would be counted in calculating the CSL, an August 17 SOMS note states that the CSL remained at 14,000 du. GX 22, at 145.

[131] As discussed above, in its Exceptions, Respondent contended that ''the only orders that were held by SOMS were those that also have the name of a Compliance Department employee in the ''Decision By'' column and in most cases, notes in the ''Notes'' column. Resp. Exceptions, at 13. While there are two entries for orders in in the SOMS notes on August 3, 2010, neither entry includes the name of an employee or notes explaining the decision that was made on the shipment.

[132] The dispensings included 4,493 du of OxyContin 80; 1,915 du of OxyContin 40; 60 du of OxyContin 30; 1,800 du of OxyContin 20; 690 du of OxyContin 10; and 810 du of oxycodone 5; it also included 1,723 du of Endocet 10/650; 7,352 du of Endocet 10/325; 162 du of Endocet 7.5/325; 2,075 du of oxycodone 5/325; and 375 du of Roxicet 5/325. RX 2F, at 12–13, 15, 17, 20, 23.

(representing that all controlled substances comprised 40 percent of all dispensings).

As with the previous URs, with the exception of carisoprodol, the top ten drugs dispensed were controlled substances, whether this was determined on the basis of the number of prescriptions or the number of dosage units. *Id.* at 12. So too, the financial data for drugs such as oxycodone 15 and 30, as well as alprazolam 2, were blacked out. *Id.* And once again this information was ignored by Respondent.

Also on August 19, Medical Plaza placed an order for 20,000 du of oxycodone 30 mg. GX 22, at 145. Upon placing this order, Medical Plaza's oxycodone orders totaled 42,500 du on a rolling 30-day basis, more than three times the CSL of 14,000 du. GX 10F, at 42.

Regarding the order, the SOMS note states: ''ok to ship 64 bottles of Oxy 30mg, order was edited from 200 to 64. Another order can be resubmitted after 9/1/10.'' GX 22, at 145. Moreover, a note in the Ship to Memos of the same date states: ''maintain 18600.'' GX 22, at 142. While Respondent shipped only 6,400 du (bring the total filled orders to 28,900 du), GX 10F, at 42; Respondent's various records contain no explanation as to why the order was approved even though the order placed the Medical Plaza over the CSL (both before and after editing), whether the CSL was 14,000 du, 18,600 du, or even if the CSL had been revised upwards (to 24,300) based on the July orders. Moreover, the order was not reported as suspicious.

On September 1, Respondent filled Medical Plaza's order for 10,000 du of oxycodone 30 mg. GX 10F, at 42. On a rolling 30-day basis, Medical Plaza orders totaled 28,600 and thus again exceeded the CSL. *Id.* The SOMS note for the order states: ''rwr Oxy w/in monthly buying pattern leaves 8600 as of 9/1.'' GX 22, at 145. Here again, the fact that the CSL had been exceeded was ignored and Respondent failed to contact Medical Plaza and obtain an explanation for the order and a new UR.

On September 7, Medical Plaza placed an additional order for oxycodone and the evidence shows that Respondent shipped 8,600 du of oxycodone 30. GX 10F, at 42. The corresponding SOMS note states: ''rwr Oxy edited to meet CSL.'' GX 22, at 145. While the evidence does not establish order's size before it was edited, upon filling the order, Respondent had shipped 25,000 du of oxycodone 30 on a rolling 30-day basis. GX 10F, at 42. Thus, even if the CSL had been reset at 24,300 du based on Medical Plaza's July orders, Respondent again filled an order which placed the pharmacy over its CSL. Yet there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order or a new UR.

On October 1, Respondent filled an order for 16,800 du of oxycodone 30. GX 10F, at 42. Upon filling this order, Respondent had shipped 25,400 du of oxycodone 30 within the rolling-30-day period and thus exceeded the CSL. *Id.* While there are multiple SOMS entries for orders that were placed on this date, two of which indicate that Ms. Seiple reviewed them, the only notation for either of these orders is ''rwr'' or release with reservation. GX 22, at 146. No further explanation exists anywhere in Medical Plaza's file explaining why Respondent filled the oxycodone 30 order, and there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order and a new UR.

On November 5, Respondent filled an order for 8,400 du of oxycodone 30 mg, and on December 1, it filled two orders totaling 16,800 du of oxycodone 30 mg. GX 10F, at 42. While the November 5 order did not exceed the CSL, upon filling the December 1 order, Respondent had shipped to Medical Plaza 25,200 du on a rolling 30-day basis and thus exceeded the CSL. GX 10F, at 42. As for the two December 1 SOMS entries, only one provides the name of a reviewer (Ms. Seiple) and the accompanying note merely states: ''rwr.'' GX 22, at 146. Again, no further explanation exists in Medical Plaza's file for why Respondent filled the order, and there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order and a new UR.

On January 4, 2011, Medical Plaza placed an order for 20,000 du of oxycodone 30 mg. GX 22, at 143. According to the SOMS, the order was edited to 16,800 du, *id.,* and according to the Government's evidence, this amount was shipped. GX 10F, at 42. An MFR note of the same date states: ''Keep Oxy @16,800'' and ''Don't Ship over'' with an arrow pointing to ''16,800,'' as well as ''CSL is 14k.'' RX 2F, at 4.

Additional notes in the same MFR entry, which appear to have been made by Ms. Seiple, state: ''inquire on vendors McKesson/?'' and ''said they use quite a bit of insurance on oxy? How then can their [sic] be a profit?'' *Id.* A further entry includes the names of two distributors (McKesson and Keysource) and indicates that Medical Plaza was being reimbursed by insurance at a lower rate ($32.00) than the cost of the oxycodone ($39.00) and was ''losing money.'' [133] *Id.*

The same day, Respondent obtained a new UR from Medical Plaza. *Id.* at 31. The UR, which covered the month of December 2010, showed that Medical Plaza had dispensed 58,173 du of oxycodone 30 mg and 7,006 du of oxycodone 15 mg and that its total dispensings of all drugs were 190,760 du.[134] *Id.* at 31–32, 42, 53. Moreover, in contrast to the previous URs, the financial data for oxycodone and other highly abused drugs were not blacked out and showed that Medical Plaza was making profits approximately three times its acquisition cost for oxycodone 30.[135] Thus, contrary to what Ms. Seiple expressed in the MFR, Medical Plaza was clearly not losing money on oxycodone.

On February 1, 2011, Respondent filled an order from Medical Plaza for 10,000 du of oxycodone 30, and on February 2, it filled an order for 6,800 du of the drug. GX 10F, at 42. Notes written on the UR and in the MFRs show that Ms. Seiple reviewed the UR and determined that oxycodone in the dosage strength of 30 mg and 15 mg amounted to ''63K'' out of ''190K'' or ''33%'' of its dispensings.[136] RX 2F, at 5. An MFR note of February 2 indicates that Ms. Seiple raised with Wayne Corona the ''reimbursement issue w/ insurance'' and that Corona stated that the issue was ''not a problem.'' *Id.* at 4. Still another MFR note made by Ms. Seiple on the same day states: ''68 bottles of oxy released per committee RWR'' and ''purchasing multiple NDC on product—Monitor.'' *Id.* at 5.

According to an MFR note, on March 2, 2011, Medical Plaza placed an order for 16,800 du of oxycodone 30mg, which was released with reservation. *Id.* However, an MFR note of March 3 made

[133] The entry also states that ''released 100 of 168 bottles ordered.'' RX 2F, at 4. However, while I find that the order was edited, the Government's evidence establishes that Respondent shipped 16,800 du of oxycodone 30 to Medical Plaza. GX 10F, at 42.

[134] While this represented a decrease in Medical Plaza's dispensings, by this date, law enforcement and regulatory authorities had begun cracking down on rogue pain clinics in Florida.

[135] With respect to oxycodone (NDC 00406–8530–01), Medical Plaza dispensed 23,960 du; its acquisition cost was $11,631.61 and its profit was $35,482.44. RX 2F, at 31. With respect to oxycodone (NDC 57664–0224–88), Medical Plaza dispensed 14,078 du; its acquisition cost was 11,262.40 and its profit was $32,483.17. *Id.* With respect to oxycodone 30 (NDC 52152–0215), Medical Plaza dispensed 10,721 du; its acquisition cost was $4,458.87 and its profit was $25,190.92. *Id.* With respect to oxycodone 30 (NDC 10702–0000–01), it dispensed 8,014 du; its acquisition cost was $6,972.18 and its profit was $19,108.37. *Id.*

[136] The actual figures are 65,179 du and 34 percent.

by Ms. Seiple states: ''suspended sales until physicians list is provided and reviewed by compliance committee in addition to site visit.'' *Id.* Continuing, the note states: ''Account will remain on CH [compliance hold] until detailed physicians list and review is completed.'' *Id.*

Yet a SOMS note dated March 4, 2011 states: ''rwr-oxy @qty 168.0 3–4–11,'' thus indicating that the March 2 order was filled after Medical Plaza had purportedly been placed on compliance hold. GX 22, at 143; *see also* GX 10F, at 42. Notably, Medical Plaza's file does not contain a physicians list and an MFR entry for April 1, 2011 states: ''CH—no information sent to date for review.'' RX 2F, at 5. While the SOMS notes contain entries suggesting that additional controlled substance orders were placed on March 7 and April 13, 2011, *see* GX 22, at 143; the Government's printout of filled orders does not include any additional orders after March 4, 2011.[137] However, Respondent never reported any of Medical Plaza's orders as suspicious.

As for Respondent's distributions to Medical Plaza, Ms. Seiple's declaration was comprised primarily of the same testimony she provided with respect to the previous pharmacies. For example, Ms. Seiple noted that before shipping controlled substances to Medical Plaza, Respondent verified that its Florida pharmacy license and DEA registration were valid and that it obtained a copy of the most recent DOH inspection. She also asserted that based on the description provided by Medical Plaza as to its policies and procedures, Respondent believed that the pharmacy understood its obligations to prevent diversion ''and was taking affirmative steps'' to prevent diversion. RX 103, at 66. Yet in contrast to previous surveys, Respondent did not ask how the pharmacy ensured that the prescriptions were issued by doctors acting in accordance with the standard of care, let alone how the pharmacy ensured that the prescriptions it filled were being issued for a legitimate medical purpose.

Ms. Seiple further asserted that based on a due diligence survey and the onsite inspection that was conducted on June 18, 2009, Respondent obtained information that ''Medical Plaza was located in a medical center with 60 physicians, and the pharmacy serviced patients from that medical center and an adjacent hospital.'' *Id.* at 66–67. Ms. Seiple then asserted that ''[t]his accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* Yet during the site visit, Respondent's inspector had noted that the pharmacy *did not fill prescriptions for practitioners who were primarily engaged in pain management. See* RX 2F, at 60.

So too, the mere presence of 60 doctors located in the same medical office building, without any investigation into the doctors' specialties and the drugs they would prescribe in the course of their respective professional practices does not justify the volume of pain medications being dispensed by Medical Plaza or the percentage of oxycodone the pharmacy was dispensing relative to other drugs. Also, Respondent did not even obtain a UR until August 11, 2009, at which point it had been selling oxycodone to Medical Plaza for more than four months, and that UR showed that oxycodone comprised more than 51 percent of the pharmacy's total dispensings. Moreover, the percentage of Medical Plaza's total dispensings comprised by oxycodone alone was more than 2.5 times the 20 percent figure provided by DEA during the Compliance Review for all controlled substances as a percentage of a pharmacy's total dispensings.

As with the previous pharmacies, Ms. Seiple asserted that ''[a]fter Medical Plaza's account was approved, [the] SOMS . . . identified and held any order for controlled substances placed by Medical Plaza that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 67. Here again, the SOMS was not even operational until August 2009, more than four months after Medical Plaza had begun purchasing controlled substances from Respondent.

Moreover, even after the SOMS became operational, there were numerous instances in which Medical Plaza's orders placed it over the CSL on a rolling 30-day basis and yet Respondent failed to obtain an explanation for the order, or a new UR, even though these steps were required by Respondent's policy and procedure for reviewing held orders. And in numerous instances when orders were either deleted or edited, Respondent failed to file a suspicious order report.

While Ms. Seiple further asserted that ''[o]n some occasions, the Compliance Department would request [Medical Plaza] to provide a UR,'' *id.,* it obtained only four URs over the course of the nearly two-year period in which it distributed oxycodone to the pharmacy. And when it obtained URs for the months of November 2009 and July 2010, it ignored information showing that the pharmacy was dispensing increasing quantities of oxycodone, as well as that Medical Plaza's dispensing of oxycodone products comprised 62 percent of its total dispensings.

So too, while Medical Plaza represented at various points that 70 to 80 percent of the prescriptions were paid for by third party payors (such as insurance and Medicare/Medicaid), the financial data showing the profits on its sales of oxycodone 30 and 15 were blacked out on all but the final UR it provided. Yet there is no evidence that Respondent ever questioned Medical Plaza as to why it blacked out the data. Moreover, when Respondent did obtain the final UR, the data (which were not blacked out) showed that Medical Plaza was making profits three times or more its acquisition cost on generic oxycodone 30 and 15 products.

Ms. Seiple documented her concerns as to how Medical Plaza could be making any money given that its cost for the oxycodone was more than the amount that insurance would reimburse for it, as well as that she had raised the issue with Wayne Corona, who overruled her concerns. While Ms. Seiple asserted that the URs and other information were ''consistent with the pharmacy's business model as explained by [its PIC] and confirmed in the June 2009 site inspection,'' she failed to address why Respondent did not question Medical Plaza as to why the financial data for its controlled substance dispensings were blacked out on the URs. Ms. Seiple also failed to address why Respondent continued selling controlled substances even after the fourth UR showed that Medical Plaza was not ''losing money'' on its dispensings of oxycodone but making substantial profits.

Ms. Seiple acknowledged that Respondent did not report any of Medical Plaza's orders as suspicious, asserting that ''[b]ased on [its] extensive investigation, it determined that the orders it shipped to Medical Plaza were not suspicious.'' RX 103, at 68. Here again, however, Respondent simply accepted whatever reason it could find that it believed would justify ignoring the evidence provided by the URs regarding the level of Medical Plaza's dispensings of oxycodone and continued to distribute the drugs to Medical Plaza. Thus, while—as Ms. Seiple admitted—Respondent was obviously ''aware of the volume of oxycodone and other controlled drugs being dispensed by Medical Plaza and

[137] The Government's printout of ARCOS data would not have included schedule IV drugs such as alprazolam. 21 CFR 1304.33(d). Nor would it have included drugs such as tramadol and carisoprodol, which were subject to the SOMS.

the percentage of controlled drugs dispensed relative to other drugs,'' it had no valid basis for failing to report the orders as suspicious.

Temple Terrace Pharmacy D/B/A Superior Pharmacy

Superior Pharmacy, a community pharmacy located in Temple Terrace, Florida, became a customer of Respondent in January 2008. RX 2H, at 81; RX 103, at 72. Prior to Superior's first purchase of controlled substances, Respondent obtained copies of its DEA registration and State license. RX 2H, at 18–19.

On May 2, 2008, an account manager completed a Schedule Drug Limit Increase Request Form, requesting an increase in the amount of solid dose oxycodone products Superior could purchase and noting on the form that Superior was using 25,000 du per month. *Id.* at 83. Thereafter, on May 9, 2008, Respondent verified that Superior's PIC, as well as another officer of the entity, held active Florida pharmacist licenses. *Id., see also id.* at 79–80.[138]

As part of reviewing Superior's request, on June 6, 2008, Respondent contacted Superior to complete a Due Diligence Report Form. *Id.* at 81. On the form, Respondent documented that Superior filled an average of 130 prescriptions per day and that 15 percent of the prescriptions were for schedule II drugs; Superior also reported that controlled substance prescriptions comprised 20 percent of the prescriptions. *Id.* Superior represented that it did not do mail order, that it serviced one nursing home but had no contracts with such facilities, that it accepted insurance as well as Medicare and Medicaid, and that 90–95 percent of the prescriptions were paid for by insurance. *Id.*

Elsewhere on the form, Respondent lined out the section which asked whether the pharmacy had ''[r]elationships with specific doctors/clinics,'' thus indicating that Superior had no such relationship. *Id.* As for its policies and procedures, Superior reported that it prevented doctor shopping by verifying prescriptions, by not providing early refills, and by keeping a patient profile. *Id.* at 82. As for how it ensured that doctors exercised proper standards of care, Superior replied that it did a ''license check.'' *Id.* Superior also reported that it had refused prescriptions because the quantities were large, the prescription looked strange, or it could not verify the prescriptions with the doctor. *Id.* As for whether it had ever refused to fill prescriptions written by ''a certain physician,'' Respondent's employee noted that Superior had ''not cut off doctor, but refuses scripts often.'' *Id.* While the form also included the question of whether ''the pharmacy practices due diligence on specific prescribers,'' the box next to this question was left blank with a small line drawn in the space for providing a description.[139] *Id.*

Finally, Respondent's employee noted that she had requested that Superior provide its ''[m]ost recent state inspection report'' and a ''[c]omplete usages controls/non-controls of one full calendar month.'' *Id.* Of further note, Respondent's employee noted that Superior's pharmacist had said ''they are way to busy to deal with this,'' and that after she requested the additional documents, the pharmacist ''said she doubts she will *ever* fax that to me.'' *Id.*

However, on June 11, Superior faxed to Respondent a UR and a copy of its most recent DOH inspection report. As the fax cover sheet from Superior notes, the documents were faxed ''so that our quota on C2 may be increased.'' *Id.* at 74. But as the cover sheet explained, the UR, which covered the period of January 1 to through June 10, 2008, only included Superior's ''top 100 drugs dispensed.'' *Id.; see also id.* at 71–72.

As for the UR, it showed that oxycodone 30 mg was the drug most dispensed by Superior during the period, with total dispensings of 337,201 du or 63,503 du per month. *Id.* at 71. It also showed that Superior had dispensed 21,779 du of oxycodone 15 and 48,341 du of Endocet 10/325 during the period. *Id.*

On June 24, 2008, a consultant for Respondent conducted a site visit at Superior. *Id.* at 65. According to the consultant's report, Superior did not engage in internet business and sold ''minimal'' front store items. *Id.* at 65. The consultant also reported that Superior filled 100 prescriptions per day, of which 25 percent were for controlled substances. *Id.* at 66. While Superior reported that it did not service nursing homes and hospice programs, it reported that it serviced a juvenile inpatient facility. *Id.* The pharmacy further reported that 10 percent of its business was cash and 90 percent was paid for by either insurance or Medicare/Medicaid. *Id.* Next, Superior reported that it had three distributors in addition to Respondent. *Id.* at 67. Superior also acknowledged that it filled prescriptions for pain management clinics and provided the names of four pain management physicians, their DEA numbers, and indicated that they practiced in Tampa.[140] *Id.* at 70.

In the additional comments section of his report, Respondent's consultant wrote that the pharmacy shared its ''waiting area'' with ''a pain/weight control clinic.'' *Id.* The consultant further documented that ''[t]he pharmacy is located within a space that it shares with Superior Medical Center. This center specializes in weight loss and pain management. Many of their prescriptions originate within the clinic.'' *Id.* at 69–70. Included with the report were two photographs which showed the front of the pharmacy and its signage. The top portion of Superior's sign read: ''SUPERIOR PHARMACY • WALK IN CLINIC'' and the bottom portion read: ''Pain Management & Weight Loss.'' *Id.* at 68.

On July 1, 2008, Respondent printed out the Web page for Superior Medical Center. *Id.* at 49. The left side of the page promoted Superior Medical Center with the words ''Pharmacy • Pain • Weight Loss'' underneath. *Id.* On the right side, the page promoted Superior Pain Clinic with a banner that read: ''Are You Experiencing Pain?'' then listing various cause of pain, followed by ''Stop suffering in silence. >> Let us help you!'' *Id.*

The center of the page contained the heading ''Superior Medical Centers are here to help you!'' along with additional blurbs promoting its pain management clinic (''Don't live in pain. Trust the medical professionals at Superior Pain Clinic to help you enjoy life again!''), its weight loss and walk-in clinics,[141] and the pharmacy (''Superior Pharmacy is your neighborhood drug store offering personalized customer service and free home delivery.''). *Id.* Still other blurbs offered a ''free office visit or $20 dollar credit on RX'' for referring ''a friend or family'' and promoted that ''No Appointment Needed.'' *Id.*

On the same day, Respondent approved an increase in Superior's oxycodone purchasing limit to 25,000

[138] It also re-verified that the Superior held a valid state license and a DEA registration. RX 2H, at 77–78.

[139] Off to the right of this question (in and near the margin) is the notation: ''Tampa—100 mile radius.'' RX 2H, at 82. While the form contains other notations in the right margin, including one which is dated ''6/23/09,'' *id.,* it is unclear when this notation was made.

[140] In the form's section which lists the names of the four pain physicians, the name ''Merced'' is also listed without a DEA number and the name of the city in which he practiced. RX 2H, at 70. A note in the margin dated ''9–25–09'' suggests that this name was added on that date.

[141] Other photographs in the due diligence file show that the Pain Clinic and Walk-In Clinic were one and the same. RX 2H, at 28.

du per month. *Id.* at 83. While the record contains no evidence regarding the level of Superior's oxycodone purchases before April 1, 2009, the evidence shows that during April 2009, Respondent filled numerous orders totaling 16,800 du of oxycodone 30; 4,800 du of oxycodone 15; 1,200 du of Endocet 10/650; and 6,000 du of Endocet 10/325; for a total of 28,800 oxycodone products. GX 10F, at 43–44. There are, however, no notes discussing any of these orders.

On May 1, 2009, Superior placed orders, which Respondent filled, totaling 25,000 du of oxycodone 30. GX 10F, at 44. Here again, there are no notes discussing the orders.

On June 2, Superior placed orders, which Respondent filled, totaling 25,000 du of oxycodone 30. *Id.* Moreover, on June 24, Superior placed orders, which Respondent filled, for 30,000 du of oxycodone 30; 5,000 du of oxycodone 15; and 5,000 du of Endocet 10/325. *Id.* Respondent thus shipped a total of 65,000 du of oxycodone products to Superior during the month. Here again, there are no notes discussing any of these orders and the orders were not reported as suspicious even though they were more than double the April and May orders.

On June 18, Respondent obtained a second UR from Superior, which covered the month of May. *Id.* at 57–64; 96–104. Notably, with the exception of carisoprodol, which was then controlled under Florida law but not the CSA, each of the top 25 drugs was a controlled substance under federal law. *Id.* at 96. Moreover, the top four drugs were oxycodone products, three of which were different manufacturers' oxycodone 30 products, the other being Endocet 10/325. *Id.* Also among the most dispensed drugs were the stronger formulations of the benzodiazepines alprazolam (1 mg and 2 mg) and diazepam (5 mg and 10 mg), as well as other narcotics including oxycodone 15 mg and the strongest formulation of combination drugs containing either 7.5 or 10 mg of hydrocodone. *Id.*

As for Superior's dispensings of oxycodone, the UR showed that during May, it had dispensed a total of 60,274 du of oxycodone 30; 6,272 du of oxycodone 15; and 11,641 du of Endocet 10/325. RX 2H, at 96, 99, and 103. During the month, Superior's total dispensings of all prescriptions products were 209,481 du. *Id.* at 64. Thus, Superior's dispensings of oxycodone 30 alone comprised 28.8 percent of its total dispensings, and its dispensings of its top three oxycodone products (78,187 du) comprised 37.3 percent of its total dispensings.

On June 23, Respondent conducted a due diligence assessment (apparently by telephone) and re-verified that Superior held a DEA registration and a Florida Pharmacy license. RX H2, at 53, 56. According to the due diligence assessment, Superior did not claim that its primary customer base was workers compensation, pain management, or bariatric patients.[142] *Id.* at 51. Yet as found above, during the site visit, Respondent's consultant had reported that Superior shared space with a pain management and weight loss clinic [143] and that Superior's staff had told him that ''[m]any of their prescriptions originate within the clinic.'' *Id.* at 70.

Moreover, Superior now reported that it filled ''280'' prescriptions per day and that its ''daily ratio of controls to noncontrols [was] ''50/05'' [sic]. *Id.* Yet during the site visit, Superior had reported that it filled 100 prescriptions per day and that 25 percent of the prescriptions were for controlled substances. *Id.* at 66.

As for its policies and procedures, Superior reported that it did not fill prescriptions for patients and prescriptions written by doctors, unless the patients and doctors were within ''a 100 mile radius around Tampa.'' *Id.* at 52. As for its procedures to prevent doctor shopping, Superior advised that it called and verified all controlled prescriptions and watched the patients, and as for its procedures to ensure the prescribers were exercising proper standards of care, it asserted that it would ''[c]all and verify.'' *Id.* While Superior reported that it had ''refused to fill a prescription'' if it was ''too soon,'' it also advised that it had never ''decided to permanently stop filling scripts for a certain physician.'' *Id.*

Next, Superior provided the names of two physicians whose controlled substance prescriptions it filled (Dr. Mercedes and Dr. Hubang). *Id.* The same day, Respondent printed out a license verification and practitioner profile for the aforementioned Dr. Merced (but not a Dr. Mercedes) from the Florida DOH Web site. *Id.* at 54–55. Of note, the printouts showed that Dr. Merced's address of record was in Jamestown, North Carolina and not Tampa. *Id.*

Moreover, Respondent did not obtain printouts for either a Dr. Mercedes or a Dr. Hubang, and it did not conduct any further investigation into these physicians who were practicing pain management at Superior. *See generally* RX 2H. As for the latter, MFR notes dated September 25 spell the latter's name as Mubang. RX 2H, at 1. Yet there is no evidence that Respondent's compliance department conducted a license verification on a Dr. Mubang either, even though the notes indicated that Respondent was aware that he was writing prescriptions at the Superior Pain Clinic. *See generally* RX 2H. Nor did it check the license status of any of the physicians who Superior had previously identified as pain management physicians whose prescriptions it filled. And while various forms in the Due Diligence file indicate that Respondent conducted a Google Search of Superior Pharmacy, *id,* at 50–52, it did not conduct a Google Search of the doctors who were working at the Superior Medical Center. Had it done so, it would likely have come across a press release issued on July 16, 2008 by the Florida Department of Law Enforcement announcing the arrest of John Nkolo Mubang ''for allegedly trafficking in prescription drugs while he worked as an internal medicine doctor at a Tampa medical facility he owns and operates.'' [144]

Finally, the form provided a place to note either ''unusual answers'' or other relevant information. *Id.* at 52. In this place, Respondent noted: ''60% open door and 45% clinic'' [sic]. *Id.*

The next day (June 24), Respondent filled Superior's orders for 30,000 du of oxycodone 30; 5,000 du of oxycodone 15; and 5,000 du of Endocet 10/325. GX 10F, at 44. It did not report the orders as suspicious, notwithstanding that Superior's June orders were 40,000 du and 2.6 times greater than its May orders and despite the various inconsistencies in the information it possessed regarding Superior's business.

On July 1, Respondent filled Superior's orders for 45,000 du of oxycodone 30 and 200 du of Endodan, a drug combining oxycodone and aspirin. GX 10F, at 43–44. Moreover, on July 23, Respondent filled Superior's orders for 20,000 du of oxycodone 30, thus resulting in total shipments of 65,200 du for the month. *Id.* at 44. There is, however, no documentation explaining why the orders, which exceeded Superior's purchasing limit, were filled. Nor were the orders reported as suspicious.

[142] Indeed, it is unclear what Superior reported as its primary customer base, as the box for a ''community'' pharmacy was not checked (nor the box for ''other'') and there is no description next to the box that was checked. RX 2H, at 51.

[143] Superior did report that it was located within a medical clinic. RX 2H, at 51.

[144] Pursuant to 5 U.S.C. 557(e), I take official notice of the aforesaid press release, which can be accessed at *http://www.fdle.state.fl.us/Content/News/2008/July-2008/Hillsborough-County-Doctor-Charged-with-Prescripti.aspx.* Respondent shall have ten (10) business days from the date of issuance of this order to refute the above facts by filing a motion with this Office.

On August 11, Respondent filled Superior's order for 40,000 du of oxycodone 30. GX 10F, at 43. However, while there are SOMS notes for orders placed on August 6 and 7—thus indicating that the system was then functioning—there are no entries for orders placed on August 11. GX 24, at 106.

Moreover, on August 28, Respondent filled Superior's order for 35,000 du of oxycodone 30, thus bringing its total shipments of oxycodone 30 to 75,000 du or the month. GX 10F, at 43. While there are multiple orders listed in the SOMS notes with the date of August 27, several of which list the name of an employee who approved the order and notations such as ''to ship within current size limit for 30 day period,'' the notes do not specify which drugs these orders were for. GX 24, at 106. Moreover, because the record contains no evidence as to Superior's orders before April 1, 2009, there is insufficient evidence as to its six-month ordering history and thus, its oxycodone CSL cannot be determined as of this month.

On September 14, Respondent filled Superior's orders for 30,000 du of oxycodone 30 mg. GX 10F, at 43. Moreover, on September 24, Respondent filled an order for 5,000 du of Endocet 10/325. GX 10F, at 43. According to a note in the MFRs, on September 24, Superior placed three orders ''for 30k [thousand] pills'' and the order was ''held.'' RX 2H, at 1. While this entry does not specifically identify that the order was for oxycodone, an MFR entry for the next day supports the inference that it was.

The note, which bears Ms. Seiple's initials, states that she ''researched [Superior's] file and looked [at] the site visit as well as Web sites from 2008,'' noting that ''[t]he pharmacy is located inside clinic.'' *Id.* Ms. Seiple then wrote that she called the ''pain clinic and inquired about service'' and ''if I would come in for service d[id] they have a pharmacy inside [the] clinic. They said yes.'' *Id.* Continuing, Ms. Seiple wrote that ''per Web site & pics [photos,] orders are being deleted customer on CH.'' *Id.* Ms. Seiple further noted that Superior ''owes 60 K most due 10/10 9/21'' and ''will tell account @ limit for month.'' *Id.* Ms. Seiple then wrote that she would encourage another employee ''to get payment'' and she would ''not tell customer'' that it was ''on non controls til [sic] paid in full.'' *Id.* Ms. Seiple then noted that Superior was ''on compliance review.'' *Id.*

To the right of this statement are more notes stating ''Additional updated Due Diligence Survey updated,'' below which were the following bullet points: ''File updated,'' ''location inside clinic,'' ''limits reduced,'' ''280 scripts a day,'' and ''practitioner that write scripts Dr. Mercedes'' and ''Dr. Mubang.'' *Id.* Still other notes for this entry included the names ''Dr—Merced'' and ''John Mubang,'' along with the number ''280'' surrounded by a circle, and ''65k to 25k.'' *Id.* Of note, however, all of this information was at least three months old and much of it had been acquired 14 months earlier. Also, while the order was placed on compliance hold, Respondent did not obtain an explanation for the order from Superior, which it then verified.

Respondent did, however, obtain a new UR, which covered the month of August 2009. *Id.* at 31–46. The UR showed that Superior had dispensed 80,302 du of oxycodone 30; 4,070 du of oxycodone 15, and 7,655 du of Endocet 10/325; it also showed that its total dispensings were 242,818 du. RX 2H, at 32, 34, 41, 46. Thus, Superior's dispensings of oxycodone 30 alone amounted to 33 percent of its dispensings, and its dispensings of the three oxycodone products amounted to 37.9 percent of its total dispensings. Moreover, here again, most of the drugs (19) among the top 25 drugs dispensed by Superior were controlled substances and included other narcotics such as methadone and hydrocodone, as well as three formulations of alprazolam and two formulations of diazepam. RX 2H, at 32. Of further note, carisoprodol was the third most dispensed drug. *Id.*

Notwithstanding this information and the notations indicating that Superior had been placed on compliance hold and non-controlled status, or alternately, that its CSL had been reduced to 25,000 du of oxycodone, on September 30, Respondent filled three orders totaling 30,000 du of oxycodone 30 mg. GX 10F, at 43. Entries in the SOMS notes made the same day suggest that the orders did not even trigger a review as they do not contain the name of a person who reviewed the order nor contain any notes regarding the order. GX 24, at 106.

On October 26, Respondent shipped to Superior orders for 20,000 du of oxycodone 30. GX 10F, at 43. Yet on November 2, Respondent shipped to Superior three orders totaling 25,000 du of oxycodone 30. *Id.* The SOMS notes for this date include three entries, none of which include the name of a reviewer or a note, thus indicating that the orders were not held for review. GX 24, at 106. Yet entries in the Ship to Memos and MFRs state that on November 3, the account was reviewed by the committee and ''reduce[d] from 65k to 25k'' and that Superior had to ''give non control [sic] orders.'' *Id.* at 105; *see also* RX 2H, at 1. Neither the notes nor Ms. Seiple's testimony explain why Superior's limit had not actually been reduced on September 25, as Ms. Seiple had documented in the MFR note of that date.

According to an MFR note, on or about November 17, Superior placed an order for 25,000 du of oxycodone. RX 2H, at 2. The MFR note states that ''as of 11/3 per committee [pharmacy] need [sic] to give a non control [sic] order before releasing Oxy order sent email to rep.'' *Id.* Continuing, the note states: ''Acct is at their [sic] limit for the month[.] [O]rder will be deleted.'' *Id.* The note further states that an employee of Respondent contacted Superior's PIC, who stated that ''he didn't know his limits were drop [sic] to 25k.'' *Id.* Respondent did not, however, report Superior's oxycodone order as suspicious. Moreover, the next day, Respondent approved orders totaling 2,500 du of hydrocodone, which were shipped the following day. GX 10F, at 43.

An MFR note of November 19 states that Superior's pharmacist was being called ''due to wrong [sic] fill 8109 product'' and that its ''limits cut.'' RX 2H, at 2. Continuing, the note states: ''per Wayne collect moneys and terminate,'' ''put on CH until paid,'' ''gradually reduced allotment to collect moneys'' and ''owes 46k.'' *Id.* Still another note for this date (which is written in the space for dating an entry) states: ''partnership in clinic'' and ''[b]oth connected owns both.'' *Id.*

According to an MFR entry of November 30, on this date Superior placed two orders for 200 bottles (20,000 du) of oxycodone 30. RX 2H, at 2. Other notes in this entry include: ''Ike own [sic] clinic & pharmacy,'' ''1% on non-controls'' and ''owes 31k.'' *Id.* A SOMS note of the same date by Ms. Seiple states: ''ok to ship do not ship over 10k on oxy this month without committee review.'' GX 24, at 107. And while a December 1 MFR entry then states: ''order holding'' and ''TT [talk to] Teri,'' an MFR entry for December 2 reads ''CSL reduced in SOMS to 10k,'' followed by (in blue ink) ''RWR terminate—once bill is pd.'' *Id.*

The same day (December 2), Respondent shipped to Superior 10,000 du of oxycodone 30. GX 10F, at 43. Respondent did not report the order as suspicious even though it knew that Superior's pharmacist owned both the pharmacy and the pain clinic.

Moreover, on December 7, Respondent filled an order for 200 du of hydrocodone/ibuprofen tablets, a schedule III controlled substance. *Id.*

According to an MFR note, on December 10, the compliance committee reviewed Superior's status. RX 2H, at 2. While the MFR note states that the account was terminated (and also that Superior still owed money), *id.,* a note in the Ship to Memo states: ''do not ship controls without review by jen or wayne.'' GX 24, at 105.

While there is no evidence that Respondent filled any controlled substance order for Superior after December 7, 2009, on January 11, 2010, Respondent conducted a site visit at the pharmacy. RX 2H, at 21–29. On the form, Respondent's inspector documented that Superior reported that controlled substances (in schedule II–V) constituted 50 percent of its dispensings; the inspector circled the figure and wrote ''too high,'' which he underlined for emphasis. *Id.* at 23. He further noted that there was ''[a] pain management doctor in the same place of business,'' which he also circled. *Id.* at 24. And in the space for providing a general description of the pharmacy, he wrote: ''A busy 4-lane roadway in a strip mall w/a pain clinic inside the pharmacy.'' *Id.*

The inspector further recommended that a compliance review be conducted based on the fact that controlled substances comprised 50 percent of Superior's dispensings. *Id.* at 21. The inspector also checked that he had observed suspicious activity outside of Superior, noting that there were ''several persons hanging outside pharmacy & sitting in vehicles—20–30 year olds—not using canes or walking with limps—talking about getting their meds!'' *Id.*

On a second site visit recommendation which is dated two days later, the inspector noted that he had observed ''6 people out front of pharmacy *talking about getting their oxys* as I walked in!'' *Id.* at 29. He also noted that there were ''[n]umerous persons 20–35 yrs. old, hanging inside & outside pharmacy to by [sic] oxys with no apparent *disabilities*! No one limping or using canes.'' *Id.*

While Respondent subsequently terminated Superior, Respondent's compliance staff had known since the original site visit that both a purported pain management clinic and the pharmacy were operating out of the same retail space. Yet for nearly a year and a half, Respondent failed to raise any questions as to the ownership of the clinic and the relationship between the physicians who practiced there and the pharmacy owner.

Regarding Respondent's distributions to Superior Pharmacy, Ms. Seiple noted that before shipping controlled substances to the pharmacy, Respondent verified that its Florida pharmacy license and DEA registration were valid and obtained a copy of the most recent DOH inspection. She also asserted that based on the description provided by Superior as to its policies and procedures, Respondent believed that the pharmacy understood its obligations to prevent diversion ''and was taking affirmative steps'' to prevent diversion. RX 103, at 73. Ms. Seiple did not, however, address what significance she attached to the note on the Due Diligence Report Form (next to the question whether the pharmacy practiced due diligence on specific prescribers) which states, ''Tampa—100 mile radius,'' and thus suggests that Superior would fill prescriptions for prescribers as long as they were located within 100 miles of Tampa.

Next, Ms. Seiple asserted that because during the June 2008 site inspection, Superior's PIC had ''explained that [its] business model included filling prescriptions for a juvenile in-patient facility, and a weight-loss and pain management facility located in an adjacent office . . . [t]hese factors accounted for the volume of controlled substances being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* However, while the consultant reported that Superior claimed it was servicing a juvenile in-patient facility, Respondent obtained no information regarding the facility, including its name, the number of patients it treated, the type of conditions it treated and the drugs prescribed in the course of treatment, and the names of its doctors. Thus, the mere fact that Superior provided prescriptions for this facility falls well short of justifying the volume of its oxycodone dispensings and the percentage of its dispensings comprised by oxycodone.

As for Ms. Seiple's assertion that the pain management and weight loss clinic were ''located in an adjacent office,'' Respondent's consultant actually reported that ''[t]he pharmacy is located within a space that it shares with Superior Medical Center.'' RX 2H, at 70. Of further note, interspersed with the pages of the consultant's report were photographs showing the store front and its signage; these photos clearly showed that the pharmacy and clinic were located in the same space. *Id.* at 68.

Moreover, one week after the consultant conducted his inspection, Respondent obtained a printout of Superior's Web page. The Web page clearly showed that Superior was marketing itself as both a pain clinic and pharmacy, thus providing a form of one-stop shopping. And a second printout of Superior's Web page—which was not obtained until September 2009—provided the same street address for both the pharmacy and the pain clinic. Thus, while the presence of Superior's pain clinic may well have been a factor which ''accounted for the volume of controlled substances being dispensed, and the percentage of oxycodone dispensed relative to other drugs,'' this does not establish that those dispensings were for a legitimate medical purpose.

In her declaration, Ms. Seiple did not address why, in light of the information she had obtained that the clinic and pharmacy shared the same space and were marketed together, Respondent failed to investigate the relationship between the pharmacy and pain clinic until 15 months later.[145] *See generally* RX 103, at 72–75. Nor did Ms. Seiple explain why it took 17 months for her to even ask Superior's PIC about the ownership of the clinic. *See id.* Moreover, while at the hearing Respondent asserted that in early 2009, it had cut off selling to physicians who were directly dispensing oxycodone to their patients, Ms. Seiple offered no explanation for why this policy did not warrant cutting off Superior given that it promoted itself as both a pain clinic and pharmacy. *See id.* Nor did she explain why Respondent continued to distribute oxycodone to Superior even after she called the pain clinic and was told that there was ''a pharmacy inside [the] clinic.'' *See id.; see also* RX 2H, at 1.

The rest of Ms. Seiple's assertions regarding Superior's ordering and dispensing patterns are similarly unavailing. For example, she asserted that ''[a]fter Superior's account was approved, [the] SOMS . . . identified and held any order . . . that deviated from its typical volume, pattern or frequency'' ' and that these orders were released only after review by the Compliance Department. RX 103, at 73–74. She also asserted that ''[b]ased on [Respondent's] extensive investigation,

[145] As found above, two weeks before the site visit, Respondent conducted a phone survey to evaluate Superior for an increase in its oxycodone purchasing limit. RX 2H, at 81. One of the questions on that form specifically asked if the pharmacy had ''[r]elationships with specific doctors/clinics?'' *Id.* Respondent's reviewer left the answer block blank and added scribble on the line provided for explaining the answer. *Id.*

While this non-answer was clearly inconsistent with the information obtained during the site visit, there is no evidence that Respondent investigated whether the form was completed in this manner because Superior's PIC had denied the existence of any such relationship, or because Respondent's employee falsified the form or failed to ask the question.

it determined that the orders it shipped to Superior were not suspicious.'' *Id.* at 75. And she asserted that ''[t]he URs and other information provided by Superior were consistent with the pharmacy's business model as explained by the customer. *Id.* at 74.

Here again, Respondent filled numerous orders for oxycodone products during the period between April 1 and early August 2009 during which the SOMS was not even operational. Moreover, while the evidence shows that Superior's oxycodone limit was set at 25,000 du per month effective July 1, 2008, and that Respondent shipped it a total of 28,800 du (for all oxycodone products) in April 2009 and 25,000 of oxycodone 30 during May 2009, Respondent shipped it a total of 65,000 due of oxycodone products during June 2009. Even though the June orders were more than double the April and May orders and the purported 25,000 du limit, Ms. Seiple did not deem them suspicious. So too, she did not report the July orders, which totaled more than 65,000 du, as suspicious.

Notwithstanding that various orders for 30,000 du of oxycodone 30 were held on September 24, 2009, prompting Ms. Seiple to place a call to the pain clinic during which she was told that the pharmacy was located inside the clinic, followed by her deleting the orders, the orders were not reported as suspicious. Moreover, the compliance hold was short-lived as only six days later, Respondent filled three orders from Superior for 30,000 du of oxycodone 30. And while notes made in various documents indicate that Superior's CSL had been reduced to 25,000 du, these orders were shipped without any review and were not reported as suspicious.

Here again, Ms. Seiple failed to address why these orders were not reported as suspicious and were shipped. She also failed to address why various orders in October and early November 2009 did not even trigger review even though the orders placed Superior well over the 25,000 du CSL which was supposedly instituted on September 25, 2009.

So too, in her declaration, Ms. Seiple failed to explain why in December 2009, Respondent shipped 10,000 more du of oxycodone 30 even though Ms. Seiple had by then determined that Superior's PIC owned both the pharmacy and the pain clinic. And here again, Respondent failed to report the order as suspicious. In short, Ms. Seiple's assertion that Respondent ''determined that the orders it shipped to Superior were not suspicious'' (RX 103, at 75) is disingenuous.

As for her further assertion that the URs and other information provide by Superior were consistent with the pharmacy's business model as explained by its PIC, the evidence does show that the PIC explained at various points that much of the pharmacy's business involved filling the prescriptions written by the doctors at his pain clinic. Indeed, this has been reported by Respondent's consultant following the site visit, RX 2H, at 69–70; as well as documented in the report of the June 23, 2009 due diligence assessment which noted that 45 percent of the prescriptions were from the clinic. *See id.* at 52. Yet while during the June 2008 site visit, the PIC had reported that 25 percent of the prescriptions it filled were for controlled substances, during the June 2009 due diligence assessment he now reported that 50 percent of the prescriptions were for controlled substances. Moreover, the May 2009 UR showed that with the exception of carisoprodol, each of the top 25 drugs dispensed by NDC code was a controlled substance, with three of the top four drugs being oxycodone 30 products (the other being Endocet 10). Also among the top 25 drugs were multiple narcotics including still more oxycodone products, including three oxycodone 15 products, OxyContin in both 40 and 80 mg dosage, three hydrocodone products, methadone, two hydromorphone products, and five benzodiazepines. *Id.* at 96. Contrary to Ms. Seiple's assertion, the information Respondent obtained from Superior was not consistent with that of a pharmacy that was dispensing only legitimate prescriptions but rather that of a pharmacy that was engaged in suspicious activity.

Morrison's Rx

Morrison's Rx (hereinafter, Morrison's) is a community pharmacy located in Sunrise, Florida. RX 2G, at 127. According to Ms. Seiple, Morrison's established its account with Respondent in September 2007. RX 103, at 69. Also according to Ms. Seiple, prior to Respondent's first distribution of controlled substances to Morrison's, Respondent conducted a due diligence survey, obtained a credit application and a Dun & Bradstreet report. *Id.* While the record also establishes that Respondent obtained a copy of Morrison's DEA registration in September 2007, Ms. Seiple made no claim that Respondent verified that Morrison's and its PIC held state licenses prior to shipping, and there is no evidence that the licenses were verified until an April 2008 site visit.

As for Respondent's initial due diligence survey, Morrison's reported that its daily prescription average was 265 and that controlled substances comprised 60 percent of the prescriptions; it also reported that 35 percent of the prescriptions were for schedule II drugs. RX 2G1, at 1. As for Morrison's due diligence procedures, the PIC reported that she would call the doctor when a physician was a new prescriber, for ''unusual prescriptions,'' and if a patient was ''too early.'' *Id.* The PIC further represented that patients were required to provide their driver's license number and that she would refuse to fill prescriptions if she suspected a patient was ''doctor shopping,'' was ''too early,'' was presenting ''forged scripts,'' or was ''visibl[y] intoxicat[ed].'' *Id.* Finally, the PIC stated that if a patient presented ''too many scripts,'' she would tell the patient that he/she ''can only fill one'' and that she would ''[v]oid scripts when the doctor authorizes.'' *Id.*

Prior to the completion of the due diligence survey, Morrison's provided utilization reports but only for the oxycodone products it sold. *Id.* at 130–46. It also provided a list of some 22 pain management doctors whose prescriptions it filled, along with the names and addresses of their clinics. *Id.* at 148–49. There is no evidence, however, that Respondent's staff conducted any further inquiries into the licensure status of these physicians.

As for the URs, they showed Morrison's dispensings of each oxycodone product (by dosage and by NDC code) for the months of September and October 2007, as well as for a portion of November. The URs did not, however, show Morrison's total dispensings of all products.

With respect to oxycodone 30, the URs showed that during September, Morrison's dispensed 1,256 prescriptions totaling 227,801 du, an average of 181 du per prescription. RX 2G, at 135–36. As for October, the URs showed that Morrison's dispensed 1,466 prescriptions totaling 262,773 du, an average of 179 du per prescription. *Id.*

With respect to oxycodone 15, the URs showed that during September, Morrison's dispensed 211 prescriptions totaling 23,814 du, an average of 113 du per prescription. *Id.* at 132–33. As for October, the URs showed that Morrison's dispensed 227 prescriptions totaling 24,449 du, an average of 108 du per prescription. *Id.*

According to a memo in Morrison's due diligence file, on April 1, 2008, an employee of Respondent requested a re-

evaluation of Morrison's purchasing limits ''due to a glitch in the CSOS system which enabled the pharmacy to order over their [sic] limit.'' *Id.* at 128. Respondent's employee documented that she had verified the licenses of both the pharmacy and its PIC; she also documented that Morrison's had reported that 40 percent of the prescriptions were schedule II drugs and that it was filling 250 rather than 265 prescriptions per day. *Id.*

As part of the update, Respondent's employee obtained Morrison's most recent state inspection reports (which found a single violation in that its compounding records were not properly maintained). *Id.* at 109. She also obtained a UR for the period January 1 to April 1, 2008, which showed the dispensings of the top 500 drugs (by NDC code). *Id.* at 115. With respect to oxycodone 30, the UR showed that during the period, Morrison's had dispensed 1,088 prescriptions totaling 189,947 du, an average of 63,316 du per month and 174.6 du per prescription. *Id.* The UR further showed that during the period, Morrison's dispensed 153 prescriptions totaling 15,547 du of oxycodone 15, an average of 5,149 du per month and 101 du per prescription.[146] *Id.* at 115, 123. Oxycodone 30 alone accounted for more than 38 percent of the dispensings listed on the report. Moreover, while the UR's ranking did not actually list the drugs in decreasing order by the number of units dispensed, even a cursory review shows that controlled substances (and carisoprodol) comprised nearly all of the top 15 drugs Morrison's dispensed.

Notwithstanding the information provided by the UR, a note on the bottom of the re-evaluation of limits memo states that Respondent approved Morrison's ''for 50k.'' *Id.* at 128. The note, however, is undated.[147] *Id.*

On April 24, Respondent's consultant made a site visit. *Id.* at 110–14. While the consultant verified that Morrison's held a valid state license and DEA registration and that its PIC held a state license, he also noted that the pharmacy sold a ''very limited'' selection of front store items and did not sell medical supplies other than by special order. *Id.* at 110–11. He further noted that the pharmacy had purchased drugs from three other distributors, that it filled 200 prescriptions on an average day, that 30 percent of the prescriptions were for controlled substances, and that 20 percent of the pharmacy's business was paid for with cash. *Id.* at 112. He also noted that Morrison's serviced ''1 nursing home'' and one ''inpatient facility'' which was identified as St. Joseph; however, the report included no further information as to the type of treatment provided at the inpatient facility, its size, and the types and quantity of prescriptions that were being filled for its patients. *Id.* So too, the report contained no information as to the size of the nursing home, and the types and quantity of prescriptions that Morrison's was filling for its patients.

Next, the consultant noted that the pharmacy filled prescriptions for pain management clinics and listed the names of five doctors, their locations, and their DEA numbers. *Id.* at 113. There is, however, no evidence that Respondent conducted any further inquiries regarding these doctors such as license verifications and whether they had any specialty training or board certification in pain management.

Finally, the consultant provided ''additional comments.'' *Id.* Therein, the consultant wrote:

> The pharmacy is set up [with] only a waiting area in the front—no front store merchandise. The pharmacy area has a small stock of Rx drugs. It seems to be professionally operated. The pharmacist indicated that she isn't filling as many CII prescriptions as she used to as many of the physicians in her area now dispense themselves. The pharmacy services primarily elderly patients.

Id. at 113–14.

A second ''Schedule [sic] Drug Limit Increase Request Form'' establishes that on or about July 28, 2008, Morrison's requested an increase in its oxycodone ordering limit to 100,000 du per month. *Id.* at 104. There is, however, no documentation as to whether the request was granted.

On January 30, 2009, Respondent obtained from Morrison's various documents including its ''policy and procedure'' for dispensing controlled substances to treat pain. *Id.* at 48–50. It also obtained a UR for the period of November 1, 2008 through January 30, 2009, which showed the dispensings of 34 schedule II drugs listed by their NDC. *Id.* at 46. With respect to oxycodone 30, the UR showed that Morrison's dispensed 1,839 prescriptions totaling 335,114 du, an average of 111,705 du per month and 182 du per prescription. *Id.* As for oxycodone 15, the UR showed that Morrison's dispensed 851 prescriptions totaling 77,417 du, an average of 25,806 per month and 91 du per prescription. *Id.*

Thereafter, on February 2, Respondent's account manager sought an increase in Morrison's solid dose oxycodone ordering limit, noting that its monthly usage was 200,000 du and that it qualified for the increase both because it was a ''long-term'' customer and a ''large full-line pharmacy.'' *Id.* at 51. Written on the form is the notation: ''Table need usage report.'' *Id.* However, there is a further notation on the request form stating that on a date, the month of which is obscured, Morrison's was approved to purchase 200,000 du of oxycodone per month.[148] *Id.* Respondent did not obtain a new UR until May 6, 2009. *Id.* at 100.

Subsequently, on February 17, an employee of Respondent completed a due diligence report form on Morrison's. *Id.* at 3–4. Therein, Morrison's reported that it was now filling 180 prescriptions per day. *Id.* at 3. Morrison's further reported that controlled substances comprised 30 to 60 percent and schedule II drugs comprised 15 to 30 percent of the prescriptions it filled. *Id.*

The form also included several questions regarding Morrison's policies and procedures. *Id.* at 4. As for how it ensured that prescribers were exercising proper standard of care, Morrison's asserted that ''[i]f they get a large Qty of CIIs they get a copy of [the] MRI and if anything is ever questionable they call the doctor.'' *Id.* Morrison's further asserted that it had refused to fill prescriptions because the refill was too soon, the ''script are [sic] questionable'' and for an ''extremely lrg. Qty.''

Morrison's PIC further reported that she had stopped prescriptions for ''1 physician that was under investigation.'' *Id.* Apparently, short of an investigation, Morrison's did not permanently stop filling prescriptions for any physician

[146] While these figures clearly represented a substantial decrease in the volume of Morrison's oxycodone dispensings, the reason for this became apparent three weeks later during a site visit, when Morrison's PIC told Respondent's consultant ''that she isn't filling as many CII prescriptions as she used to as many of the physicians in her area now dispense themselves.'' RX 2G, at 113–14.

[147] The due diligence file also includes a Schedule Drug Limit Increase Request Form, which is dated ''3/31'' and which requested an increase in Morrison's solid dose oxycodone ordering limit to 50K based on an ''exemption'' Respondent provided for a ''large full line pharmacy.'' RX 2G, at 105. The record is otherwise unclear as to what criteria were used to determine if a pharmacy was qualified as such. A further note on the bottom of this page which is dated April 29, 2008, states: ''Leaving at 50k Re-Eval 6 mos. Call & informed Jen Seiple sales rep.'' *Id.*

[148] There are additional documents in this time period including the result of a Google search conducted on Morrison's, printouts from Morrison's Web site, a printout on Morrison's from a Web site known as LegitScript.com, and a Dunn and Bradstreet report. RX 2G, at 54–74. While the printout from the LegitScript Web site stated that the pharmacy met LegitScript's ''Internet pharmacy verification standards,'' *id.* at 62–63, it did not otherwise address whether Morrison's was filling legitimate prescriptions. *See id.* at 62 (''LegitScript simply represents that, at the time that LegitScript reviewed the Web site, available information indicated that the Web site met or did not meet our standards as represented on this Web site.'').

even though it claimed that it had refused to fill prescriptions because the refill was too soon, the ''scripts [we]re questionable,'' or were for an extremely large quantity.

As for whether it filled prescriptions written by out-of-state or out-of-area doctors, Respondent's employee noted ''no. She's in South Florida; if someone comes from N. Florida she wouldn't or if they came from the west coast they wouldn't.'' *Id.* Unclear is whether this answer was referring to the location of the prescriber or the persons presenting the prescriptions. Moreover, as for whether the PIC would fill prescriptions for out-of state patients, Respondent's employee noted that the PIC would fill ''only if they are visiting or on vacation.'' *Id.*

The final question on the form asked if ''the pharmacy practice[d] due diligence on specific prescribers.'' *Id.* Respondent's employee wrote: ''They practice due dilligence [sic] on all prescribers.'' *Id.* No further explanation was provided as to what Morrison's due diligence involved.

Thereafter, during the month of April 2009, Respondent filled numerous orders placed by Morrison's for oxycodone products which totaled 171,700 du of oxycodone 30; 37,200 du of oxycodone 15; 6,400 du of Endocet 10/325; 400 du of Endocet 10/650; 500 du of oxycodone 5/325; 300 du of oxycodone 80 mg; and 1,300 du of oxycodone 40 mg. GX 10F, at 22–24. During this month alone, Respondent shipped to Morrison's orders totaling 217,800 du of oxycodone.

On May 6, 2009, Respondent obtained a UR which showed Morrison's dispensings during the period of January 1, 2009 to May 6, 2009 but covered only the top 100 drugs dispensed. RX 2G, at 101–03. Oxycodone 30 was the top drug dispensed, with 1,868 prescriptions totaling 335,895 du, an average of 81,726 du per month [149] and 180 du per prescription. *See id.* at 101–2 (line entries #s 1 & 80). Moreover, oxycodone 15 was the second largest drug dispensed by quantity, with 882 prescriptions totaling 79,991 du, an average of 19,463 du per month and 90.7 du per prescription. *Id.* at 101. Thus, Respondent's April distributions of oxycodone 30 were more than double Morrison's average monthly dispensings of the drug, and its April distributions of oxycodone was nearly two times (1.9) Morrison's average monthly dispensings. Yet there is no evidence that Respondent contacted Morrison's and questioned the orders, and Respondent did not report any of the orders as suspicious.[150]

Throughout May 2009, Respondent filled numerous orders totaling 141,200 du of oxycodone 30; 10,800 du of oxycodone 15; 9,300 of Endocet 10/325; 1,000 du of Endocet 10/650; 500 du of oxycodone 5/325; 700 du of oxycodone 40; and 300 du of oxycodone 80. GX 10F, at 22–25. In total, Respondent shipped 163,800 du of oxycodone products to Morrison's during the month. Here again, Respondent's shipments of oxycodone 30 exceeded Morrison's monthly average dispensings (according to the previous UR) by a substantial margin, *i.e.,* more than 59,000 du or more than 76 percent. Once again, there is no evidence that Respondent contacted Morrison's regarding its oxycodone 30 orders—all of which were placed over the course of three days (May 26–28), GX 10F, at 22; and questioned the orders. Nor did it report the oxycodone 30 orders as suspicious.

In June 2009, Respondent filled orders totaling 81,600 du of oxycodone 30; 39,900 du of oxycodone 15; 14,300 du of Endocet 10/325; 1,000 du of Endocet 10/650; 400 du of oxycodone 80; and 300 du of oxycodone 40. GX 10F, at 22–25. While these orders, which totaled 137,500 du, marked a reduction from the total amount Respondent had filled for Morrison's in the previous months, the pharmacy's oxycodone 15 orders were still more than double the amount of its average monthly dispensings of the drug according to the previous UR.

In July 2009, Respondent filled numerous orders totaling 141,300 du of oxycodone 30; 48,000 du of oxycodone 15; 9,100 du of Endocet 10/325; 1,200 du of Endocet 10/650; 700 du of oxycodone 80; and 200 du of oxycodone 40. GX 10F, at 22–25. Morrison's oxycodone orders thus totaled 200,500 du. As was the case two months earlier, Morrison's orders for oxycodone 30 were 61,000 du (76 percent) greater than its average monthly dispensings of the drug per the existing UR, and its orders for oxycodone 15 were nearly 2.5 times larger than its average monthly dispensings of the drug. Here again, there is no evidence that Respondent inquired as to why Morrison's was ordering these quantities. Moreover, Respondent failed to file a suspicious order report for any of the oxycodone 30 and 15 orders.

Through the first 17 days of August 2009, Respondent filled orders totaling 101,600 du of oxycodone 30; 39,600 oxycodone 15; 4,300 du of Endocet 10/325; 900 du of Endocet 10/650; 500 du of Endocet 5/325; 400 du of oxycodone 80; and 300 du of oxycodone 40. GX 10F, at 22–26. These orders totaled 147,600 du.

In contrast to the orders that were placed between April 1 and July 31, 2009, there are SOMS notes for these orders, including several entries indicating that the orders were reviewed prior to shipping. GX 23, at 151. Specifically, there is a SOMS note for an order placed on August 5, 2009 (on this date 13,200 du of oxycodone 30 and 4,800 du of oxycodone 15 were shipped) which lists Ms. Seiple as the decision-maker and states: ''ok to ship UR supports order.'' GX 23, at 151.

Of note, there is no documentation that Ms. Seiple contacted Morrison's to obtain an explanation for the order which she then independently verified. Moreover, Respondent did not obtain a new UR until August 17. RX 2G, at 10–28.

Likewise, while the SOMS notes indicate that the oxycodone orders that Morrison's placed on August 11 and 12 were subject to review, the notes indicate that orders were released because they were under the current size limit.[151] GX 23, at 151. Here again, there is no evidence that Respondent contacted Morrison's and obtained an explanation for the orders. So too, while the SOMS notes indicate that the oxycodone orders Morrison's placed on August 13 and 14 were also subject to review, the accompanying explanations for why the orders were released merely state: ''Ok to ship reviewed by jss'' and ''ok to ship per jss.'' *Id.* Here again, there is no evidence that Respondent

[149] The average was calculated by adding the total days of the report through May 5 (125) and dividing it by the average number of days in a month in a non-leap year (30.41); the total dispensings were then divided by this figure (4.11) to determine the average monthly dispensings.

[150] As noted repeatedly, Respondent frequently used the URs to justify the release of orders, reasoning that if an order was less than the amount shown to have been dispensed, it was supported by the UR and was ''ok to ship.'' This, however, was not the case with Morrison's.

[151] Of note, Respondent's Policy 6.2, which set forth the procedures for the review and disposition of those orders which were held by the SOMS, did not distinguish between the various reasons why an order was held. Thus, whether an order was held because it was of an unusual size, it deviated substantially from a normal pattern, or the orders were of unusual frequency, the same procedure of calling the customer and obtaining an explanation for the order, which was independently verified, followed by requesting a UR, was required by its Policy.

Policy 6.2 was revised on August 14, 2009 though the manner in which it was revised is unclear on the record. Even so, it is obvious that Morrison's orders were greatly in excess of the amounts its most recent UR (which was then three months old) showed were being dispensed on a monthly basis. Yet this did not prompt Respondent's compliance department to even obtain an explanation for the orders, let alone a new UR, before shipping the orders.

contacted Morrison's and obtained an explanation for the order or a new UR. Yet Respondent's SOMS materials state that ''a [r]eason code and notes will also be provided as additional detail supporting the decision'' whether to accept or reject an order. RX 78, at 64.

As found above, on August 17, a DEA Diversion Investigator specifically identified Morrison's as one of Respondent's customers whose oxycodone orders were of concern. Tr. 217–18 (testimony of DI); *id.* at 1154–55 (testimony of former employee); GX 48A, at 5; GX 12, at 23. The same day, Respondent obtained a new UR, which showed Morrison's dispensings of some 836 prescription products during July 2009. RX 2G, at 10–28. The UR showed that Morrison's had dispensed 1,006 prescriptions totaling 196,069 du of oxycodone 30, an average of 195 du per prescription, and 576 prescriptions totaling 63,658 du of oxycodone 15, an average of 110.5 du per prescription. *Id.* at 11. Here too, the UR showed that such highly abused drugs as alprazolam 2 mg (more than 39,700 du), Endocet 10/325, methadone, and carisoprodol were the largest drugs dispensed by quantity. *Id.*

The next day, Morrison's placed orders for 8,400 du of oxycodone 30; 1,200 oxycodone 15; 300 Endocet 10/325; and 200 methadone. RX 2G, at 9. The same day, Respondent placed Morrison's on compliance hold. GX 23, at 150. According to an entry in the MFRs, on August 20, 2009, Respondent deleted Morrison's August 18 orders and terminated it as a controlled substances customer. RX 2G, at 8. However, Respondent did not report these four orders as suspicious.

In her declaration, Ms. Seiple offered the same explanations as to why Respondent failed to report Morrison's orders as suspicious as she did with the previous pharmacies. For example, she asserted that because Morrison's provided a copy of its written policies and procedures to prevent diversion, Respondent believed that the pharmacy understood its obligation to prevent diversion. RX 103, at 69–70. Next, she asserted that because Morrison's PIC explained that the pharmacy's ''business model included servicing a nearby nursing home and an in-patient facility, . . . filling prescriptions for a large number of elderly patients who lived in a nearby residential area,'' as well as ''prescriptions for patients of pain management clinics,'' this ''accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* at 70.

As before, Respondent did not inquire further into the number of residents at the nursing home who were receiving prescriptions for oxycodone 30. Nor did it even inquire into the type of treatment being provided at the aforesaid ''inpatient facility,'' the number of patients, and the number of patients who were receiving oxycodone prescriptions. So too, Respondent made no inquiry into the number of elderly patients who were receiving oxycodone 30. Thus, these factors do not account for the volume of pain medications being dispensed and the percentage of oxycodone dispensed relative to other drugs.

As for the lengthy list of pain management doctors which Morrison's PIC provided to Respondent, this may well account for the large volume of pain medications being dispensed and the percentage of oxycodone dispensed relative to other drugs. However, here again, notwithstanding that Morrison's was dispensing more than 250,000 du of oxycodone 30 per month, Respondent conducted no further inquiries into the physicians' licensure status and whether they had any specialized training or board certification in pain management. Moreover, several physicians on this list were also customers of Respondent who were terminated at various points prior to April 1, 2009. *Compare* RX 2G, at 148–49, *with* RX 62, at A2–A3 (Drs. Moulton Keane, Martin E. Hale, Joseph M. Ossorio, Gerald J. Klein, and Lucien Armand). Thus, the fact that Morrison's provided this list does not establish that its dispensings of oxycodone were consistent with legitimate medical purposes.

Next, Ms. Seiple asserted that ''after Morrison's account was approved, [the] SOMS systems identified and held any orders for controlled substances placed by Morrison's that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 70. As found above, Respondent filled numerous oxycodone orders from April 1 through July 31, 2009, and on multiple occasions, Morrison's monthly orders were far in excess of what the most recent UR showed it was dispensing on a monthly basis. These orders clearly were not held by the SOMS, because the SOMS was not yet operational. Nor is there any evidence that these orders were reviewed. And the orders were not reported to DEA even though they deviated substantially in terms of their size and were clearly suspicious.

As for the orders that Morrison's placed during August 2009, there are SOMS notes for several of them indicating that the orders were held for review. However, the notes show that some of the orders were released without the compliance department obtaining an explanation for the orders from the pharmacy, and others were released without documenting the reason for releasing the order. Of note, in her declaration, Ms. Seiple only asserted that the orders were reviewed and made no claim that the Compliance Department contacted Morrison's and obtained an explanation for the orders, which it then verified. *Id.*

Ms. Seiple acknowledged that Respondent continued to sell oxycodone to Morrison's until the DIs ''inadvertently revealed during the August 2009'' meeting that the Agency was investigating the pharmacy and ''the account was then placed on non-controlled status.'' *Id.* at 72. She then asserted that Respondent ''did not report a suspicious order placed by Morrison's because no order was pending at that time.'' *Id.*

However, as found above, the day after Morrison's was identified by the DIs (whether as a customer whose orders should be of concern or as a target of an investigation), Morrison's placed four orders for nearly 10,000 du of oxycodone (most of which was for the 30 mg tablets), as well as methadone. Yet none of these orders were reported, and while Ms. Seiple deleted the orders, this does not refute the fact that Morrison's placed the orders and Respondent failed to report them.[152]

[152] I acknowledge that the ALJ found Ms. Seiple's testimony credible and clearly gave it substantial weight. However, much of Ms. Seiple's testimony is either amply refuted by the extensive documentary evidence of record or is unresponsive to other evidence. Accordingly, I decline to give it substantial weight for reasons which should be evident by now. *See Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951) (''The findings of the [ALJ] are to be considered along with the consistency and inherently probability of testimony. The significance of [her] report, of course, depends largely on the importance of credibility in the particular case.'').

For example, in discussing Superior Pharmacy, Ms. Seiple asserted that during the June 2008 inspection, its pharmacist explained that its business model including filling prescriptions for . . . a weight loss and pain management facility *located in an adjacent office.''* RX 103, at 73 (emphasis added). Yet the 2008 inspector's report clearly stated that ''[t]he pharmacy is located within a space that it shares with Superior Medical Center,'' RX 2F, at 70; and the January 11, 2010 inspection report noted that: ''A Pain Mgmt doctor in the same place of business,'' as well as that the pharmacy was located ''in a strip mall w/a Pain Clinic inside the pharmacy.'' *Id.* at 24. So too, photographs in Superior's due diligence file show that the pharmacy and clinic used the same waiting area and that the counters for the pharmacy and clinic were only feet apart.

Ms. Seiple further mischaracterized the evidence when she asserted that Respondent ''has never

Continued

Respondent's Other Evidence

Respondent elicited the testimony of Joanna Shepherd-Bailey, Ph.D., who testified as an expert in statistics. Tr. 1576–77. Ms. Shepherd-Bailey testified that she reviewed Respondent's monthly oxycodone shipments to each of its Florida pharmacy customers for the period of April 2009 through July 2011 and prepared charts which compare the monthly shipments to the seven pharmacies at issue (which are represented by red dots) with the monthly shipments to all of Florida pharmacy customers (which are represented by blue dots). RX 102, at 7; *see also* RX 69–75. According to Ms. Shepherd-Bailey, the charts show that the ''shipments to the DEA-identified pharmacies rarely stand out from the rest of the monthly shipments'' and that ''for many of the months, shipments to the DEA-identified pharmacies are squarely in the mid-range of monthly shipments.'' RX 102, at 7. Ms. Shepherd-Bailey also testified that she prepared a Z-score analysis to determine the extent to which the monthly shipments to the seven pharmacies were atypical when compared to the rest of the shipments. *Id.* According to Ms. Shepherd-Bailey, her analysis ''confirms that most of the monthly shipments to the [seven] pharmacies do not stand out as atypical'' and that ''fewer than half of the monthly shipments to the [seven] pharmacies are statistically significant at the 0.05 significance level.'' *Id.* Ms. Shepherd-Bailey thus concluded that Respondent's ''shipments to the [seven] pharmacies did not stand out as unusually large'' and that ''the shipment volume to [them] would not have appeared extraordinary to'' Respondent. *Id.*

However, to the extent this evidence was offered to refute the allegation that Respondent failed to report suspicious orders, I find it unpersuasive for several reasons. First, the analysis ignores the significant information obtained by Respondent with respect to each of the seven Florida pharmacies. Second, there is no evidence that Respondent's compliance department ever conducted a similar analysis during the course of its dealings with the pharmacies. Third, in determining whether a pharmacy's order was of unusual size, Respondent's SOMS did not compare the order with those of other pharmacies but compared the order only to the customer's previous orders. Fourth, because the analysis was based only on the shipments made to Respondent's Florida customers during the acknowledged oxycodone epidemic in the State to the exclusion of its shipments to customers in other States, I conclude that the analysis suffers from selection bias. Finally, even ignoring the selection bias, in some instances, the charts show that the shipments to several of the pharmacies were among the highest monthly shipments. *See* RX 71 (shipments to Englewood); RX 74 (shipments to Morrison's).

Respondent also submitted for the record copies of numerous suspicious order reports it filed with DEA.[153] *See* RX 61A–C. However, these reports were in the numerical format used to submit them to the Agency and Respondent offered no evidence explaining the circumstances giving rise to the decision to file the reports. Moreover, as to the pharmacies at issue in this proceeding, it is undisputed that Respondent filed only a single suspicious order report, that being upon its termination of The Drug Shoppe for ordering alprazolam. *See* GX 40, at 14; RX 103A, at 47.

Respondent also entered into evidence copies of lists it had previously submitted to DEA of those customers it terminated. However, a former member of Respondent's compliance department testified that in his opinion, ''the customers who were easily suspended or terminated from purchasing controlled substances from [it] were not the big money accounts.'' GX 52, at 7. (Decl. of Eric Schulze).

As to whether Respondent acknowledges any misconduct and has undertaken any remedial measures, Respondent stipulated that it:

> does not accept responsibility for any alleged wrongdoing in this matter. Furthermore, any evidence presented by [it] of changes, modifications or enhancements [it] made to its internal Policies and Procedures in the ordinary course of business, on its own accord, or based on alleged guidance or communications from the [DEA] does not constitute evidence of remedial measures. This stipulation is binding during the administrative hearing before DEA as well as any appellate litigation that may occur after a Final Order is issued by the Administrator.

ALJ Ex. 8.

Discussion

The Public Interest Analysis

Section 304(a) of the Controlled Substances Act (CSA) provides that ''[a] registration . . . to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 . . . inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). With respect to an entity registered to distribute controlled substances in schedules I or II, Congress directed that the following factors be considered in making the public interest determination:

> (1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, or industrial channels;
>
> (2) compliance with applicable State and local law;
>
> (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (4) past experience in the distribution of controlled substances; and
>
> (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(b). These factors are considered in the disjunctive. I may rely

cancelled, deleted, or edited orders to bring customers within their controlled substance limit . . . to make suspicious orders appear non-suspicious, or to otherwise thwart review by the Compliance Department.'' RX 103, at 13. However, as found above, Respondent repeatedly engaged in these practices and Ms. Seiple offered no alternative explanation for why Respondent deleted and edited those orders that were held by the SOMS, especially those which placed a pharmacy over its CSL.

Also, with respect to each of the pharmacies, Ms. Seiple asserted that ''after [the respective pharmacy's] account was approved, the SOMS identified and held any order for controlled substances . . . that deviated from its typical volume, pattern or frequency.'' *See, e.g., id.* at 54. However, the SOMS was not even operational during the months of April through July 2009, and yet Respondent filled numerous oxycodone orders during this period placed by each of the pharmacies while failing to report them as suspicious.

The ALJ also gave weight to Ms. Seiple's testimony ''that orders held by SOMS for each of the . . . pharmacies in question were not shipped until reviewed and approved by the Compliance Committee.'' R.D. 172 (other citations omitted). The issue, however, is not simply whether the orders were reviewed and approved, but whether the compliance department investigated those orders that were held by the SOMS, by obtaining an explanation for the order which it then verified. Ms. Seiple's testimony is simply unresponsive to the evidence which shows that, with respect to nearly every order discussed above, Respondent failed to contact the pharmacy and obtain an explanation for the order which it then independently verified. Also, as found above, the evidence shows that, in several instances, oxycodone orders were still shipped, notwithstanding that the pharmacy's account had been placed on compliance hold and was to be reviewed by the compliance committee.

Finally, as for Ms. Seiple's testimony that based on its due diligence, Respondent determined that the orders placed by each of the pharmacies were not suspicious notwithstanding the information it had obtained as to the volume of oxycodone and the percentage of controlled to non-controlled drugs being dispensed, as explained above, I give little weight to her testimony.

[153] As discussed previously, in its Exceptions, Respondent sought a finding that ''[a]s of August 18, 2009, [it] had detected and reported to DEA suspicious orders of controlled substances after April 1, 2009.'' Resp. Exceptions, at 18. However, the earliest suspicious order reports contained in the Exhibit it submitted are dated August 6, 2009. RX 61A, at 1.

on any one or a combination of factors and give each factor the weight I deem appropriate in determining whether to revoke a registration or to deny a pending application for renewal of a registration. *See Green Acre Farms, Inc.,* 72 FR 24,607, 24,608 (2007); *ALRA Laboratories, Inc.,* 59 FR 50,620, 50,621 (1994). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

The Government bears the burden of proving that Respondent's continued registration would be inconsistent with the public interest. 21 CFR 1301.44(e). Where, however, the Government establishes a *prima facie* case, the burden shifts to Respondent to show why its continued registration would not be inconsistent with the public interest. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62,315, 62,323 (2012); *Southwood Pharmaceuticals, Inc.,* 72 FR 36,487, 36,502 (2007).

In this case, the Government contends that the evidence with respect to factors one, four and five establishes that Respondent's continued registration would ''be inconsistent with the public interest.'' 21 U.S.C. 823(b). The ALJ, however, rejected nearly the entirety of the Government's case, including its allegations that Respondent repeatedly failed to obtain an explanation for orders that were held by the SOMS, and found that the Government has proved only that Respondent had failed to report a single suspicious order, that being an order placed by Englewood Specialty Pharmacy the day before it was terminated as a customer. As noted in the discussion of the procedural history, both parties also filed extensive exceptions to the ALJ's legal conclusions. To the extent their contentions have not been previously addressed, they are discussed below where applicable.

Factors One and Four—Maintenance of Effective Controls Against Diversion Into Other Than Legitimate Channels and Past Experience in the Distribution of Controlled Substances

Pursuant to 21 CFR 1301.71(a), ''[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.'' This regulation further directs that ''[i]n order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.'' 21 CFR 1301.71(a).

At issue here is Respondent's compliance with the requirements pertaining to the detection and reporting of suspicious orders which are found at 21 CFR 1301.74(b). This regulation provides:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Id. at 1301.74(b).

The parties dispute the scope of this regulation. More specifically, Respondent contends that ''suspicious orders are only those [orders] that are of an unusual size, that deviate substantially from a normal pattern, or which are of an unusual frequency.'' Resp. Exceptions, at 3 n.1. It argues that the regulation's use of the word ''include'' was intended to limit the scope of the regulation to the three enumerated categories. *Id.* at 24–27. As support for its contention, Respondent points to the draft of the regulation as published in the 1971 Notice of Proposed Rulemaking, which provided that ''suspicious orders may include, but are not limited to'' the three categories, and argues that the rule was subsequently amended to its present text to provide the industry with ''greater predictability and clarity with respect to the security requirements (including the definition of 'suspicious order' ''). *Id.* at 28–29. And finally, it asserts that the ALJ's reading of the regulation—as simply setting forth three non-inclusive examples of what constitutes a suspicious order—violates due process by failing to provide fair warning ''of what constitutes a suspicious order, or when a report is required of a registrant.'' *Id.* at 30–31.

I reject Respondent's contentions. As the ALJ recognized, the Supreme Court has explained that ''the term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle.'' *Federal Land Bank of St. Paul* v. *Bismarck Lumber Co.,* 314 U.S. 95, 100 (1941) (citing *Phelps Dodge Corp.* v. *NLRB,* 313 U.S. 177, 189 (1941)).[154] *See also Dong* v. *Smithsonian Institution,* 125 F.3d 877, 880 (D.C. Cir. 1997) (citing *Federal Land Bank*) (''the word 'includes' normally does not introduce an exhaustive list but merely sets out examples of some 'general principle' ''). Indeed, ''this interpretation fits with common dictionary definitions and examples.'' *DIRECTV Inc.* v. *Budden,* 420 F.3d 521, 527–28 (5th Cir. 2005) (discussing definitions given by The American Heritage Dictionary of the English Language (1976) and Webster's Third New World Dictionary (1961)). *See also* Black's Law Dictionary 831 (9th ed. 2009) (defining ''include'' as meaning ''[t]o contain as a part of something • The participle *including* typically indicates a partial list'').

Nor do I attribute any significance to the alteration of the regulation's text between the Notice of Proposed Rulemaking and the Final Rule. As Black's explains, ''some drafters use phrases such as *including without limitation* and *including but not limited to*— which mean the same thing'' as ''including.'' *Id.* While it is true that the **Federal Register** notice which promulgated the final rule states that ''[m]any manufacturers and distributors objected to security controls set forth in §§ 301.92 to 301.97'' and that ''[m]ost of these paragraphs have been revised to meet the objections filed,'' 36 FR 7776, 3776 (1971), these provisions imposed numerous other security requirements. Thus, this statement is too general to conclude that the drafters of the suspicious order reporting rule intended to depart from the common accepted meaning of the term ''include'' and instead set forth a limit on the scope of the rule.

Moreover, limiting the scope of suspicious orders to only those orders which are of unusual size, deviate substantially from a normal pattern, or are of unusual frequency would have ill-served the CSA's purpose of preventing the ''illegal . . . distribution, . . . possession and improper use of controlled substances.'' 21 U.S.C. 801(2). Under Respondent's view, even if it had acquired actual knowledge (let alone developed a suspicion) that a customer was ordering controlled substances from it for the purpose of diverting them, it would have no obligation to report the order as long as the order was of a usual size, did not deviate substantially from the customer's normal ordering pattern, or was consistent with the usual frequency of the customer's orders. But even orders that do not fall within the three categories set forth in 21 CFR 1301.74(b) can be diverted. Thus, I agree with the ALJ's reasoning ''that a pharmacy's

[154] Respondent distinguishes *Federal Land Bank of St. Paul* v. *Bismarck* on the ground that ''in *Bismarck* there was a 'general principle' to apply, and the Court interpreted the word 'including' consistent with that principle.'' Resp. Exceptions, at 25. This argument goes nowhere because there is also a ''general principle'' to apply here, that being the duty to report suspicious orders.

business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency.'' R.D. at 154.

Nor do I find persuasive Respondent's contention that construing the regulation as encompassing orders that are suspicious by virtue of circumstances other than those of size, pattern, or frequency denies it fair warning.[155] The regulation requires a distributor to report suspicious orders, and those who participate in a highly regulated industry such as the distribution of prescription controlled substances should know that one of the CSA's core purposes is to prevent prescription drug abuse and the diversion of drugs to persons who seek to abuse them.

As the Supreme Court explained in *United States* v. *Moore,* 423 U.S. 122 (1975), ''Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.'' *Id* at 135 (citations omitted). *See also* 21 CFR 1306.04(a) (''A prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.''); *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (explaining that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'').

Thus, viewed in light of the CSA's purpose of preventing drug abuse and diversion, ''a person of ordinary intelligence [has] fair notice of what'' the regulation requires. *FCC* v. *Fox Television Stations, Inc.,* 132 S.Ct. 2307, 2309 (2012) (quoting *United States* v. *Williams,* 553 U.S. 285, 304 (2008)); *see also General Elec. Co.* v. *EPA,* 53 F.3d 1324, 1329 (D.C. Cir. 1995) (''If, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expect parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation.'') (citing *Diamond Roofing Co.* v. *OSHRC,* 528 F.2d 645, 649 (5th Cir. 1976).

Construing the regulation as requiring the reporting of an order, when circumstances other than the order's size, pattern, or frequency render the order suspicious, is fully encompassed by the regulation's text. *Cf. Pennsylvania Dept. of Corrections* v. *Yeskey,* 524 U.S. 206, 212 (1998) (''[T]he fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.'') (internal quotations and citations omitted). It is also supported by the Agency's public statements, including its administrative precedents. *See Southwood Pharmaceuticals, Inc.,* 72 FR 36,487 (2007).

Based in part on the ALJ's conclusion that she was bound by the interpretation of 21 CFR 1301.74 given by the Deputy Assistant Administrator in his December 2007 letter, R.D. at 154, Respondent argues that the various statements contained in ''these letters . . . impose substantive and binding requirements on DEA registrants'' and therefore cannot be enforced absent their promulgation through notice and comment rulemaking.[156] Resp. Exceptions, at 32; *see also id.* (''Ironically, the ALJ's recognition of the Rannazzisi Letters as binding on Masters and on herself—in this and in future cases—cements their status as *illegally promulgated* substantive rules.'').

It is true that the ALJ deemed herself to be bound by the position taken in the 2007 letter issued by the Deputy Assistant Administrator of the Office of Diversion Control. R.D. at 154 (''I am without authority to reject a position the Agency has taken on a matter of law. This is true even where the Agency's position is announced by means other than the formal adjudication process.''). In support of her conclusion, the ALJ cited *CropLife America* v. *EPA,* 329 F.3d 876 (D.C. Cir. 2003), a case involving EPA's decision to cease considering third-party human studies in evaluating the safety of pesticides, which was announced in a letter and press release. In a parenthetical, the ALJ set forth her understanding of *CropLife* as standing for the proposition ''that an ALJ does not have authority to ignore an Agency position announced in a press release.'' R.D. at 154.

While in *CropLife,* the D.C. Circuit rejected the EPA's argument that its ALJs could nonetheless ''rule on particular third-party human studies,'' it noted that the directive ''says no such thing'' and that the EPA Administrator's ''statement prohibiting the agency from considering such studies'' was ''unequivocal.'' 329 F.3d at 882. Indeed, contrary to the ALJ's understanding (in this matter), in rejecting the EPA's contention that the position was merely a policy statement and not a binding regulation, the D.C. Circuit did not rest on the fact that the position was taken in a press release but on the agency's intent to ''create[ ] a '' 'binding norm' '' that is '' 'finally determinative of the issues or rights to which it [was] addressed.' '' '' 329 F.3d at 881 (quoting *Chamber of Commerce* v. *U.S. DOL,* 174 F.3d 206, 212 (D.C. Cir. 1999) (quoting *Pacific Gas & Elec. Co.* v. *FPC,* 506 F.2d 33, 38 (D.C. Cir. 1974))). As the D.C. Circuit noted, the press release had stated that ''the [EPA] *will not consider* or rely on any [such] human studies in its regulatory decision making.'' *Id.* (emphasis added). Thus, the court concluded that ''EPA has enacted a firm rule with legal consequences that are binding on both petitioners and the agency, and petitioners will be afforded no additional opportunity to make the arguments to the agency that they now present in this petition.'' *Id.* at 882.[157]

[155] Of note, Respondent's Policy 6.2 states that ''[a]ll orders that have been held for review that Masters does not fill for the reasons set out in Section III(b)(ii), above, shall be considered 'Suspicious Orders' according to 21 CFR 1301.74(b) and reported to the'' DEA. RX 78, at 33. Among the reasons listed are that ''[t]he customer's file, including survey responses and site visits, indicates that the customer may be engaged in inappropriate business practices, [or] [t]he customer refuses to provide Masters with the information necessary to complete its evaluation.'' *Id.* Unexplained by Respondent is why evidence that a customer may be engaged in inappropriate business practices becomes relevant to the determination of whether an order is suspicious only if that order triggers a SOMS hold.

[156] It should be noted that the ALJ actually only relied on the 2007 letter, and not the earlier letter of September 27, 2006. R.D. at 154. The latter set forth multiple examples of characteristics present in the ordering patterns of ''pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose.'' GX 3, at 3. It also suggested a number of questions that a distributor should ask a pharmacy customer in ''determin[ing] whether a suspicious order is indicative of diversion.'' *Id.* The letter then advised that the questions were ''not all-inclusive'' and that ''the answer to any of these questions'' would not necessarily be determinative of ''whether a suspicious order is indicative of diversion.'' *Id.*

[157] So too, in rejecting EPA's contention that the press release was only a policy statement and thus not subject to judicial review, the court examined both ''the effects of the [EPA's] action'' and the EPA's ''expressed intentions.'' 329 F.3d at 883 (citing, *inter alia, Cmty. Nutrition Inst.* v. *Young,* 818 F.2d 943, 946 (D.C. Cir. 1987) and *Molycorp., Inc.* v. *EPA,* 197 F.3d 543, 545 (D.C. Cir. 1999)). The

The ALJ did not analyze whether the Rannazzisi letters were intended to, or even could, have binding effect in this proceeding. However, a review of the letters shows that they were not intended to have binding effect but were simply warning letters.

The 2007 letter, which primarily discussed the obligation to report suspicious orders, also noted that ''registrants that routinely report suspicious orders, yet fill these orders without first determining that [the] order is not being diverted into other than legitimate medical, scientific, and industrial channels, *may* be failing to maintain effective controls against diversion.'' GX 4, at 2 (emphasis added). Continuing, the letter stated: ''[f]ailure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. 823 and 824, *and may result in the revocation of the registrant's DEA Certificate of Registration.'' Id.* (emphasis added). Contrary to the ALJ's understanding, this simply is not language that manifests an intent to bind the Agency.

Nor is the 2006 letter fairly read as manifesting an intent to bind the Agency. While the letter notes that ''in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate . . . channels,'' the letter then explains that the ''[f]ailure to exercise such due diligence *could, as circumstances warrant,* provide a statutory basis for revocation or suspension of a distributor's registration.'' GX 3, at 2 (emphasis added).

Moreover, that an official vested with prosecutorial authority issues a letter advising entities that he views certain conduct as violative of a regulation or as conduct which is ''inconsistent with the public interest,'' does not establish that those entities are foreclosed from challenging that interpretation in any subsequent proceeding. Indeed, under the Department of Justice's regulations, the ultimate authority to determine the meaning of DEA's regulations, as well as whether certain conduct is ''inconsistent with the public interest,'' is vested in the Office of the Administrator and Deputy Administrator. *See* 28 CFR 0.100(b) & 0.104 (Appendix to Subpart R of Part O—Redelegation of Functions);[158] *see also Jeffery J. Becker,* 77 FR 72,387, 72,388–91 (2012) (rejecting Government's interpretation of Agency disposal rule); *Edmund Chein,* 72 FR 6580, 6593 (2007) (rejecting Government's interpretation of rule requiring that electronic records be readily retrievable). However, while the ALJ erred in deeming herself to be bound by the letters, I conclude that her error was non-prejudicial.

Respondent further argues that the letters do not ''merely restate or interpret obligations already present in the regulations,'' but rather ''supplement DEA regulations with additional and burdensome obligations on registrants'' and ''represent[s] a fundamental change to the regulations.'' Resp. Exceptions, at 33 (citing *Syncor Int'l. Corp.* v. *Shalala,* 127 F.3d 90, 96 (D.C. Cir. 1997) and *Paralyzed Veterans of Amer.* v. *DC Arena,* 117 F.3d 579, 586 (D.C. Cir. 1997)). Thus, it argues that the Agency was required to announce the positions taken in the letter by engaging in notice and comment rulemaking. Respondent's argument is not well taken.

At issue in *Syncor* was the FDA's decision to supersede earlier guidelines which ''unequivocally stated that nuclear pharmacists who operated an accelerator to produce radioactive drugs to be dispensed under a prescription . . . were not required to register under [Section] 510 of the Food, Drug, and Cosmetic Act.'' 127 F.3d at 93. The earlier guidelines also stated ''that if a nuclear pharmacist was not required to register,'' other requirements of the FDCA, ''including the new drug provision and compliance with current good manufacturing practices, would not apply.'' *Id.* However, more than ten years later, the FDA issued a ''Notice,'' which the Agency alternatively referred to in its text as ''guidance'' and as a ''policy statement.'' *Id.* at 92. Therein, the FDA stated that manufacturers of these drugs were required to comply with several of the FDCA's provisions, including those pertaining to adulteration, misbranding, new drugs, and registration listing of all drugs it manufactured. *Id.*

The *Syncor* court rejected the FDA's contention that the Notice was merely an interpretive rule, explaining that the Notice ''does not purport to construe any language in a relevant statute or regulations; it does not interpret anything. Instead, FDA's rule uses wording consistent only with the invocation of its general rulemaking authority to extend its regulatory reach.'' *Id.* at 95. The court specifically noted the FDA's statement that '' 'having considered the available information, including that presented to the agency at the hearing and in written materials, FDA has *concluded* that radiopharmaceuticals *should be regulated* under the provisions of the Federal Food, Drug, and Cosmetic Act.' '' *Id.* And the court also noted that in issuing the earlier guidelines, FDA had ''made a careful, considered decision not to exercise the full extent of its regulatory authority . . . over nuclear pharmacies in 1984,'' and that the agency had previously said that '' 'where the nuclear pharmacy is operating within applicable local laws regulating the practice of pharmacy and only prepares and dispenses a radioactive drug upon receipt of a ''valid prescription,'' the pharmacy exemption [of section 510(g)(1)] clearly applies.' '' *Id.* (quoting FDA, Nuclear Pharmacy Guideline; Criteria for Determining when to Register as Drug Establishment (1984)).

In *Syncor,* the court further explained that a policy statement ''merely represents an agency position with respect to how it will treat—typically enforce—the governing legal norm. By issuing a policy statement, an agency simply lets the public know its current enforcement or adjudicatory approach. The agency retains the discretion and authority to change its position—even abruptly—in any specific case because a change in its policy does not affect the legal norm.'' *Id.* at 94.

Thus, *Syncor* provides no support for Respondent. As for its contention regarding the scope of what constitutes a suspicious order,[159] no decision of

court concluded that ''there is little doubt that the directive in the . . . Press Release 'binds private parties [and] the agency itself with the ''force of law,''' and thus constitutes a regulation,'' because it ''clearly establishes a substantive rule declaring that third-party human studies are now deemed immaterial in EPA regulatory decisionmaking.'' *Id.* (quoting *General Elec. Co.* v. *EPA,* 290 F.3d 377, 382 (D.C. Cir. 2002)).

[158] While Section 7 of the Appendix authorizes the Deputy Assistant Administrator ''to exercise all necessary functions with respect to the promulgation and implementation of'' regulations related to the Diversion Control Program, it further provides ''that final orders in connection with suspension, denial or revocation of registration shall be made by the Deputy Administrator of DEA.''

[159] The breadth of Respondent's contention is not entirely clear. More specifically, it takes issue with the ALJ for ''reiterat[ing] the conclusion that the regulatory criteria that define a suspicious order . . . 'are disjunctive and are not all inclusive,' '' thus suggesting that it believes that all three criteria must be met for any one order to be suspicious. Resp. Exceptions, at 33 (quoting R.D. at 154). Yet the plain language of the regulation makes clear that these are disjunctive as the word ''orders'' precedes each of the three criteria.

While I reject Respondent's contention that it has not received fair notice that suspicious orders are not limited to the three criteria set forth in the regulation, as explained later, I agree with its contention insofar as the Government contends that

Continued

this Agency has previously interpreted the rule as being limited to only those orders that meet all three criteria. Nor has DEA ever held that suspicious orders are limited only to those orders that meet one of the criteria set forth. Thus, in contrast to *Syncor,* this is not a matter in which DEA has changed its position to impose a new requirement beyond that already required by its regulation.

As for Respondent's reliance on *Paralyzed Veterans,* that case has now been expressly overruled by the Supreme Court on the very proposition for which it is cited by Respondent. *See Perez* v. *Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1206–07 (2015) (''Because an agency is not required to use notice-and-comment procedures to issue an initial interpretative rule, it also is not required to use those procedures when it amends or repeals that interpretive rule.''). As the Supreme Court further recognized in *Perez,* ''[o]ne would not normally say that a court 'amends' a statute when it interprets its text. So too can an agency 'interpret' a regulation without 'effectively amend[ing]' the underlying source of law.'' *Id.* As explained above, the suspicious order regulation requires the reporting of all suspicious orders; notice and comment rulemaking is not necessary to impose liability on Respondent where the evidence shows that it failed to report an order which was suspicious because of the circumstances surrounding a customer's business or dispensing practices.

Respondent also takes issue with the ALJ's discussion of the position taken in the letters that '' ''in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders'' and that the duty to report suspicious orders ''is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.'' '' Resp. Exceptions, at 33–34 (quoting R.D. at 163 n.94 (quoting GXs 3 and 4)).

Respondent, however, misstates the ALJ's reasoning. The ALJ discussed the letters only after noting that, under the DEA regulations and the Agency's decision in *Southwood Pharmaceuticals, Inc.,* ''the duty to maintain effective controls against diversion is separate from the duty to detect and report suspicious orders,'' and that in *Southwood,* the two duties were analyzed ''separately under factor one.'' R.D. at 163 (citing 72 FR at 36,487–98). *See also* 21 CFR 1301.71(a) (''All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.''). The ALJ further explained that under *Southwood,* ''because registrants have a general duty to maintain effective controls against diversion, they may not ignore indicators of diversion simply because they come in forms other than suspicious orders. *Southwood* specifically mentions that this general duty to prevent diversion includes the duty to perform due diligence.'' R.D. at 163 (citing 72 FR at 36,500). The ALJ thus explained that ''Respondent has an ongoing duty to ensure that the controlled substances it distributes are not being diverted by at least performing meaningful due diligence on its customers.'' *Id.* Indeed, it was only in a footnote after her discussion of *Southwood* that the ALJ noted the letters' discussion of the due diligence responsibilities that are part of a distributor's obligation to maintain effective controls against diversion. *See id.* n.94 (''This interpretation of the interplay between the duty to maintain effective controls and the duty to report suspicious orders comports with the guidance the Agency gave to Respondent in 2006 and 2007.'') (citing GXs 3 and 4).

Eventually acknowledging that the Agency's due diligence rule was announced in an adjudication, thus rendering its arguments regarding the effect of the letters irrelevant, Respondent contends that ''reliance on'' Southwood ''not only as a 'basis for this action,' but also through the ALJ Recommendation, is in error.'' Resp. Exceptions, at 37. This is so, Respondent argues, because ''[t]he decision provided little legal precedence'' as ''it relies on [a] 2001 DEA Guidance on internet pharmacies, and its opinion turns on the specific facts presented to the ALJ.'' *Id.* Respondent thus contends that ''[i]f the DEA, including the ALJ[,] wants to apply *Southwood*'s approach in this or future cases, then DEA must amend its binding regulations through the processes set forth in the APA.'' *Id.*[160]

The Supreme Court, however, long ago rejected the contention that an agency must announce all rules it adopts only through notice and comment rulemaking. *See NLRB* v. *Bell Aerospace Co.,* 416 U.S. 267, 290–95 (1974); *SEC* v. *Chenery Corp.,* 332 U.S. 194, 199–204 (1947). Moreover, because the due diligence rule was announced in an adjudication, Respondent was of course, free to argue why the rule should not be applied in this matter as it has here. However, the reasons offered by Respondent for why *Southwood* should not be applied to its conduct are unpersuasive.

As for Respondent's contention that *Southwood* should not be followed because, in that case, the Agency relied in part on the 2001 Guidance Document, Respondent's argument is not entirely clear. Apparently, Respondent's argument is that the 2001 Guidance Document (which was published in the **Federal Register** and provided by DEA personnel to Southwood during a briefing) had set forth the Agency's view as to the potential illegality of dispensing controlled substances via the internet because such prescriptions did not arise out of a valid doctor-patient relationship.[161] Thus, the company had fair notice that the pharmacies to which it was distributing controlled substances were filling unlawful prescriptions. *See* 72 FR at 36,500–01 n. 23.

Yet *Southwood* also noted that during a conference call conducted by a DEA representative with the firm, the DEA representative had discussed several Supreme Court decisions including *United States* v. *Moore* and *Direct Sales Co.,* v. *United States,* 319 U.S. 703 (1943). 72 FR at 36,492. Of note, *Moore* discussed the provisions of both the CSA (and its predecessor, the Harrison Narcotic Act, 38 Stat. 785 (1914)) that prohibit a physician from dispensing controlled substances other than in the course of professional practice. *See* 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a). As for *Direct Sales,* it upheld the conviction of a registered manufacturer and wholesaler for conspiracy to violate the

''pursuant to the regulation, it was the responsibility of the registrant to review controlled substance orders previously shipped to a terminated . . . customer to determine whether those previously shipped orders were in fact suspicious.'' Gov. Br. 126.

[160] Respondent then contends that '' 'an administrative agency may not slip by the notice and comment rule-making requirements needed to amend a rule by merely adopting a *de facto* amendment to its regulation through adjudication.' '' Exceptions, at 37 (quoting *Marseilles Land & Water Co.* v. *FERC,* 345 F.3d 916, 920 (D.C. Cir. 2003). However, *Marseilles Land* involved an ambiguous regulation. Moreover, DEA has not previously interpreted the regulation as limited to only those orders which are of unusual size, deviate substantially from a normal pattern, or are of unusual frequency, and the interpretation is supported by the regulation's plain meaning as well as agency precedent. As the D.C. Circuit has recognized, ''[a]lthough the agency must always provide 'fair notice' of its regulatory interpretations to the regulated public, in many cases the agency's pre-enforcement efforts to bring about compliance will provide adequate notice.'' *General Elec. Co.* v. *EPA,* 53 F.3d 1324, 1329 (D.C. Cir. 1995).

[161] The existence of a valid doctor-patient relationship is a long-standing requirement for establishing that a prescription has been issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *See George Mathew,* 75 FR 66,138, 66,145–46 (2010) (citing cases).

Harrison Narcotic Act by supplying a physician with morphine ''in such quantities, so frequently and over so long a period it must have known he could not dispense the amounts received in lawful practice and was therefore distributing the drugs illegally.'' 319 U.S. at 705.

The *Southwood* decision also noted that the DEA representative had discussed with the firm's management the suspicious order reporting rule, the requirement under the CSA that prescriptions be issued for a legitimate medical purpose in accordance with 21 CFR 1306.04(a), and its obligations to maintain effective controls against diversion. 72 FR at 36,492. The DEA representative also discussed with the firm's management various facts that should be considered in evaluating its customers, including the percentages of controlled to non-controlled drugs dispensed by the typical retail pharmacy (5 to 20 percent controlled versus 80 to 90 percent non-controlled), the typical monthly quantity being purchased by brick and mortar pharmacies of the drug at issue (hydrocodone), the size and frequency of orders, and the range of products ordered by the pharmacy. *See id.* The decision also noted that the DEA representative had specifically identified several of the firm's pharmacy customers as engaged in suspicious activity. *Id.*

Thus, I am unpersuaded by Respondent's suggestion that *Southwood* should not be followed because it involved an entity engaged in distribution to pharmacies that were filling internet prescriptions. Resp. Exceptions, at 3. As *Southwood* makes clear, a distributor's duty to perform due diligence on its customers stems from the requirement that a registrant ''shall provide effective controls and procedures to guard against theft and diversion of controlled substances,'' 21 CFR 1301.71(a), as well as the registration requirements of section 823, which, in the case of a distributor, direct the Agency, in making the public interest determination, to consider the ''maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical . . . channels.'' 21 U.S.C. 823(b); *see also id.* § 823(e).

As for the scope of the duty to perform due diligence, *Southwood* makes clear that doing ''nothing more than verifying a pharmacy's DEA registration and state license'' is not enough. 72 FR 36,498. Rather, a distributor must conduct a reasonable investigation ''to determine the nature of a potential customer's business before it'' sells to the customer, and the distributor cannot ignore ''information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices.'' *Id.* Thus, where, for example, a customer provides information regarding its dispensing practices that is inconsistent with other information the distributor has obtained about or from the customer, or is inconsistent with information about pharmacies' dispensing practices generally, the distributor must conduct ''additional investigation to determine whether [its customer is] filling legitimate prescriptions.'' *Id.* at 36,500. So too, depending upon the circumstances, a distributor may need to perform site visits before it engages in any distribution of controlled substances. Moreover, the obligation to perform due diligence is ongoing throughout the course of a distributor's relationship with its customer. *See generally id.* at 36,498–36,500.

Accordingly, I reject Respondent's exceptions as set forth in pages 23–37 of its Exceptions Brief.

Failure To Report Suspicious Orders

As explained above, I agree with the ALJ that ''a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy which engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious.'' R.D. at 154.

Notwithstanding her conclusion, the ALJ analyzed only four orders placed by the pharmacies on or after April 1, 2009 to determine whether they were suspicious, either because the pharmacy's business model, dispensing patterns, or other characteristics made the orders suspicious, or because the orders were of unusual size, pattern or frequency. *See generally* R.D. at 154–60, 168–70. Rather, her discussion focused primarily on the Government's theory that upon terminating a customer for compliance reasons, Respondent had an obligation to review the customer's prior orders, including those which were shipped, to determine if any of them were suspicious, and if so, report them.[162]

Noting that the regulation requires the reporting of a suspicious order ''when discovered by the registrant,'' the ALJ explained that ''the term 'when discovered' implies a duty to report orders Respondent has actually discovered to be suspicious.'' R.D. at 155 (quoting 21 CFR 1301.74(b)). The ALJ further reasoned that:

> When Respondent releases an order held by SOMS, decides to conduct additional due diligence, and then terminates the customer based on the findings of the investigation, Respondent has in fact ''discovered'' a suspicious order. Put another way, if the additional due diligence Respondent conducts pursuant to a potentially suspicious order held by SOMS fails to justify the shipment of that order, then the order is suspicious and must be reported. Similarly, if an order causes Respondent to conduct additional due diligence and leads Respondent to believe that a pharmacy's business model or other characteristics make it likely that controlled substances will be diverted, then the order should be reported to DEA. This is so because an order is not only suspicious by virtue of its internal properties—*i.e.,* being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order].

Id. at 155–56.

While I agree with most of the ALJ's analysis, I disagree with two aspects of it. First, as to the ALJ's suggestion that only those orders which are ''actually discovered'' are subject to reporting, the ALJ asserted that ''this does not incentivize registrants to turn a blind eye to suspicious activity'' because ''[w]hile a distributor-registrant maintains an active account for a customer, the registrant has an ongoing duty to conduct meaningful due diligence and to detect suspicious orders from that customer.'' *Id.* at n.88. The ALJ then reasoned that ''[t]urning a blind eye will not negate that duty, and the Government can prove a violation . . . by showing that a suspicious order should have been detected through meaningful due diligence or an effective suspicious orders monitoring program.'' *Id.*

Yet turning a blind eye is an apt description of the manner in which Respondent reviewed the orders placed by the seven Florida pharmacies and the information it obtained from them. Moreover, the ALJ's discussion of the orders placed by City View shows that were her interpretation of the regulation adopted, it would do exactly that, *i.e.,* incentivize registrants to turn a blind eye.

More specifically, the ALJ reasoned that:

> The March 2010 UR showed a significant increase in oxycodone dispensing by City View-almost double the amount it dispensed in September 2009. Although these concerns were present since at least March 2010,

[162] This, however, was not the Government's only theory as to why the orders were suspicious. Gov. Br. 118, 121–24.

which was the time period covered by the most recent UR, they were not *actually* discovered by Respondent until its review in December 2010. Thus, failing to report the December 6 order was not a violation simply by virtue of the order's close proximity to the termination date.

R.D. at 159.

The ALJ's reasoning is inconsistent with her previous statement that ''[l]imiting the duty to report suspicious orders to orders *actually* discovered does not incentivize registrants to turn a blind eye to suspicious activity.'' *Id.* at n.88. Rather, consistent with the ALJ's earlier statement that a violation can be proved ''by showing that a suspicious order should have been detected through meaningful due diligence or an effective suspicious orders monitoring program,'' *id.,* I hold that an order has been discovered to be suspicious and the regulation has been violated where the registrant has obtained information that an order is suspicious but then chooses to ignore that information and fails to report the order. Moreover, a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices. Nor, in assessing whether a pharmacy's orders are suspicious, can it ignore information it has obtained as to the scope of drug abuse in a particular area in which it distributes controlled substances. Certainly, a registrant cannot claim that it has conducted meaningful due diligence or has an effective suspicious orders monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer's dispensing practices.

The ALJ's reasoning is erroneous for a second reason. In the ALJ's view, the standard for reporting an order as suspicious is that due diligence must ''lead[ ] Respondent to believe that a pharmacy's business model or other characteristics *make it likely* that controlled substances will be diverted.'' R.D. at 155. (emphasis added). I reject the ALJ's reasoning because it conflates the standard for whether an order can be shipped consistent with the obligation to maintain effective controls against diversion with that for whether the order must be reported as suspicious.[163]

Suspicion as to the existence of a circumstance (*i.e.,* that a customer is engaged in diversion) is simply a far lower standard of proof than whether it is ''likely'' that the circumstance exists. For example, Black's Law Dictionary defines suspicion as ''[t]he apprehension or imagination of the existence of something wrong based only on inconclusive or slight evidence, or possibly no evidence.'' Black's Law Dictionary 1,585 (9th ed. 2009); *see also* Webster's Third New International Dictionary of the English Language 2304 (1976) (defining ''suspicious'' as ''arousing or tending to arouse suspicion'' and defining ''suspicion'' as ''the act or an instance of suspecting: Imagination or apprehension of something wrong . . . without proof or on slight evidence''). Moreover, even the concept of ''reasonable suspicion,'' *see Terry* v. *Ohio,* 392 U.S. 1 (1968), does not require proof that it is likely a crime will be committed, but only ''[a] particularized and objective basis, supported by specific facts, for suspecting a person of criminal activity.'' Black's, at 1,585. Accordingly, the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.

Thus, while I agree that a distributor's investigation of the order (coupled with its previous due diligence efforts) may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor ''inform'' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed.

Noting that Respondent eventually concluded that each of the pharmacies were likely diverting controlled substances and terminated them as customers, the Government points to the regulation's provision which requires that a suspicious order be reported ''when discovered'' and argues that ''[t]he regulation makes no distinction between orders that are pending or have already been shipped.'' Gov. Proposed Findings of Fact and Conclusions of Law, at 126. It further notes the testimony of a Diversion Investigator and argues that ''[p]ursuant to the regulation, it was the responsibility of the registrant to review controlled substance orders previously shipped to a terminated . . . customer to determine whether those previously shipped orders were in fact suspicious.'' *Id.* at 126.

The ALJ rejected the Government's contention, explaining that while the regulation's '' 'when discovered' provision implies a duty to report orders that are *actually* discovered, it implies no duty to review all prior orders placed by a pharmacy terminated for compliance reasons.'' R.D. at 156. Continuing, the ALJ reasoned that:

> [a] registrant's duty in regards to a certain customer has ended when the registrant has made the decision to permanently discontinue sales of controlled substances to that customer and has reported to DEA all *known* suspicious orders from that customer. So long as past orders were, at the time they were placed and shipped, reasonably justified by meaningful due diligence, the registrant has no duty to review all such past orders when new information places the legitimacy of the customer under question.

Id.

The ALJ then noted that the ''only guidance'' provided by the Agency as to the meaning of the ''when discovered'' provision is that found in the 2007 letter. As the ALJ noted, that letter explained that:

> [t]he regulation also requires that the registrant inform the local DEA Division Office of suspicious orders *when discovered* by the registrant. Filing a monthly report of completed transactions (*e.g.,* [an] ''excessive purchase report'' or ''high unit purchases'') does not meet the regulatory requirement to report suspicious orders.
>
> When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating ''excessive purchases'' do not comply with the requirement to report suspicious orders, even if the registrant calls such reports ''suspicious order reports.''

Id. at 156–57 (quoting GX 4, at 1–2).

The ALJ thus explained that ''the main purpose of the 'when discovered' provision is to prevent distributors from simply filing 'daily, weekly, or monthly' suspicious order reports.'' *Id.* at 157. The ALJ also noted that ''periodic reports delay the reporting of suspicious orders that are placed at the beginning of the period, meaning that DEA cannot act quickly when necessary,'' and that because periodic reports could include multiple orders, these reports ''can make it difficult for the Agency to determine why each order was deemed suspicious.'' *Id.*

I agree with the ALJ that the purpose of the ''when discovered'' language is to impose a time period for ''informing'' the Agency about a specific suspicious order. The plain language of the regulation simply creates no express obligation on a distributor who has terminated a customer for engaging in

[163] It should be noted that while Respondent agreed in the MOA to report suspicious orders in a particular manner, the regulation requires only that the registrant ''*inform* the Field Division Office . . . in his area.'' 21 CFR 1301.74(b) (emphasis added).

suspicious activity to go back through previously shipped orders and re-evaluate whether those orders should now be deemed suspicious, and if so, inform the Agency.

Moreover, while an Agency's reasonable interpretation of its own regulation is entitled to deference, *Martin* v. *OSHRC,* 499 U.S. 149, 150 (1991) (other citations omitted), the Deputy Assistant Administrator's letter suggests that the ''when discovered'' language has an entirely different purpose than what the Government now urges for it. But most significantly, neither of the letters notified the regulated community that upon terminating a customer for engaging in suspicious activity, a distributor must then review the customer's previous orders (going back to some unspecified date) to determine if they were also suspicious. In short, if the Government wishes to impose such a requirement on distributors, it must provide pre-enforcement notice of its intent to do so. *See General Elec. Co.* v. *EPA,* 53 F.3d at 1329–30 (collecting cases); *see also Gates & Fox Co.,* v. *OSHRC,* 790 F.2d 154, 156 (D.C. Cir. 1986) (while ''[c]ourts must give deference to an agency's interpretation of its own regulations . . . [w]here the imposition of penal sanctions is at issue . . . the due process clause prevents that deference from validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires''); *see also Diamond Roofing Co.,* v. *OSHRC,* 528 F.2d 645, 649 (5th Cir. 1976).

Thus, liability can be imposed on Respondent only with respect to those orders which, based on the then-existing circumstances, it should have determined were suspicious and reported to the Agency. However, this matter presents the additional issue of whether Respondent violated the suspicious order rule when it failed to notify the Agency of numerous orders that were held by the SOMS and which were not properly investigated.

As found above, the SOMS held those orders that were of unusual size, unusual pattern, or unusual frequency; thus, where an order was held, that order met the specific criteria of a suspicious order as set forth in 21 CFR 1301.74(b). Indeed, in the materials it provided to the Agency, Respondent specifically represented that ''[t]he purpose of the [SOMS] is to ensure that potentially suspicious orders are flagged and reviewed by the compliance department.'' RX 78, at 59. As Respondent also represented, the SOMS' function was to ''[h]old[ ] all orders for controlled drugs that *meet or exceed the criteria set out in 21 CFR 1301.74(b),''* those being ''orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.'' *Id.* at 32 (emphasis added).

As found above, Respondent further represented that under its Policy 6.2, where an order was held by the SOMS, it would call the customer and obtain ''[a]n explanation for the order,'' and that it would then ''independently verify any information provided with this explanation.'' *Id.* Respondent also represented that it would request ''[a] current utilization report, listing all of the pharmaceuticals (DEA Schedule and non-schedule) that the pharmacy has dispensed in the most recent calendar month.'' *Id.* The Policy then required that the ''customer's entire file [be] examined.'' *Id.*

Thus, even were I to find that, pursuant to its due diligence obligations, Respondent had conducted a meaningful investigation of each of the pharmacies, upon receiving an order which met one of the aforesaid criteria, Respondent was still required to investigate the order and determine that it was not suspicious. Accordingly, where Respondent entirely failed to investigate an order by contacting the pharmacy and obtaining an explanation for why the order exceeded the aforesaid criteria, which it then independently verified, it cannot now claim that the order was not suspicious. If it chose not to investigate, then it was obligated to report the order.[164]

Applying these principles, I find that the Government has proved by a preponderance of the evidence that Respondent repeatedly failed to report suspicious orders with respect to each of the seven Florida pharmacies. Pertinent to each of the Florida pharmacies, the evidence shows that Respondent's senior officials were, at the time of the orders at issue here, well aware of the serious problem of diversion and drug abuse, and in particular, the diversion and abuse of oxycodone, then existing in the State of Florida.

As found above, both Mr. Corona, Respondent's former Vice-President, and Mr. Smith, Respondent's owner/CEO, acknowledged in their testimony that they were well aware of the oxycodone epidemic then occurring in the State of Florida and that oxycodone 30 was a highly abused substance which was ''being obtained surreptitiously and unlawfully in Florida.'' Tr. 1072. As Mr. Corona testified, Florida's oxycodone epidemic was common knowledge at both Respondent and in the drug industry in general, with Corona further testifying that Florida was ''the 'wild west and . . . a free for all' when it came to the sale and dispensing of oxycodone.'' GX 51B, at 9 ¶ 31. Indeed, it was this knowledge that prompted Mr. Smith to travel to the State in early 2009 (before it entered the MOA) and check out the pain clinics, only to discover that the pain clinics were advertising in a manner that he thought was ''very unethical'' because the ads would show ''young kids sitting around a pool in bathing suits with big smiles on their faces.'' Tr. 1074.

This is not to say that Respondent's knowledge of the extensive oxycodone problem in the State of Florida was, by itself, enough to render suspicious all orders Respondent received from all of its Florida customers. It was, however, information that Respondent was obligated to consider in evaluating the orders it received from its Florida customers. Yet the evidence shows that Respondent's employees did not ''consider the geographic locations of its Florida pharmacy customers'' in reviewing their orders. I now turn to each of the pharmacies.

Tru-Valu

The evidence shows that prior to April 1, 2009, Respondent had acquired substantial information raising a strong suspicion as to the legitimacy of Tru-Valu's business practices. Specifically, at various points, Respondent obtained information that controlled substances comprised an abnormal percentage of its dispensings. On May 28, 2008, Respondent's consultant noted that 40 percent of the prescriptions Tru-Valu filled were for controlled substances and that the PIC acknowledged that the pharmacy ''fill[ed] a large number of

[164] While the above discussion is based on the specific policies at issue here, it should be clear that while conducting a meaningful investigation of a customer is a necessary part of a distributor's due diligence obligations, even where the investigation provides no reason to question the legitimacy of the customer's dispensing practices, upon receipt of an order meeting one of the criteria set forth in 21 CFR 1301.74(b), the order must either be reported as suspicious or investigated. However, where an order is investigated, the investigation must dispel the suspicion in order to excuse a distributor from its obligation to report the order. Of further note, reporting an order as suspicious does not excuse a distributor that seeks to fill that order from its obligation to ''to exercise due diligence to avoid filling suspicious orders that might be diverted.'' GX 3, at 2. *See also* GX 4, at 1 (''Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.'').

narcotic prescriptions each day'' and had ''pushed for this business with many of the area pain doctors.''

Moreover, just six days earlier, Respondent had obtained a utilization report for the month of April 2008, which showed Tru-Valu's dispensings of its top 300 drugs. While this apparently was not a complete UR, it nonetheless revealed significant information calling into question the legitimacy of Tru-Valu's controlled substance dispensings.

More specifically, the UR showed that Tru-Valu's dispensings of three highly abused drugs were predominant, with its dispensings of oxycodone 30 totaling 132,506 du; its dispensings of methadone 10 totaling 53,842 du; and its dispensings of alprazolam 2mg totaling 55,120 du; these three drugs alone constituted 241,000 du out of a total of 340,000 du for that month. By contrast, even though hydrocodone was the most widely prescribed drug nationally during this period, *see* RX 81, at 47; Tru-Valu's dispensings of this drug did not even total 3,000 du, a fraction of the oxycodone.

Further, in January 2009, Tru-Valu requested an increase in its oxycodone purchasing limit, and reported that 50 percent of the prescriptions it filled were for controlled drugs and 25 percent were for schedule II drugs. Respondent obtained a UR for December 2008, and while it showed only the top 200 drugs dispensed, it showed that Tru-Valu had dispensed more than 192,000 du of oxycodone 30 during the month (out of the total dispensings listed on the report of 300,000 du), an increase of nearly 60,000 du and more than 50 percent from the previous UR. The UR also showed that the pharmacy had dispensed 27,628 du of alprazolam 2 mg and 11,848 du of methadone 10, each of which is a highly abused controlled substance.[165] And the UR showed that with the exception of carisoprodol, which was then non-controlled under the CSA (but controlled under Florida law and highly sought after by drug abusers for use with narcotics and benzodiazepines), each of the top ten drugs dispensed was a controlled substance.

As explained above, in the *Southwood* decision, which was published in the **Federal Register,** the Agency had noted that the ratio of controlled to non-controlled substances dispensed by a typical retail pharmacy ranged up to 20 percent for controlled versus 80 to 90 percent for non-controlled drugs.[166] *See* 72 FR at 36,492. Thus, based on the UR alone, as of April 1, 2009, Respondent had substantial information which raised a strong suspicion as to the legitimacy of Tru-Valu's dispensing practices.

It is of no consequence that the Government did not produce a statistical study to show how many standard deviations Tru-Valu's dispensing ratio as reflected by the URs was outside that of a typical retail pharmacy. As explained above, to conclude that an order is suspicious, the information presented to the distributor is not required to establish, to a statistical certainty, that a pharmacy was likely diverting controlled substances. Rather, the evidence must only create a suspicion, a standard which is less than that of probable cause. And aside from the volume of Respondent's oxycodone and controlled substance dispensings, Respondent also knew that Tru-Valu was actively seeking out business from the area's pain doctors, even though in early 2009, Respondent's owner/CEO had determined to stop selling to pain doctors who were engaged in direct dispensing.

Throughout this proceeding, Respondent has vigorously argued that it is unfair to fault it for failing to analyze the URs to determine whether the pharmacies' dispensing ratios were consistent with the figures discussed at the August 2009 review (which had also been published several years earlier in *Southwood*) [167] because the Government did not specifically identify this as a deficiency in its policies and procedures as part of the Compliance Review.

While I have previously rejected Respondent's contention that the Government should be estopped from faulting it for failing to use the URs for this purpose, as well as the ALJ's discussion that the MOA bars sanctioning Respondent for failing to use the URs for this purpose, the ALJ also opined that the Government had not proved that Respondent's failure to use the URs for this purpose ''rendered [its] anti-diversion program ineffective under 21 CFR 1301.71(a).'' R.D. at 190.

The ALJ explained that ''the parties seem to agree that controlled substance ratios are an important aspect that should be investigated prior to shipping controlled substances.'' *Id.* at 188. Noting Ms. Seiple's declaration that Respondent ''was aware of the dispensing ratio of controlled to non-controlled substances'' of the seven pharmacies, *id.* (citing RX 103, at ¶¶ 158, 177, 204, 225, 244, 284, 303, 319), the ALJ then noted that ''[r]ather than using URs for every customer . . . Respondent used the information reported by site visits, phone surveys, and initial due diligence to estimate the ratios.'' *Id.* at 188.

The ALJ then explained that the issue appears to be ''whether Respondent's failure to analyze URs every time an order was held violated Respondent duties under DEA regulations.'' *Id.* at 189. The ALJ opined:

> The Government has offered no evidence that accurate information regarding controlled substance ratios can *only* be acquired through URs. In fact, the Government's own guidance it provided to Respondent specifically instructed Respondent to conduct this inquiry via questionnaires. This is precisely what Respondent has done. It is contradictory for DEA to instruct Respondent at the Compliance Review that it should ask its customers about their controlled substance ratios, and now insist that *only* URs can be the basis for such information.
>
> The fact that Respondent actually analyzed URs on several occasions to determine customers' controlled substance ratios is evidence that such analysis is helpful. Respondent does not dispute that. But the fact that a certain method of gathering and analyzing information is *helpful* does not force the conclusion that the method is

[165] As found above, the UR only listed the top 200 drugs dispensed. While the UR likely did not reflect all of the dispensings, Respondent could have asked Tru Valu for a complete UR. Thus, it cannot now hide behind its failure to do so.

[166] As noted previously, *Southwood* was published in the **Federal Register** in 2007, as well as on the Agency's Web site. As a participant in a highly regulated industry, Respondent is properly charged with knowledge of the contents of the decision, which involved an entity registered as a distributor which was charged with similar violations. *See United States* v. *Southern Union Co.,* 630 F.3d 17, 31 (1st Cir. 2010) (''[T]hose who manage companies in highly regulated industries are not unsophisticated . . . . It is part of [a company's] business to keep abreast of government regulations.''); *cf. Fed. Crop Ins. Corp.* v. *Merrill,* 332 U.S. 380, 384–85 (1947) (''Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the **Federal Register** gives legal notice of their contents.'') (citations omitted); *California* v. *FERC,* 329 F.3d 700, 707 (9th Cir. 2003) (''Publication in the **Federal Register** is legally sufficient notice to all interested or affected persons regardless of actual knowledge or hardship resulting from ignorance, except those who are legally entitled to personal notice.'').

[167] The ALJ opined that *Southwood* ''includes no mention of controlled substance ratios as a red flag for diversion.'' R.D. at 188. However, as explained above, *Southwood* did discuss the ratio of controlled to non-controlled dispensing at a typical retail pharmacy. *Southwood* did not further discuss the ratio as an indicator of diversion because there were ample other red flags presented by Southwood's customers, including the quantities of hydrocodone that the distributor was selling to various internet pharmacies and its retail pharmacy customers, as well as evidence that the pharmacies were engaged in filling unlawful prescriptions. Moreover, in the September 2006 letter, the Deputy Assistant Administrator specifically advised distributors (including Respondent) that they should be asking their customers ''[w]hat percentage of the . . . business does dispensing controlled substances constitute?'' GX 3, at 3.

absolutely necessary to provide effective controls against diversion. This is especially true when there are other methods of gathering necessary information, as is the case here.

Id.

I agree with the ALJ that using the URs to actually determine a customer's controlled to non-controlled dispensing ratio ''is helpful'' in assessing whether a pharmacy's dispensing patterns are consistent with legitimate pharmacy dispensing practices. Indeed, because the URs are compiled from a pharmacy's dispensing records, the URs should typically present an accurate report as to the pharmacy's actual dispensings.

By contrast, surveys and questionnaires typically rely on nothing more than estimates, and it is certainly within the realm of possibility (if not likely) that a pharmacist who was diverting drugs would report substantially lower levels of controlled substance dispensings than he was actually engaged in; indeed, as discussed throughout, this appears to have been the case with respect to several of the pharmacies. The distribution of controlled substances is a highly regulated industry for good reason. Those who choose to engage in the distribution of controlled substances are not free to ignore relevant information, and indeed are obligated to make distribution decisions based on the most accurate information they have obtained. I thus reject the ALJ's reasoning. [168]

So too, the ALJ also rejected the Government's contention that Respondent ignored large increases in the quantities of oxycodone being dispensed, such as the increase in Tru-Valu's oxycodone dispensings between the April and December 2008 URs. *See* R.D. at 191–95. Framing the issue as ''whether increases in monthly dispensing volumes are indicative of diversion,'' the ALJ noted that ''*Southwood* does not indicate that increases in monthly dispensing volumes could indicate diversion or that comparing URs is a necessary method of due diligence.'' *Id.* at 192–93. The ALJ also noted that while the 2006 letter to distributors addressed various circumstances that may be indicative of diversion, it only ''list[ed] 'characteristics in [illegitimate pharmacies'] pattern[s] of ordering controlled substances.' '' *Id.* at 193 (quoting GX 3, at 3). According to the ALJ, the list provided in the letter was ''unhelpful . . . because the comparisons . . . do not involve monitoring *ordering* patterns, but *dispensing* patterns.'' *Id.* The ALJ then reasoned that because there is no evidence ''that DEA told Respondent to compare URs in order to identify increases in monthly dispensing volumes,'' it would be unfair to sanction Respondent for failing to do so. *Id.* at 194.[169]

It is true that *Southwood* did not discuss whether an increase in the monthly dispensing volume for a particular drug is an indicator of diversion. Yet in holding that the distributor's due diligence program was ineffective, *Southwood* did note that in the case of several of the pharmacies, ''Respondent actually distributed even

[168] As found above with respect to each of the pharmacies, some (but not all) of the survey and site visit forms used by Respondent phrased the question in terms of the percentage of prescriptions that were for controlled substances (and schedule II controlled substances) rather than in terms of the percentage of dosage units or ratio of controlled to non-controlled drugs. Of further note, the ALJ rejected the testimony of a DI that Respondent should have been comparing the pharmacies' statements as to the percentage of the prescriptions comprised by controlled substances (and schedule II drugs) with the information on the URs to look for inconsistencies. Notwithstanding that she ''recognize[d] that inconsistencies in information provided by a customer during the due diligence process can be a red flag that should at least trigger further investigation,'' R.D. at 190 (citing *Southwood*), she then concluded that using the URs ''would not be helpful because it would amount to an 'apples and oranges' comparison.'' *Id.* at 191.

However, while the URs provided by Tru-Valu did not provide data as to the number of prescriptions filled for each drug, the ALJ ignored that the URs provided by five of the pharmacies (Drug Shoppe, Englewood, City View, Medical Plaza, and Morrison's) did provide the data and yet Respondent never compared the figures. And while making those calculations may have required totaling the respective number of prescriptions for schedule II drugs and all controlled substances, given the predominance of controlled substances in the dispensings, an accurate estimate generally could have been made by simply totaling up the controlled substances on the first few pages of the URs.

Most significantly, the ALJ entirely ignored that the URs provided by Englewood actually totaled the number of prescriptions for each schedule of controlled substances as well as for the non-controlled prescription drugs, and yet Respondent failed to compare the data with what Englewood's pharmacist reported.

Respondent contends that comparing a pharmacy's representation as to the percentages of prescriptions comprised by controlled substances and schedule II drugs to the UR data showing the volume of dosages is an apples to oranges comparison. This begs the question of to what Respondent intended to compare the prescription percentages provided by each pharmacy to determine if it was engaged in illegitimate dispensing. Of note, in the case of City View, Ms. Seiple documented her ''concerns regarding [the number] of doses dispensed as opposed to noncontrols'' and that she had spoken with the pharmacy ''multiple times regarding ratio of controls [sic] & noncontrols [sic].''

So too, on several occasions, Respondent's inspector submitted a site visit report and a recommendation, noting that the dispensing percentages reported by a pharmacy were either ''a little high'' or ''high,'' and recommended that the Compliance Department obtain a new UR and compare it with the information obtained during the site visit. As found above, these recommendations were not followed. According to Ms. Seiple, this was because Respondent's Policies did not ''specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers 'high' or 'a little high.' '' RX 103A, at 45. Ms. Seiple did not, however, address what percentage, if any, Respondent considered to be suspicious. This suggests that Respondent's purpose in asking the question was to create the illusion that it was conducting due diligence.

Notwithstanding that the dispensing ratio figures provided in *Southwood* and during the August 2009 briefing refer to dosage units, generally for most of these pharmacies, the percentage of prescriptions for controlled substances would actually be lower than the percentage of dispensings when calculated using dosage units, due in part, to the large quantities of oxycodone being dispensed per prescription. Moreover, in 2008, DEA noted that ''controlled substances constitute between 10 percent and 11 percent of all prescriptions written in the United States.'' DEA, *Electronic Prescriptions for Controlled Substances,* 73 FR 36722 (2008) (Notice of Proposed Rulemaking).

Thus, while a comparison of the percentages reported by Tru-Valu to the 20/80 ratio figure is not a precise comparison, when a pharmacist reports that the percentage of the prescriptions comprised by controlled substances is well above the 20 percent figure, it nonetheless is an indicator (red flag) of diversion. As explained above, in May 2008, Tru-Valu told Respondent's consultant that controlled substances comprised 40 percent of the prescriptions it dispensed (more than double the figure) and in July 2010, Tru-Valu told Respondent's inspector that 60 percent of the prescriptions were for schedule II drugs and that 60 to 80 percent of the prescriptions were for all controlled substances.

[169] The ALJ also asserted that ''it appears that the only evidence that increases in a pharmacy's monthly sales are indicative of diversion was [the DI's] opinion, which was based solely on his experience as a diversion investigator. This is not sufficient to put the industry on notice of DEA's position that such conduct is sanctionable.'' R.D. at 194. The ALJ's reasoning conflates the issue of whether an increase in a pharmacy's dispensings of a particular drug is an indicator of diversion with that of whether the Agency was required to provide notice.

As for whether the DI's testimony is enough to establish that an increase in a pharmacy's dispensing volume of a particular drug is an indicator of diversion, at least one federal appeals court has held that a diversion investigator with sufficient experience can testify as an expert regarding the ''common red flags suggestive of an illicit pharmaceutical operation.'' *United States* v. *Lovern,* 590 F.3d 1095, 1102 (10th Cir. 2009). According to the DI's declaration, at the time of the hearing, he had ten years of experience as a DI and had investigated nine distributors. GX 49B, at 1. Moreover, while there may be a legitimate explanation for why a pharmacy has experienced an increase in the volume of its controlled substance dispensings, it is hardly assailable that a large increase is an indicator of diversion, especially when the increase involves a drug highly sought after by drug abusers. Indeed, it is within the Agency's experience that drug-seeking patients and drug-dealing doctors seek out those pharmacies that will fill their prescriptions with no questions asked. *See East Main Street Pharmacy,* 75 FR 66,149, 66,152 (2010) (discussing relationship between physician convicted of drug dealing and pharmacy, pursuant to which physician directed all of his patients to fill their prescriptions at the pharmacy); *see also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62,316, 62,321 (2012) (discussing patients travelling 200 miles from doctor's office to pharmacy).

larger quantities of the drug [hydrocodone] to them'' after it had received information that pharmacies were likely engaged in unlawful dispensing. 72 FR at 36,500.[170]

As for the 2006 letter, it is true that the letter did not specifically identify increases in a pharmacy's dispensings of highly abused controlled substances as an indicator of diversion. However, the letter did not purport to set forth an all-inclusive list of the circumstances present with those pharmacies engaged in diversion, and some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. *See Holiday CVS, L.L.C., d/b/a/CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62,316, 62,322 (2012). This is especially true when the drug is a potent narcotic which is known to be highly sought after by drug abusers, and even a cursory review of the pharmacy's dispensing data would establish that the pharmacy's already high levels of dispensing have increased even more.[171]

The ALJ further expressed her hesistancy ''to recommend sanctions based on a method of due diligence that has never been identified by DEA in any regulation, guidance, training, or case.'' R.D. at 194. To the extent the ALJ's opinion suggests that DEA has not provided the industry with sufficient notice ''that such conduct is sanctionable,'' *id.,* as discussed previously, the suspicious order rule provides fair notice to distributors as to their obligation to notify the Agency of suspicious orders they receive. Due Process does not require the Government to identify every conceivable circumstance which may render an order suspicious, or to identify every step a distributor must take to determine whether a particular order is suspicious. I therefore respectfully reject her reasoning.

I acknowledge that prior to April 1, 2009, Respondent engaged in various due diligence efforts, including conducting a site visit and a phone survey in response to Tru-Valu's request for an increase in the amount of oxycodone. I find, however, that these measures did not sufficiently dispel the suspicion created by the other information Respondent had obtained from Tru-Valu, particularly the December 2008 UR data (that being the most recently obtained UR until October 2009). That UR showed that Tru-Valu's dispensing of oxycodone 30 alone accounted for nearly 64 percent of its dispensings and represented an increase of more than 50 percent from the level of its previous UR. Thus, Tru-Valu's dispensings of this single dosage (which is also the strongest dosage of immediate release oxycodone which is commercially available) were more than three times the level of all controlled substances dispensed by a typical retail pharmacy.

The UR also showed that, with the exception of carisoprodol, which was then controlled only under Florida law (and which subsequently was federally controlled, based in part on its abuse potential when used as part of a drug cocktail which included narcotics and benzodiazepines),[172] each of the top ten drugs dispensed was controlled under the CSA, including alprazolam 2 mg. These facts alone created not merely a suspicion, but a strong one at that, that Tru-Valu was diverting controlled substances. Also, the 2008 site visit, which was the only time Respondent obtained information as to the names of the pain management doctors whose prescriptions were being filled by Tru-Valu, revealed that two of them were doctors Respondent terminated when its CEO decided to cut off sales to direct dispensers because of their unethical marketing practices.

Moreover, at the 2008 visit, the PIC disclosed that he was actively seeking out the business of area pain doctors. Unexplained by Respondent is why a pharmacist who was actively seeking out the business of physicians prescribing narcotics would then risk alienating those physicians by refusing to fill their illegitimate prescriptions. Yet Respondent simply ignored this potential conflict on the part of Tru-Valu's PIC.

As noted above, from April 1, 2009, through the date of the Compliance Review, Respondent filled monthly orders for oxycodone products totaling 25,300 du (April), 25,000 du (May), and 24,000 du (both June and July). None of the orders were reported to DEA as suspicious. For reasons explained previously, I hold that they were suspicious.

Even were I to ignore the existence of these red flags (which I decline to do), I further find that even after Respondent implemented the SOMS and its new policies and procedures, Respondent continued to fail to report suspicious orders. As noted above, on November 30, 2009, Tru-Valu placed orders for 7,200 du of oxycodone 30; 14,400 du of oxycodone 15; and 1,000 du of oxycodone 10/325, bringing its total monthly orders to 26,200 du and exceeding the 25,000 du CSL. Yet there is no evidence that the orders were held for review and they were not reported as suspicious.

Moreover, in February 2010, Tru-Valu's orders totaled 46,800 du, thus exceeding the CSL by nearly 22,000 du. While Respondent's Compliance Department documented that it contacted Tru-Valu and was told by its pharmacist that a local supermarket had closed and that he was ''getting some of [its] business,'' Respondent failed to comply with its Policies and Procedures by independently verifying the pharmacist's explanation. It also failed to obtain a new UR as required by its Policies and Procedures and did not do so until April 1, 2010.[173]

[170] While *Southwood* did not specifically note the preceding months' orders in that portion of the decision which held that the distributor had violated the suspicious order rule when it failed to report the orders placed by a pharmacy which had ordered 2.1 million du in a single month, the opinion had earlier set forth the quantity of the distributions made to the pharmacy each month. *See* 72 FR 36,489 (listing monthly orders); *id.* at 36,501 (observing that distributor ''did not report any of [pharmacy's] purchases as suspicious. . . . It did not do so even in November 2006, when it distributed more than 2.1 million dosage units of hydrocone to'' the pharmacy).

[171] Citing *Holiday CVS,* the ALJ also reasoned that ''DEA has recognized that increased sales by a pharmacy, alone, are not necessarily indicative of diversion.'' R.D. at 193 (citing 77 FR at 62,324 n.33). However, the ALJ then acknowledged that ''[t]he Administrator stopped short of stating that increased controlled substance sales are *never* a red flag, but emphasized that such increases could be 'explained by an increase in legitimate prescriptions.' '' *Id.*

In *Holiday CVS,* the Government took exception to the ALJ's ruling which barred it from admitting evidence of the pharmacy's oxycodone purchases. The Administrator upheld the ALJ's ruling, noting that the evidence did not establish a violation of the CSA's prescription requirement, 21 CFR 1306.04(a), which requires proof by reference to a specific prescription that a pharmacist knowingly (or with willful blindness) dispensed a prescription which lacked a legitimate medical purpose and was issued outside of the usual course of professional practice. *See* 77 FR at 62,324 n.33.

Here, however, the issue is simply whether the oxycodone orders placed by the seven pharmacies were suspicious. Certainly a substantial increase in a pharmacy's oxycodone orders is an indicator of suspicious activity, notwithstanding that upon investigating the orders, the pharmacy may have a legitimate explanation for the increase, which ultimately dispels the suspicion.

[172] *See Placement of Carisoprodol into Schedule IV,* 76 FR 77,330, 77,338 (2011) (noting that ''the drugs most frequently used in combination with carisoprodol that presented in [Emergency Department] visits were opioids (hydrocodone, oxycodone), benzodiazepines (alprazolam, diazepam, clonazepam), alcohol, and illicit drugs (marijuana, cocaine)); *see also id.* at 77,342–43 (testimony of various law enforcement officials regarding use of carisoprodol in combination with narcotics and benzodiazepines); *Paul H. Volkman,* 73 FR 30,630, 30,637 (2008) (testimony of expert in pain management noting that physician's prescribing of drug cocktails which included an opioids, a benzodiazepine, and carisoprodol ''greatly increased the chance for drug abuse, diversion, [and]/or addiction'').

[173] The ALJ rejected the Government's contention that Respondent did not follow its policies and

Not only does this evidence support a finding that Respondent failed to comply with its Policies and Procedures, it also supports a finding that Respondent failed to report suspicious orders. As Respondent represented to the Agency, ''[t]he purpose of the [SOMS] is to ensure that potentially suspicious orders are flagged and reviewed by the compliance department.'' RX 78, at 59. As Respondent further represented, the SOMS' function was to ''[h]old all orders for controlled drugs that meet or exceed the criteria set out in 21 CFR 1301.74(b),'' those being ''orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.'' *Id.* at 32. Thus, where Respondent failed to comply with its policies and procedures and obtain an explanation for an order which it independently verified, as well as a new UR, those orders are properly deemed suspicious. I therefore find that Respondent violated 21 CFR 1301.74(b) when it failed to report those orders in February 2010 which placed Tru-Valu over its CSL.

The following month, Respondent shipped an even larger quantity of oxycodone to Tru-Valu (55,200 du, including 43,200 du of 30 mg and 12,000 du of 15 mg). Tru-Valu's orders exceeded even the new CSL and were again justified on the ground that a supermarket had closed, yet Respondent still had not independently verified this explanation. Nor did it obtain a new UR until April 1, 2010, after it had filled the March orders. Moreover, the evidence shows that on March 31, 2010, Respondent deleted an order for oxycodone 15. However, none of these orders were reported as suspicious even though Tru-Valu had again exceeded the CSL and placed orders of unusual size.

These episodes provide a further reason to conclude that Respondent did not maintain effective controls against diversion. As found above, the SOMS calculated a customer's CSL based on ''[t]he highest monthly total [invoiced to the customer] from the preceding six months.'' RX 78, at 60. Thus, if Respondent approved an increase in the quantity of a drug family, regardless of whether it had complied with its Policies and Procedures by obtaining an explanation for the order, independently verifying that explanation, and obtaining a new UR, the increased amount would become the new CSL and thus allow the customer to order even larger quantities of controlled substances without even triggering a SOMS hold and further review.

Thus, in April 2010, Respondent filled orders totaling 48,000 du. While these orders were apparently held for review because they violated either the pattern or frequency parameter (as they were the first orders placed for the month and placed on the 27th day), Respondent deemed the orders non-excessive because they were under the previous month's total of 55,200, even though the previous month's orders were never properly investigated and justified. I conclude, however, that the orders were suspicious because they violated either the frequency or pattern parameter and were never properly justified.

Of further note, several weeks prior to filling the April 27 orders, Respondent obtained a UR for the month of February 2010. This UR showed that Tru-Valu had dispensed more than 192,000 du of oxycodone 30; 38,563 du of oxycodone 15; and 30,655 du of alprazolam 2 mg; these drugs alone accounted for more than 81 percent of Tru-Valu's dispensings. The UR also showed that the top ten drugs dispensed were formulations of oxycodone, methadone, or alprazolam, and 17 of the top 20 drugs were controlled. Yet the April 27 orders were not reported as suspicious.

The SOMS notes show that Tru-Valu placed additional oxycodone orders in May 2010, which were flagged for review because its orders were increasing and there was a change in its buying pattern because another distributor had cut back its allocation. While notes in the MFRs suggest that Respondent obtained this explanation from the pharmacist, there is no evidence that Respondent ever independently verified this explanation, as required by its Policies and Procedures.

According to Respondent's records, on May 18, 2010, Tru-Valu placed another order which clearly placed it over its CSL. While Respondent deleted the order, it failed to report the order as suspicious. Later, it also edited an order for oxycodone 15 (May 27), reducing it from 12,000 to 7,200 du, while again failing to report it. Indeed, Respondent frequently deleted or edited orders to bring a customer within its CSL and yet never reported the original orders as suspicious.

However, the suspicious order regulation requires the reporting of an *order,* regardless of whether the order is rejected entirely or edited by reducing the amount that is actually shipped. As explained in *Southwood,* the purpose of the regulation is ''to provide investigators in the field with information regarding potential illegal activity in an expeditious manner.'' 72 FR at 36,501. That purpose was undermined by Respondent when it either entirely deleted orders—thus treating them as if they had never been placed—or edited the orders by reducing their size to place the customer at or below the CSL—thus treating them as if they had been placed in smaller amounts than those that would trigger reporting. I thus find that Respondent repeatedly violated the regulation by failing to report those orders which it either deleted entirely or edited downwards in size.[174]

procedures by independently verifying the pharmacist's explanation, reasoning that ''by relying solely on the lack of documentation, the Government is attempting to improperly shift the burden of proof to Respondent.'' R.D. at 173. As explained in my discussion of the Government's Exceptions, I respectfully reject the ALJ's reasoning.

[174] The Government argued ''that Respondent regularly edited and/or deleted held orders in order to keep the particular customer within their CSL.'' Gov. Proposed Findings of Fact and Conclusions of Law, at 123. Rejecting this contention, the ALJ explained:

> This argument meets the common sense test, but fails to rise to the level of proving a violation of a legal requirement. First, the Respondent's witnesses affirmatively asserted that their actions to edit or delete an order were not linked to the suspicious nature of the order itself. Rather, orders were edited and deleted for business reasons, not diversion-avoidance reasons. This testimony was not contradicted by any other witnesses in this matter. Next, the record establishes that due diligence was done upon the order prior to making the determination to edit or delete it. Accordingly, I find that the Government has failed to prove that the Respondent's practice of editing and deleting orders violated [its] duty to maintain effective controls against diversion or the duty to detect suspicious orders. R.D. at 196.

I respectfully disagree with the ALJ's reasoning. As for the assertion that the compliance department's ''actions to edit or delete an order were not linked to the suspicious nature of the order itself'' but were done for business reasons, as found above, in nearly every instance in which an order was edited or deleted, the original order placed the respective pharmacy over its CSL and thus rendered the order to be of unusual size. RX 78, at 60. Moreover, there are comparatively few instances in which Respondent documented that an order was edited or deleted for such reasons as that the customer had not purchased enough non-controlled products to meet its ''ratio'' or because product was being allocated due to a market shortage.

As for the ALJ's further assertion that ''[t]his testimony was not contradicted by any other witnesses,'' R.D. at 196, earlier in her decision the ALJ specifically noted the testimony of both Mssrs. Corona and Schulze on this issue. *Id.* at 98. Mr. Corona testified, however, that ''[i]t was common practice for [the] Compliance Department to either edit or delete orders for controlled substances if the order was above the customer's threshold and there was not a reason to increase the threshold. Though this was not intentionally done to subvert [Respondent's] responsibility to report suspicious order [sic], in effect, this practice did just that.'' GX 51B, at 9 ¶ 30.

To similar effect, Mr. Schulze testified that ''[i]t was a common practice for compliance clerks to reduce orders or delete orders to keep a customer within its CSL for the rolling 30 day period, as can be seen in the due diligence file Memo For Record

Continued

Moreover, Respondent failed to report the May 18 and May 27 orders as suspicious notwithstanding that: (1) It had shipped 65,200 du of oxycodone during the month; (2) it had deleted entirely the May 18 order; (3) it had reduced the May 27 order; and (4) several days later, it noted in the Memo for Records, that the May 27 orders, which resulted in the shipment of 24,000 du of oxycodone 30 and 7,2000 du of oxycodone 15, had been released without committee review and been filled by mistake and that 25,000 du was the level at which Tru-Valu's oxycodone orders were to be reviewed.

Notwithstanding the above, in June 2010, Respondent filled orders totaling 33,600 du. While the June 15 order for 12,000 du of oxycodone 30 placed Respondent over its CSL, the order was released with reservation by the committee and not reported as suspicious. Likewise, Tru-Valu placed additional orders on June 21 and June 30 which placed it over the CSL; while the June 21 order (for 12,000 du of oxycodone 30) was cancelled by the pharmacist, it still was suspicious and should have been reported for the reasons set forth above.

Although Respondent deleted the June 30 order because it was placed too early, even assuming that Respondent contacted the pharmacist because the order was apparently re-submitted the next day, there is no documentation as to what explanation was offered by Tru-Valu's pharmacist. Nor was a new UR obtained. Here again, Respondent violated the regulation by failing to report the order as suspicious.

While based on the June orders Respondent filled, Tru-Valu's CSL was increased from the 25,000 du level noted in the June 2nd MFR entry to 33,600 du, Tru-Valu's July orders totaled 46,800 du. Yet Respondent again failed to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

In August 2010, Respondent conducted a site visit. During the visit, Respondent developed significant additional information which reinforces the conclusion that Tru-Valu was engaged in suspicious activity. This included the pharmacy's report that 60 to 80 percent of the prescriptions it filled were for controlled substances, and that 60 percent of the total prescriptions were for schedule II drugs. The inspector also reported that while it was the middle of the afternoon, the pharmacy was ''very busy'' with a ''long line of mostly younger people'' (reporting that there were 10 persons) who were ''thin, tattooed, [and] casually dressed'' and that ''more [were] coming in.'' The inspector further noted that the pharmacy had posted signs imposing a ''pill limit'' of 180 du on oxycodone 30 and 90 du on oxycodone 15; that it did not accept insurance on certain oxycodone products; and that patients ''must have a recent MRI report.'' All of these were indicia of illegitimate activity.

Ten days after the site visit, Respondent deleted an order, documenting that the order was deleted ''per review until [the] review completed.'' Yet notwithstanding all of the additional information its inspector had documented during the site visit, the order was not reported as suspicious. Moreover, on September 1, 2010, Respondent filled orders for 24,000 du of oxycodone 30 and 2,400 du of oxycodone 15. While there is evidence documenting that Respondent's compliance department spoke with Tru-Valu's PIC regarding why he did not accept insurance on certain oxycodone products, there is no documentation that Respondent inquired about the signs imposing pill limits and requiring an MRI, or about the clientele observed by the inspector. And here again, Respondent failed to report the orders as suspicious.

Nearly three weeks later, Tru-Valu ordered 26,400 oxycodone 30, thus placing it over its CSL. While Respondent edited the order by reducing it to 7,200 du, here again, Respondent failed to obtain an explanation for the order and a new UR. And here again, it failed to report the order as suspicious even though it noted that additional product should not be released until ''reservations [were] addressed.''

Yet the following day, Respondent shipped an additional 13,200 du of oxycodone 30 to Tru-Valu. While Respondent contacted the pharmacy and asked the PIC if he got a lot of out-of- state customers, it did not further inquire as to why he had posted the signs imposing pill limits and requiring an MRI. Nor did it question the PIC regarding the inspector's observation of the pharmacy's customers.

Moreover, the same day, Respondent's compliance committee conducted an account review, which included reviewing the site visit and its most recent UR, which covered the month of July 2010. This UR showed that Tru-Valu's dispensings of oxycodone 30 totaled more than 206,000 du, which was 61 percent of its total dispensings, and with its dispensings of oxycodone 15 of 32,441 du, its dispensings of these two drugs were 70.7 percent of all dispensings. The UR also showed that Tru-Valu had dispensed more than 31,000 du of alprazolam 2 mg and that nine of the top ten drugs dispensed were federally controlled substances such as oxycodone, methadone, alprazolam 2 mg (the other being carisoprodol). In addition, 18 of the top 20 were federally controlled drugs and included 11 oxycodone products, three alprazolam products, two diazepam products, methadone, and Dilaudid (hydromorphone).

Notwithstanding the information provided by the UR and the recent site visit, Respondent approved the order for 13,200 du and increased the amount of oxycodone Tru-Valu could purchase ''to the pattern high of 46,800.'' Respondent further documented that the 46,800 du figure was only 42 percent of Tru-Valu's UR, in essence using the UR as a one-way ticket to justify making additional distributions while ignoring the significant information it contained which raised a strong suspicion as to the illegitimacy of its dispensings. Here again, Respondent did not report the order as suspicious.

Moreover, upon filling an order for 14,400 du of oxycodone 30 on October 5, 2010, Respondent had shipped 58,800 du to Tru-Valu on a rolling 30-day basis, and exceeded the 46,800 du CSL. Here again, there is no evidence that Respondent contacted the pharmacy and yet the order was released with

('MFR') and SOMS shipping notes.'' GX 53, at 2–3. Mr. Schulze also testified that he was ''aware that Ms. Seiple also explicitly stated that Masters never cancelled, deleted, or edited orders to bring customers within the limits established by SOMS. That statement is simply not true.'' *Id.* at 2. *See also* GX 52, at 14 (''In the beginning of SOMS implementation, we deleted orders that exceeded the CSL and informed the customers when they could place another order. Later on, when an order was held by SOMS due to size of the order exceeding the established limit, we would edit the orders, reducing the total amount shipped to keep the customers within the CSL.''); *id.* at 15 (''In practice, we did not analyze a customer's orders to determine if they were 'suspicious' and as such were required to be reported to DEA. We were looking at orders to determine what we could justify shipping out. If the order needed to be edited to justify shipment, we would do that.'').

As explained above, because the purpose of the CSL was to determine whether a customer's orders were of unusual size and thus suspicious, Respondent's practice of editing or deleting those orders which placed a customer over its CSL subverted the SOMS. Whether Respondent's employees edited or deleted orders with the intent to subvert its obligation to report suspicious orders is irrelevant because the regulation does not require proof of any level of scienter.

As for the ALJ's statement that ''the record establishes that due diligence was done upon the order prior to making the determination to edit or delete it,'' R.D. at 196, as found above, the evidence shows that while the pharmacies submitted numerous oxycodone orders which placed them over their respective CSLs, Respondent only rarely contacted the pharmacies and obtained an explanation for why they were ordering these quantities.

reservation. Nor was the order reported as suspicious.

Only eight days later, Respondent edited an order (placed the day before) to 6,000 du (60 bottles) to keep Tru-Valu at its CSL. Yet on filling the order, Respondent had actually shipped 64,800 du of oxycodone on a rolling 30-day basis. Once again, Respondent did not contact the pharmacy and obtain an explanation for the order. Here again, it failed to report the order as suspicious.

Moreover, Respondent filled additional orders on November 1, 2010 (for 24,000 du of oxycodone 30 and 2,400 du of oxycodone 15) as well as on November 8, 2010 for 14,400 du of oxycodone 30. While these orders apparently were not held by the SOMS, given the extensive red flags raised by Tru-Valu's business practices, the orders were suspicious and should have been reported. Indeed, the evidence shows that Respondent placed Tru-Valu on non-control status only after Respondent received a letter from Mallinckrodt raising concerns about Tru-Valu.

Yet, even before April 1, 2009, Respondent had ample evidence that raised a strong suspicion as to the legitimacy of Tru-Valu's business practices and this evidence became even stronger over time. While Ms. Seiple justified Respondent's failure to report Tru-Valu's orders as suspicious on the ground that the pharmacy was actively marketing to nearby pain clinics and had provided Respondent with the names of several doctors who were writing the prescriptions, it bears noting that Respondent had previously cut off sales to two of the physicians. It also bears noting that because only a practitioner (*i.e.,* in this case, a licensed physician) can issue a prescription, the fact that Respondent was provided with the names of several doctors who were practicing pain management says nothing about whether those doctors were issuing legitimate prescriptions. Moreover, while Respondent's CEO and former Vice-President acknowledge that the company was well aware of the oxycodone crisis then ongoing in the State of Florida, Respondent took no further steps to verify the credentials of the physicians (indeed, while it obtained their names at the initial site visit, it did not subsequently update this information) and whether they had any specialty training in pain management, physical medicine, and/or addiction, all of which was readily accessible at the Florida Department of Health's Web site.

Respondent further justifies its failure to report the orders, asserting that the orders were consistent with the pharmacy's business model as represented by the PIC and confirmed during the May 2008 site visit. However, the fact that ''the URs and other information provided by Tru-Valu were consistent with the pharmacy's business model as explained by [its] PIC and confirmed in the May 2008 site inspection'' says nothing about whether the pharmacy was engaged in legitimate dispensing.

As for Ms. Seiple's contention that ''[b]ased on its extensive investigation, it determined that the orders it shipped to Tru-Valu were not suspicious,'' the fact remains that Respondent repeatedly failed to obtain an explanation for those orders that were held by the SOMS. And even in those few instances in which it did contact the pharmacy, it did not independently verify the pharmacy's explanation and it only rarely obtained a new UR.

As for Respondent's failure to obtain a new UR every time an order was held, the ALJ found that the Government had proved the allegation, noting that ''very few URs were collected, despite SOMS holding hundreds of orders over several years.'' R.D. at 201. However, the ALJ then explained that ''the relevant question . . . is not simply whether Respondent failed to follow its policies, but whether such failure rendered Respondent's system ineffective (factor one) and/or constituted negative experience distributing controlled substances so as to justify revocation (factor four).'' *Id.* (citing 21 U.S.C. 823(e)).[175]

Citing *Southwood,* the ALJ opined ''that an anti-diversion system is ineffective if 'the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of [controlled substances].'' *Id.* (quoting 72 FR at 36,502). The ALJ then explained that in contrast to *Southwood,* the Government had ''made no showing that Respondent's failure to order a recent UR for every SOMS-held order would likely result in diversion,'' noting that ''the record is void of evidence that *any* controlled substances distributed by Respondent ha[ve] been diverted.'' *Id.* at 201–02. The ALJ further reasoned that ''[t]here is also no evidence that updated URs, had they been requested, would have indicated that the drugs were likely to be diverted.'' *Id.* at 202.

The ALJ then characterized the Government's argument as being that ''*any* failure to follow *every* policy, no matter how minute, renders the Policies and Procedures *per se* ineffective, regardless of whether such failure would likely result in [the] diversion of controlled substances.'' *Id.* In the ALJ's view, ''[t]his argument falls short of the standard set forth in *Southwood* that due diligence efforts are ineffective when their 'direct and foreseeable consequence' '' is the 'likely diversion of' controlled substances.'' *Id.* (quoting 72 FR at 36,500). The ALJ thus concluded that the Government had not proved that Respondent's due diligence program was rendered ineffective by its failure to obtain a UR every time an order was held by the SOMS. *Id.*

While it is true that *Southwood* noted that the ''direct and foreseeable consequence of the manner in which [the distributor] conducted its due diligence programs was the likely diversion of'' large quantities of controlled substances, this discussion occurred in the context of describing the company's conduct in continuing to distribute the drugs even after it had obtained information from the Agency and some of its customers that the latter were likely filling unlawful prescriptions. 72 FR at 36,500; *see also id.* (noting that ''in several cases, Respondent actually distributed even larger quantities of [hydrocodone] to'' the pharmacies). *Southwood* did not, however, address whether a distributor's failure to follow its procedures for detecting and reporting suspicious orders must be shown to have resulted in the likely diversion of controlled substances in order to be actionable misconduct.

Respondent's Policy 6.2 served the purpose of identifying both: (1) Those orders which could be shipped notwithstanding that they met the criteria of unusual size, unusual pattern, or unusual frequency, because the suspicion created by the order itself was sufficiently dispelled through the procedures set forth by the policy, and (2) those orders which were to be considered as suspicious because the information obtained through those procedures did not dispel the suspicion. However, as explained above, an order can still be suspicious even if the evidence available to the distributor does not establish that the order is likely to be diverted. Thus, the Government was not required to show that Respondent's failure to follow its policy and obtain a UR was likely to result in diversion in order to establish liability. It need only show that the failure to follow the policy resulted in Respondent's failure to report suspicious orders.

As explained above, the ALJ characterized as ''minute'' the

[175] Because Respondent was distributing schedule II drugs, the correct section is 823(b), which uses the same factors as 823(e).

requirement that a new UR be obtained whenever an order was held by the SOMS. However, the record is replete with numerous instances in which orders held by the SOMS were nonetheless released without any investigation, based solely on the fact that the order was supported by the UR. Indeed, this occurred even when a new UR had not been obtained in months. And it also occurred even after Respondent's inspector noted, with respect to several of the pharmacies, that their controlled substance dispensing ratios seem high and that a new UR should be obtained and compared with the figure reported by the pharmacy.

To be sure, Respondent may well have ignored any information on those URs raising a suspicion of diversion, as it did with the few URs that were obtained. But as noted throughout this decision, the URs it did obtain contained significant information that raised a strong suspicion that the each of the pharmacies was engaged in illegitimate dispensing practices. I therefore also hold that Respondent's repeated failure to obtain a new UR whenever orders were held by the SOMS rendered its system for detecting suspicious orders ineffective.[176]

The Drug Shoppe

Prior to April 1, 2009, Respondent had acquired information raising a strong suspicion as to the legitimacy of The Drug Shoppe's dispensing practices. While The Drug Shoppe was a community pharmacy, it had previously reported that 40 percent of the prescriptions it filled were for controlled substances and 20 percent of the prescriptions were for schedule II drugs.

Moreover, the first UR obtained by Respondent showed that The Drug Shoppe's monthly dispensings of oxycodone 30 totaled 38,689 du and its dispensings of all oxycodone products totaled 56,600 du out of total dispensings of 165,068, or more than 34 percent of the pharmacy's dispensings. While The Drug Shoppe's PIC had stated that he had refused to fill prescriptions when the quantity was ''too high,'' the UR previously obtained showed that the average quantity of oxycodone 30 dispensed per prescription was 214 du.

Also, while during a site visit, the pharmacy reported that it filled for various pain management physicians and provided the names of five of the physicians, there is no evidence that Respondent even verified that the physicians were licensed and registered. Nor did it verify whether these physicians had specialty training or board certification in pain management or another related specialty.

According to Respondent's records, as of April 1, 2009, The Drug Shoppe's monthly purchasing limit was set at 50,000 du for all oxycodone products. Yet Respondent allowed The Drug Shoppe to exceed the purchasing limit by more than 5,000 du in April 2009.

In the middle of July 2009, Respondent obtained a new UR which covered the period of May 14 through July 14. Of note, the UR showed that The Drug Shoppe's monthly dispensings of oxycodone 30 had increased to nearly 53,000 du. Yet Respondent did not find this suspicious, and approved an increase from 50,000 to 62,000 du on The Drug Shoppe's oxycodone purchasing limit and filled orders totaling that amount during July.

Thereafter, the SOMS went into effect. However, even as early as the first month that the SOMS was operational, Respondent filled orders, which were held for review because they exceeded The Drug Shoppe's oxycodone CSL, without obtaining an explanation for the orders and a new UR while failing to report the orders as suspicious. For example, on August 13, 2009, Respondent filled an order for 1,000 Endocet which placed The Drug Shoppe over its CSL. While the SOMS was supposed to hold an order even if it resulted from a pharmacy's orders exceeding the CSL by a single dosage unit, the order was approved because it was ''ok to ship within current limit.'' As previously explained, if Respondent had actually contacted the pharmacy, one would expect the explanation it obtained from it to have been documented in the SOMS notes, rather than that the order was ''ok to ship within current limit.'' I therefore conclude that Respondent did not contact the pharmacy and obtain an explanation for the order, and that the order, which was not reported, was suspicious.

Further, only days later during the Compliance Review, a DEA Investigator specifically identified Respondent's distributions of oxycodone to The Drug Shoppe as ''potentially problematic.'' GX 48A, at 3, 5; GX 12, at 23. This information obviously had no impact on Respondent's evaluation of the oxycodone orders thereafter placed by The Drug Shoppe.

One week later, Respondent deleted an order because it placed The Drug Shoppe over its current limit. Yet Respondent did not report the order as suspicious. Moreover, the next day, Respondent filled an order for 19,500 du of oxycodone 30, bringing The Drug Shoppe's orders to 74,000 du of oxycodone products, with 72,500 du being for 30 mg tablets. While Respondent justified filling the order, documenting that there was a ''Large # RX's For HIV Disease State,'' there is no evidence that it independently verified that The Drug Shoppe was filling a large number of prescriptions for HIV patients as well as whether HIV patients would necessarily require oxycodone 30. Here again, while the order placed The Drug Shoppe over its CSL by 12,000 du, it was not reported as suspicious.

As noted in my findings, throughout the course of its relationship with The Drug Shoppe, the pharmacy repeatedly placed orders which, on a rolling 30-day basis, resulted in the pharmacy exceeding its oxycodone CSL by a large amount. Invariably, Respondent failed to contact the pharmacy and obtain an explanation for the order and it rarely obtained a new UR. Instead, it typically justified shipping the order, noting that the order was under the current size limit, even when the order placed The Drug Shoppe over its CSL by tens of thousands of dosage units. And it never reported any of the orders as suspicious.

Moreover, during November 2009, Respondent purportedly reduced The Drug Shoppe's oxycodone CSL to 46,500 du, yet Respondent continued to fill orders which placed The Drug Shoppe over the CSL, while also failing to contact the pharmacy and obtain an explanation for the orders and a new UR. And it failed to report the orders as suspicious.

Likewise on December 23, 2009, Respondent deleted an order for 15,500 du of oxycodone 30 because the pharmacy was already at the CSL. While Respondent contacted the pharmacy and was told that its sales representative had said that it was allotted 62,000 du, Respondent did not obtain a new UR. Moreover, the next day, Respondent shipped 13,500 du of oxycodone 30, thus bringing its shipments since December 3, 2009 to 60,000 du (of which 58,600 were for oxycodone 30). Respondent's records contain no explanation as to why it ignored that The Drug Shoppe was nearly 14,000 du over its CSL and it did not obtain a new UR. Nor did it report the order as suspicious.

As found above, throughout January 2010, Respondent filled orders that placed Respondent above the 46,500 du

[176] Where, in a given month, multiple orders were held, it would have sufficed if Respondent had obtained a new UR following the first held order, as it said it would. If that were the case, I would not find liability for failing to obtain additional URs.

CSL on nine occasions, and on several occasions, the orders even placed it above the previous CSL of 62,000. Respondent generally justified shipping the orders, reasoning that the amount ordered during the calendar month was under the CSL, notwithstanding that the determination of whether the orders exceeded the CSL was supposed to be calculated on a rolling 30-day basis. Here again, while the SOMS notes typically contained this explanation, Respondent did not document that it obtained an explanation for the order from the pharmacy and a new UR. I conclude that the orders were suspicious and should have been reported but were not.

Moreover, in the middle of January, Respondent conducted a site visit. On the report, the inspector noted in multiple places that The Drug Shoppe's dispensing ratio of 40 percent was ''a little high.'' He recommended that Respondent obtain a new UR and compare it with the site visit. Respondent did not, however, obtain a new UR for another five months. Nor did it follow its inspector's recommendation to compare the pharmacy's representation of its dispensing ratio with even the previous UR.

On January 25, 2010, The Drug Shoppe's CSL was raised to 60,000 du. Only four days later, Respondent filled more oxycodone orders, notwithstanding that they placed the pharmacy at 15,000 du over the new CSL. According to various notes, Respondent's Compliance Committee approved the increase because the order was supported by the ''ur plus 10%'' ''per company policy.'' Here again, Respondent treated the UR as a one-way ticket to justify increasing the amount it could ship, while ignoring that the UR was incomplete because it did not list The Drug Shoppe's total dispensings, as well as the significant information it contained.

As found above, on multiple occasions thereafter through June 15, 2010, Respondent filled The Drug Shoppe's oxycodone orders notwithstanding that the orders placed it over its CSL (and on some occasions because the orders were of unusual frequency). Here again, Respondent released the orders on the basis of one of three reasons: (1) That the order was under the CSL, (2) that the order was supported by the UR, or (3) that the frequency was not excessive, even though the SOMS had apparently flagged some of the orders for this reason as well. However, with the exception of an order placed on May 7, 2010, which was apparently held by the SOMS because The Drug Shoppe had placed four orders each for 9,600 du between May 3 and 7 and thus were of an unusual pattern, Respondent failed to obtain an explanation for any of these orders from the pharmacy and a new UR.[177] Nor did it report any of the orders as suspicious.

On June 15, 2010, Respondent edited an oxycodone 30 order from 9,600 du to 5,400 du. Nonetheless, this resulted in The Drug Shoppe's orders totaling 67,600 du and placing it over its CSL. While Respondent finally obtained a new UR, there is no evidence that Respondent actually obtained an explanation for the order. Nor did it report the order as suspicious.

Still later on June 25, Respondent filled an order for 6,000 du of oxycodone 30. Yet it documented in the SOMS notes that ''oxy edited to zero per csl and policy.'' Respondent offered no evidence to explain the inconsistency and did not report the order as suspicious. And several days later, The Drug Shoppe placed a further order for 3,600 du of oxycodone which was held by the SOMS. While Respondent deleted the order, noting that it could be placed after June 30, it did not investigate the order and did not report the order as suspicious.

According to the SOMS note dated July 19, 2010, The Drug Shoppe's oxycodone CSL was then at 42,420 du. Yet on this date, Respondent filled an order for 9,600 du of oxycodone 30, thus placing the total of filled orders at 46,800 du on a rolling 30-day basis and over the CSL. Of note, while the order was held by the SOMS, Respondent did not contact the pharmacist and obtain an explanation for the order. Nor did it obtain a new UR. And it did not report the order as suspicious.

Moreover, one week later, Respondent edited an order to 1,600 du ''to meet the CSL for July.'' Notwithstanding that the order (and not simply the filled amount) placed The Drug Shoppe over its CSL, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. Nor did it obtain a new UR. It did not report the order as suspicious. And the deleted amount was treated as if it had never been ordered.

As found above, on multiple occasions throughout August, Respondent filled The Drug Shoppe's orders notwithstanding that the orders exceeded the CSL referred to in the July 19 SOMS note on a rolling 30-day basis. Here again, while the orders were held by the SOMS, several of them were approved because Respondent counted them on a calendar month basis and deemed the size not excessive, thus changing its own rule. Respondent did not contact the pharmacy and obtain an explanation for the orders or a new UR. And later on August 24, 2010, Respondent filled an order, notwithstanding that the order placed The Drug Shoppe over the CSL, documenting the reason as ''RWR'' (release with reservation). Yet Respondent's Policy 6.2 contained no provision that allowed for the release of an order on this basis.[178] RX 78, at 32. Respondent did not obtain an explanation from the pharmacy for any of these orders, it did not obtain a new UR, and it failed to report any of the orders as suspicious.

On each date in September 2010 on which it filled The Drug Shoppe's oxycodone orders, the pharmacy exceeded the CSL. The explanations offered for releasing the orders included: (1) That the orders were ''within [the] monthly buying pattern'' even though the orders exceeded the CSL (Sept. 1 and 2 orders); (2) the orders were ''under csl [and] supported by ur'' or ''rwr under csl'' even when the orders placed the pharmacy more than 9,000 du over its csl (Sept. 7), or nearly 8,000 du over (Sept. 20); or (3) merely ''rwr'' even when the orders placed the pharmacy over the CSL by nearly 10,000 du (Sept. 13) and 13,000 du (Sept. 23). Of note, Respondent did not document that it had contacted the pharmacy and obtained an explanation for any of the orders and I find that it did not do so. Respondent also did not obtain a new UR. And it failed to report any of the orders as suspicious.

October 2010 brought more of the same, with The Drug Shoppe's orders exceeding the CSL on four occasions and Respondent filling the orders, typically justifying its doing so by counting the orders on a calendar-month basis. However, here again,

[177] However, while Respondent contact The Drug Shoppe at the time of the May 7 order, it did not obtain a new UR.

[178] The ALJ rejected the Government's contention that Respondent's compliance department used the notation of ''release with reservation'' or ''RWR'' to document its objection to the release of a held order. R.D. at 168–69. The ALJ rejected the contention, reasoning that ''Ms. Seiple credibly explained that RWR was actually used to identify orders that were not suspicious, but about which Respondent desired to collect more information.'' *Id.*

I conclude, however, that it is not necessary to determine what the purpose was of these notations, because in those instances in which orders were held by the SOMS, the orders already met the criteria of a suspicious order. Accordingly, even if Respondent used the notations because it ''desired to collect more information'' about the customer, *id.,* the order was still suspicious and subject to reporting.

Respondent failed to contact the pharmacy and obtain an explanation for the order and a new UR. And it failed to report the orders as suspicious.

While November 2010 brought a substantial decrease in the volume of oxycodone Respondent shipped to The Drug Shoppe, both the November 1 and November 9 orders placed the pharmacy over its CSL on a rolling 30-day basis, with the first order placing The Drug Shoppe nearly 8,700 du over its CSL. The order was released, notwithstanding that Respondent failed to obtain an explanation for the order from the pharmacy and a new UR. Again, it failed to report the order as suspicious. Nor did Respondent obtain an explanation for the November 9 order and a new UR. And it did not report the order as suspicious.

On November 18, Respondent conducted a site visit during which its inspector was told that 40 percent of the prescriptions were for controlled drugs and ten percent were for schedule II drugs. The inspector was also told that 85 percent of the controlled substance prescriptions it filled were paid for with cash. Both of these were additional indicia that the pharmacy was engaged in in suspicious dispensing practices. *See* GX 51, at 4 ¶ 12 (declaration of Wayne Corona).

Moreover, while Respondent obtained a new UR on December 15, 2010, (for the month of October), that UR showed that Respondent's dispensings of oxycodone 30 alone (49,637 du) comprised 27 percent of all drugs dispensed, and its dispensings of all oxycodone products totaled 57,601 du, or more than 31 percent of all drugs dispensed. Yet even after acquiring this additional information, Respondent continued to ship oxycodone to The Drug Shoppe through February 8, 2011, the date on which DEA Investigators went to Respondent's Kemper Springs facility and requested its file on The Drug Shoppe. Respondent failed to report any of these orders as suspicious.

I find unpersuasive Ms. Seiple's justifications for why Respondent failed to report any of The Drug Shoppe's orders as suspicious. From early on in its relationship with The Drug Shoppe, Respondent acquired substantial information raising a strong suspicion that the pharmacy was engaged in illegitimate dispensing practices. Moreover, during the August 2009 DEA briefing, Respondent's distributions to The Drug Shoppe were specifically identified as being potentially problematic.

Regarding Ms. Seiple's claim that Respondent believed that the volume of pain medications being dispensed was accounted for because the pharmacy was filling for AIDS patients, Respondent simply accepted this assertion without any further inquiry as to how many HIV/AIDS patients the pharmacy had, let alone how many of these patients were actually being prescribed oxycodone 30. Nor did Ms. Seiple address the many instances in which orders were held by the SOMS and yet Respondent filled the orders without contacting the pharmacy and obtaining an explanation (let alone then independently verifying the explanation) and a new UR.

Nor do I find persuasive Ms. Seiple's explanation as to why it took until February 2011 for Respondent to discover that The Drug Shoppe's PIC had been criminally charged with an offense related to controlled substances. Even assuming that Respondent was unaware of Mr. Agravat's criminal charge until February 2011, the due diligence file establishes that the form for the 2008 site visit included a question which asked, in part, whether any of the staff pharmacists had ever been criminally prosecuted. Notably, Respondent's consultant left the answer blank and there is no evidence that Respondent ever followed up on the omission. Moreover, none of the forms Respondent subsequently used to document its due diligence and site visits even asked this question. And in any event, there were sufficient other circumstances present that created a strong suspicion that The Drug Shoppe was engaged in illegitimate dispensing practices. I therefore reject Respondent's justifications as to why it did not report any of The Drug Shoppe's orders as suspicious prior to February 2011.

Englewood Specialty Pharmacy

Prior to April 1, 2009, Respondent had obtained substantial information creating a strong suspicion as to the legitimacy of Englewood Specialty Pharmacy's dispensing practices. For example, in a due diligence review conducted in March 2008 because Englewood was seeking an increase in its purchasing limits for oxycodone and hydrocodone, Englewood reported that 30 percent of the prescriptions it filled were for controlled substances and 15 percent of the prescriptions were for schedule II drugs. Yet the UR provided by Englewood, which covered the month of January 2008, also showed the number of prescriptions for each drug and even totaled the prescriptions for the various schedules and the non-controlled prescriptions. Notably, as found above, schedule II drugs actually comprised more than 32 percent and all controlled substances comprised 51 percent of the prescriptions dispensed.

In terms of dosage units, the UR showed that out of Englewood's total dispensings of 342,760 du for all prescription drugs, schedule II drugs comprised 161,279 du, or 47 percent of its total dispensings. Moreover, controlled substances comprised 67 percent of its total dispensings, even after counting carisoprodol as a non-controlled drug. Of further note, while a Dan Farris was the owner of the pharmacy and listed as the Pharmacist-in-Charge by the consultant who performed the September 2008 site visit, there is no evidence that Respondent ever verified Dan Farris' licensure status with the Florida Department of Health.

In September 2008, Englewood sought a further increase in its oxycodone purchasing limit, with its PIC reporting that 30 percent of the prescriptions it filled were for controlled drugs and 20 percent were for schedule IIs. However, the UR Englewood submitted showed that it filled 9,928 schedule II prescriptions and 5,595 schedule III through V prescriptions (after subtracting out carisoprodol), out of a total of 22,315 prescriptions. Thus, schedule II prescriptions comprised 44.5 percent of all prescriptions and all controlled substances prescriptions comprised nearly 70 percent of all prescriptions the pharmacy dispensed.

Moreover, in terms of dosage units, the UR showed that schedule II drugs comprised 57 percent of the total dispensings and all controlled substances (again after subtracting carisoprodol) comprised 75 percent of the total dispensings. Even assuming that the pharmacist's representations as to the percentage of the prescriptions comprised by schedule II and all controlled substances were estimates, the disparity between these statements and the actual figures as shown in the UR was too large to be ignored. Yet there is no evidence that Respondent compared the prescriptions levels on the UR with the pharmacist's statement.[179]

Most significantly, in early November 2008, Respondent finally conducted a

[179] Throughout the proceeding Respondent has argued that is unfair to fault it for failing to compare the dispensing percentages as reported by the pharmacies with those shown by the URs because neither before, nor as part of the August 2009 compliance review, did the Agency identify this as a deficiency in its procedures. While it is true that, in some instances, the pharmacy's URs did not include the number of prescriptions, in Englewood's case, the URs did and yet the information was still ignored. This suggests that Respondent's purpose in asking these questions was simply to go through the motion of conducting due diligence.

site visit at Englewood, during which its PIC reported that all controlled substance prescriptions comprised only 25 percent of the prescriptions it filled. Tellingly, Respondent's consultant wrote in his report that ''[h]e [the PIC] appears to be doing a larger narcotic business than he admits to.'' RX 2C, at 78. Yet even this did not prompt Respondent to review the information provided by the UR and compare it with the various statements the PIC had made, and most incredibly, Respondent subsequently approved Englewood to purchase 50,000 du of oxycodone per month.

Notwithstanding the purchasing limit, Respondent filled orders for more than 80,000 du in the April (30,000 over the purchasing limit), and 102,000 du in both June and July 2009 (52,000 over the purchasing limit).[180] Respondent, however, had not obtained a new UR since September 2008, and even then the June and July orders exceeded its average monthly dispensings of oxycodone 30 and 15 mg (approximately 74,000 for the two dosages combined) as shown on that report by approximately 28,000 du. Yet there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the orders and there is no evidence explaining why Respondent ignored the purported purchasing limit. Based on the circumstances presented, I conclude that the orders during these months were suspicious and that Respondent violated 21 CFR 1301.74(b) by failing to report them.

While the SOMS became operational in August 2009, Respondent filled orders placed on August 3 for 90,000 oxycodone 30 and 12,000 oxycodone 15, totaling 102,000 du, and on September 28, it filled orders for 90,000 du of oxycodone 30 and 10,000 du of oxycodone 15. Yet the SOMS notes show that neither set of orders were held for review. GX 18, at 163. As previously explained, because the SOMS recalculated the CSL every month based on the highest monthly total of doses invoiced in the preceding six months, the CSL was increased even where the orders were never properly reviewed such as in the months of June and July 2009. Here again, this supports a finding that as implemented, the SOMS was not an effective control against diversion. Moreover, with respect to the September 28 orders, Englewood was specifically identified during the August 2009 DEA briefing as a customer whose oxycodone purchases were problematic. GX 48A, at 3; GX 12, at 23. Yet Respondent even failed to report the September orders as suspicious.

In early October 2009, Respondent finally obtained a new UR (for the month of September), 11 months after it had obtained the previous UR. Of note, by du, the UR showed that schedule II drugs comprised 62 percent and all controlled substances comprised 77 percent of Englewood's total dispensings. Moreover, Englewood's monthly dispensings of oxycodone 30 had increased from 51,341 to 123,476 du.

Ms. Seiple noted that Englewood's account was ''showing usage of 150k on oxy in [the] month of September'' [181] and that the pharmacy was also purchasing from Amerisource Bergen, another distributor. Ms. Seiple further documented that she was ''very concerned w/quantity dispensed per UR'' and was recommending that Englewood be limited to 50,000 du of oxycodone until the Compliance Committee reviewed the account.[182]

While the Compliance Committee reviewed the account and adopted Ms. Seiple's recommendation to reduced Englewood's oxycodone CSL to 50,000 du, on October 27, Englewood ordered 100,000 du of oxycodone 30 and 20,000 of oxycodone 15. While the order for 30 mg was reduced to 50,000 du and the order for 15 mg was deleted, neither order was reported as suspicious as it should have been. Indeed, Ms. Seiple's documented concern over the quantity of oxycodone being dispensed by Englewood begs the question of exactly what additional evidence was required to render the orders suspicious.

On December 3, Englewood placed orders for 50,000 du of oxycodone 30 and 24,000 du of methadone. This, however, was only three days after Respondent had filled an oxycodone order for 37,500 du which placed Englewood at its CSL, which apparently had been reduced due to supply issues. While Respondent deleted the order and told the PIC that it would not fill the order until there was a review by the Compliance Committee, it did not obtain an explanation for the order or a new UR and it failed to report the orders as suspicious.

However, two weeks later, Englewood placed more orders for 50,000 oxycodone 30 and 24,000 du of methadone. While Ms. Seiple documented that she called the pharmacy and told the PIC that order would not be shipped but could be resubmitted in four days, here again, there is no evidence that Ms. Seiple asked the PIC why his pharmacy needed so much oxycodone. She also failed to obtain a new UR and failed to report the order as suspicious.

Notwithstanding the extensive evidence that Englewood was engaged in illegitimate dispensing practices, on December 28, Respondent's compliance committee conducted a new review and approved the pharmacy to purchase 50,000 du of oxycodone 30 and 24,000 du of methadone. However, the orders were not reported as suspicious. Based on the evidence, I conclude that the orders were suspicious and should have been reported.

Moreover, on Jan. 12, 2010, Respondent conducted a second site visit at Englewood. While the inspector (Mr. Chase) documented that Dan Farris was the owner and that he had never had his license suspended, there is no evidence that Respondent ever verified this information. Mr. Chase further noted that 40 percent of the prescriptions filled by Englewood were for any controlled substances and that this was ''a little high'' and that ''25 [percent] were for schedule II drugs.''

While Chase recommended that Respondent obtain a new UR and compare it with the figures provided by the pharmacist, it did not obtain a new UR until August 11, 2010, seven months later. Moreover, as found above, the most recent UR showed that schedule II drugs comprised 45 percent and all controlled substances comprised 66 percent of the prescriptions Englewood dispensed. Yet there is no evidence that Respondent's Compliance Department even examined the previous UR.

Thereafter, beginning in late January 2010, Englewood repeatedly placed oxycodone orders that exceeded the CSL on a rolling 30-day basis. While the orders were held by the SOMS, the evidence shows that the orders were filled, with the typical justification being that the orders were supported by Englewood's UR, which was already three months old (as of January) and which had prompted Ms. Seiple to

[180] As found above, the June 2009 orders were comprised entirely of 30 mg tablets, and the July orders included 100,000 du of the 30 mg tablets.

[181] This would be accurate if one only counted Englewood dispensings of oxycodone 30 and 15 (26,097 du). As found above, Englewood's dispensings of all oxycodone products, including extended release drugs, totaled nearly 216,000 du, or 44 percent of its total dispensings.

[182] Ms. Seiple also documented that she was very concerned with the quantities of methadone being dispensed by Englewood and had discussed with its PIC the size of the prescriptions and been told that they averaged 480 to 600 du per script. Yet the UR showed that the prescriptions averaged only 258 du, provided one actually bothered to add up the two line items on the UR and calculate the average per prescription. RX 2C, at 41. This was another example of Englewood's PIC providing information, the falsity of which was easily ascertainable, which Respondent ignored.

initially limit the account because of her concern with the quantities being dispensed. *See, e.g.,* RX 2C, at 2 (MFR note of Jan. 26; ''Ship per UR per Committee signed by Wayne''). And in other instances, the orders were justified as being within the CSL, even though they clearly were not. *See, e.g.,* GX 18, at 164 (April 15 order for 50,000 du of oxycodone 30 approved as ''under CSL'' even though the order placed Englewood's oxycodone orders at 139,600 du on a rolling 30-day basis); *id.* (May 26 SOMS notes: ''release order under CSL'' even though filled orders totaled 80,000 du on both a rolling 30-day and calendar month basis and subsequent notes indicate the CSL was set at 63,000). None of these orders were reported as suspicious. I hold that they were.

Indeed, the evidence shows that at Mr. Corona's direction, Respondent adopted a policy of filling Englewood's orders as long as the quantity was supported by the UR and without obtaining an explanation from the pharmacy, which was independently verified, and a new UR. *See* RX 2C, at 2. This was contrary to the representations made by Respondent to this Agency as to how its SOMS program would be operated and resulted in Respondent's failure to report numerous suspicious orders. And I further hold that this policy rendered the SOMS an ineffective system for disclosing suspicious orders. 21 CFR 1301.74(b).

Thereafter, on June 28, 2010, Respondent, which had filled an order for 50,000 du of oxycodone 30 three days earlier, edited an order from 40,000 du (400 bottles) to 13,000 (du). While the SOMS notes indicate that the order was edited down to keep Englewood at its CSL, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. It did not obtain a new UR, even though the last UR was then nine months old. Nor did it report the order as suspicious. I hold that it was.

So too, only two days later, Englewood placed another order, this being for 9,600 du of oxycodone, which Respondent deleted. While Respondent attempted to contact the pharmacy's PIC, it was unable to get a hold of him and it failed to obtain an explanation for the order. It also failed to report the order as suspicious. I hold that it was.

On July 13, Respondent filled an order for 50,000 du of oxycodone, bringing the rolling 30-day total of filled orders to 113,000 du, nearly double the CSL of 63,000. While Ms. Seiple documented that the PIC had stated that he was no longer ordering his allotment at the end of the month, the evidence shows that Englewood had been ordering large quantities (typically 50,000 du) in the middle of March, April and May 2010. Thus, although Respondent could have verified the PIC's statement simply by reviewing its own records, there is no evidence that it did so and it again failed to obtain a new UR. Nor did it report the order as suspicious even though the order placed Englewood at more than 50,000 du over its CSL. I hold that the order was suspicious.

Also, notwithstanding the PIC's statement that he was no longer ordering his allotment at the end of the month, on July 27, 2010, Englewood ordered 30,000 du, which again placed its orders over the CSL. While Respondent edited the orders to 13,000 du, it did not contact the pharmacy and obtain an explanation for the order. Nor did it obtain a new UR. And while under its policies, Respondent was required to review the entire file on Englewood before filling an order that was held by the SOMS, there is no evidence that it questioned why Englewood had ordered 30,000 du, given the PIC's statement that he was no longer ordering at the end of the month. Respondent did not report the order as suspicious. Here again, I conclude that the order was suspicious.

On August 10, 2010, Respondent filled an order for 50,000 du, bringing the total of Englewood's filled orders to 113,000 du on a rolling 30-day basis. Respondent did not contact the pharmacy and obtain an explanation for the order. Instead, Ms. Seiple released the order ''with reservation''—''pending updated UR.'' Notably, Respondent had not obtained a new UR in ten months (even though Respondent's policy required it to obtain a new UR every time an order was held by the SOMS) and it had been seven months since its inspector had recommended that it obtain a new UR. The order was not reported as suspicious. I hold that the order was suspicious.

Respondent finally obtained a UR (for July 2010) *the day after it filled the order.* The UR showed that Englewood had dispensed more than 204,000 du of oxycodone 30 during the month. The dispensings of oxycodone 30 alone comprised more than 39 percent of the pharmacy's total dispensings, and the July 2010 dispensings of oxycodone 30 showed an increase of more than 80,000 du from the prior UR. The UR also showed that with the exception of carisoprodol, the top ten drugs dispensed by volume included six oxycodone products, methadone, and two alprazolam products. Moreover, 18 of the top 20 drugs were federally controlled substances.

Yet even after obtaining this UR, which showed an even higher level of oxycodone dispensing than the September UR which had prompted Ms. Seiple's concern over Englewood's dispensing levels, Respondent continued to fill the pharmacy's orders for large quantities of oxycodone. On both August 23 and September 27, 2010, Englewood submitted orders which placed it over its oxycodone CSL, and yet on both occasions Respondent failed to obtain an explanation for the orders. While Respondent edited the August 23 order from 25,000 du to 13,000 du, Englewood's orders were still over the CSL by 13,000 du and yet Respondent did not report the order as suspicious. And while Respondent edited the September 27 order from 18,000 to 13,000 du and brought Englewood within its CSL, here again, Respondent failed to obtain an explanation for the order. Instead, Respondent treated the 5,000 du that was edited off the order as if Englewood had never ordered this additional amount and failed to report the order. I hold, however, that the order was also suspicious and that Respondent was required to report both the August 23 and September 27, 2010 orders.[183]

Respondent only terminated Englewood as a customer after a subsequent site visit, during which its inspector observed cars with both Kentucky and Tennessee license plates in the parking lot and documented that there was ''suspicious activity outside of the pharmacy.'' Yet Englewood had repeatedly presented numerous other suspicious circumstances during the course of Respondent's dealings with it.

As for Ms. Seiple's explanations as to why Respondent did not report any of Englewood's orders as suspicious, Ms. Seiple failed to address why Respondent did not verify the status of the PIC's license. While Ms. Seiple asserted that Respondent was aware of the volume of oxycodone and other controlled substances being dispensed and the percentage of controlled to non-controlled drugs, her claim that these were accounted for by the pharmacy's 'business model'' of servicing patients from two large hospitals, a number of physician's offices and ''several nearby pain clinics'' is unpersuasive. As

[183] The next day, Respondent placed additional orders for 1,200 oxycodone 20 and 600 du of oxycodone 10, bringing Englewood's rolling 30-day total to 64,800 du and over the CSL. Respondent filled the orders, notwithstanding that it failed to obtain an explanation for the orders and did not report them as suspicious, noting that this was the ''first time purchase [sic] on Oxy since 2009.''

previously explained, hospitals have their own pharmacies, and in any event, Respondent produced no evidence to support the conclusion that a pharmacy's mere proximity to a hospital would result in controlled substances being dispensed at a level more than three times (by ratio) than that of a typical retail pharmacy. So too, even if there were a number of physician's offices near the pharmacy, this does not explain why controlled substances would be dispensed at a ratio more than three times that of a typical retail pharmacy.

To be sure, Ms. Seiple also contended that Englewood ''filled prescriptions for patients from several nearby pain clinics and identified the physicians,'' and that ''[t]his accounted for the volume of pain medications and other controlled substances, including oxycodone, being dispensed relative to other drugs.'' Yet two of the doctors were located in Sarasota, a distance of approximately 47 miles from Port Charlotte, which is hardly ''nearby,'' and which begs the question as to why the pharmacy's patients were travelling this distance to get their prescriptions. And while filling prescriptions written by doctors working at pain clinics may well have accounted for the high volume of controlled substances being dispensed by Englewood, it says nothing about the legitimacy of those prescriptions. Respondent did not, however, conduct any inquiry into whether these physicians even held licenses, let alone whether they had any training or board certification in pain management or other related specialties.

Moreover, in the initial site visit report, Respondent's consultant specifically noted that Englewood's PIC ''appears to be doing a larger narcotics business then he admits to.'' Ms. Seiple totally failed to address what action, if any, she took in response to this observation as well as the other instances in which Englewood's PIC represented that the percentage of its dispensings comprised by both schedule II and all controlled substances were substantially lower than what the URs showed. This was so even though Englewood's URs showed the total number of prescriptions for each schedule of controlled substance as well as for non-controlled prescriptions drugs.

So too, putting aside that the SOMS was not even operational until August 2009, Ms. Seiple did not claim that for every order held by the SOMS, Respondent obtained an explanation for the order, let alone that it independently verified the explanation, and a new UR. Indeed, Respondent rarely obtained an explanation for the orders, and it obtained only four URs during the course of its relationship with Englewood, as Ms. Seiple conceded in her declaration. Notably, during the period from April 1, 2009 through Respondent's termination of Englewood in October 2010, it obtained a new UR only twice: Once in October 2009 (for Sept.), more than one year after it had obtained the previous UR, and again in August 2010, ten months later. Respondent also disregarded its inspector's recommendation to get a new UR following the January 2010 site visit.

Ms. Seiple's explanation for why it did not get a UR notwithstanding the inspector's recommendation was that Respondent's policies and procedures did ''not specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers 'high' or 'a little high.'' While that may be, Respondent's policies and procedures did require that a new UR be obtained whenever an order was held for review by the SOMS, and as found above, the SOMS held numerous orders after October 2009, and this continued through the following year. However, Ms. Seiple offered no explanation for why Respondent failed to comply with its Policy and Procedures applicable to the review of held orders.

Moreover, the controlled substance percentage (40) reported by the inspector was double the percentage discussed at the August 2009 compliance review, as well as double the figure noted by the Agency in *Southwood.* Unexplained by Ms. Seiple is what level of controlled substance dispensing was required to induce her to follow the inspector's recommendation. I therefore find Ms. Seiple's explanation for why it failed to obtain a new UR unpersuasive. And I further find that none of the reasons offered by Ms. Seiple for failing to report Englewood's orders as suspicious excuse Respondent's failure to do so.

City View Pharmacy

More than one year before April 1, 2009, Respondent had acquired substantial information which created a suspicion as to the legitimacy of City View's dispensing practices. More specifically, in March 2008, City View requested an increase in the quantity of solid dose oxycodone it could purchase to 20,000 du per month. In reviewing City View's request, Respondent documented that 60 percent of the prescriptions filled by the pharmacy were for controlled substances and 40 percent were for schedule II drugs. These figures placed City View well above the controlled to non-controlled dispensing ratio of a typical retail pharmacy as discussed in *Southwood.*

As part of the review, City View provided a UR for the month of February 2008. Notably, the UR showed that oxycodone 30 alone accounted for more than 24 percent of its total dispensings and oxycodone products alone accounted for more than 35 percent. Of note, during a site visit by its consultant done three months later, City View reported that all controlled substances comprised 35 to 40 percent of the prescriptions it filled and that it had purchased drugs from five different distributors during the previous 24 months.

During the site visit, City View also reported that it filled prescriptions for pain management physicians, identifying six such physicians by name and providing their DEA numbers. Yet there is no evidence that Respondent verified the credentials of these physicians.

Shortly after the site visit, Respondent approved City View to purchase 25,000 du of oxycodone per month while at the same time rejecting its request to purchase alprazolam because it was ''too new'' a customer. Unexplained is why City View was also not too new to purchase oxycodone.

Notwithstanding that City View's oxycodone purchasing limit was set at 25,000 du, in both June and July 2009, Respondent filled orders by the pharmacy totaling more than 31,000 du. Respondent did not document that it obtained any explanation for why it allowed City View to exceed the purchasing limit. Moreover, Respondent had not obtained a new UR since the March 2008 UR, more than one year earlier.

After Respondent filled an order (Aug. 3, 2009) for 20,000 du of oxycodone 30 and 2,400 du of oxycodone 15, Ms. Seiple made an entry in the Ship to Memos stating ''8/3/09 please keep on hold until UR is received per file.'' GX 19, at 111. Yet on August 25, one week after Respondent had represented to DEA that when an order was held by the SOMS, it would contact the pharmacy and obtain an explanation for the order (which it would purportedly then independently verify) as well as a new UR, Respondent filled an order for 7,600 du (which placed it at 33,000 du on a rolling 30-day basis), notwithstanding that it did not contact the pharmacy and obtain an explanation for the order and still had not obtained a new UR. Instead, it released the order on the ground that it was at the pharmacy's ''oxy limit for the month.''

Indeed, Respondent did not obtain a new UR until October 5, even though City View submitted orders on both September 1 and 14, 2009, which placed it over its CSL (according to the SOMS notes) on a rolling 30-day basis. Respondent did not contact City View and obtain an explanation for either order. Instead, it released the September 1 order, the explanation being that the order placed City View ''under current limit,'' and it released the September 14 order, the explanation being that the order placed it ''at their [sic] current limit.'' Neither order was reported as suspicious, even though they had triggered the SOMS review because they were of unusual size. However, I conclude that they were suspicious.

Still later in the month, City View placed an order for 10,000 du, which Respondent deleted, noting that its limit was 30,000 du and that it had ''already received 37,600 within 30 days.'' Moreover, while Ms. Seiple contacted the pharmacy the same date, the pharmacist did not provide the information she sought and hung up on her. While Respondent went so far as to place City View on compliance hold, it did not report the order as suspicious. I conclude that the order was suspicious.

On October 1, City View placed an order for 10,000 du of oxycodone 30. While Respondent deleted the order and left a message for the pharmacist that it would not ship without a new UR, it did not report the order as suspicious.

On October 5, Respondent finally obtained a new UR, more than 17 months after it had obtained the previous UR. The UR showed that during the month of September 2009, City View had dispensed 47,472 du of oxycodone 30. City View's dispensings of oxycodone 30 alone comprised 41 percent of its dispensings of all prescription products. With the exception of carisoprodol, the top ten drugs dispensed by quantity were comprised of three oxycodone products (30 mg, 15 mg, and 10/325 mg), four different manufacturers' alprazolam 2 mg products, one manufacturer's alprazolam 1 mg product, and a combination hydrocodone 10/500 mg product. All of these are highly abused drugs. The UR thus created a strong suspicion that City View was not engaged in legitimate dispensing practices.

Notwithstanding the information provided by the UR, on October 5, 2009, Respondent filled an order for 10,000 du of oxycodone 30. Based on the information provided by the UR, I hold that the order was suspicious, notwithstanding that the order was not held by the SOMS. GX 19, at 119. Respondent did not, however, report the order as suspicious. For the same reason, I also hold that the orders for 10,000 du which Respondent filled on October 12 and 20 were suspicious and should have been reported.[184]

On October 29, City View placed a further order for oxycodone 30, which placed its orders over its CSL on a rolling 30-day basis. While Respondent contacted the PIC and told him that the order was being deleted, it did not obtain an explanation for the order and it failed to report the order as suspicious, which it was based on the information provided by the recent UR alone.

Thereafter, the evidence shows that City View submitted orders for 10,000 du on November 2, 6, and 16, as well as December 1, 2009, each of which placed its oxycodone orders above the CSL (whether it was set at 30,000 du or 22,500 du) on a rolling 30-day basis, and in some cases at 40,000 du. While the November 16 order was edited to 2,500 du, Respondent failed to obtain an explanation for the orders from the pharmacy and a new UR. It also failed to report the orders as suspicious. I hold that the orders were suspicious based on both the information Respondent had obtained which raised a strong suspicion as to the legitimacy of City View's dispensings practices, and Respondent's failure to investigate why City View was placing orders which the SOMS had flagged for being of unusual size.

Through the rest of December 2009 and January 2010, City View's oxycodone orders did not place it over the CSL (whether it was set at 30,000 or 22,500 du). However, on February 1 and 8, Respondent filled orders for 10,000 du on each date, thus placing City View's orders at 32,500 du on a rolling 30-day basis and over the CSL. Respondent approved both orders, documenting the reason as being that the orders were under the CSL, when they clearly were not. Respondent did not contact the pharmacy on either occasion and obtain an explanation for the order and it did not obtain a new UR. Nor did it report the orders as suspicious even though the orders were flagged by the SOMS for being of unusual size. I hold that the orders were suspicious based on the information Respondent had obtained regarding City View's dispensing practices and Respondent's failure to investigate the orders.

On February 17, Respondent conducted a site visit, during which its inspector was told that schedule II drugs comprised 15 percent and all controlled substances comprised 30 percent of the prescriptions dispensed by City View. The inspector did not, however, note that City View was servicing any pain clinics. And while he recommended that a new UR be obtained and compared with the dispensing ratio reported at the site visit,[185] Respondent did not obtain a new UR until April 26, 2010, more than two months later.

The evidence shows that on February 18, as well March 3, 12, 18, and 24, 2010, City View placed orders for 10,000 du of oxycodone 30 which were held by the SOMS, typically because the orders placed the pharmacy over its CSL on a rolling 30-day basis and typically by thousands of dosage units. Invariably, the orders were filled, notwithstanding that Respondent failed to contact the pharmacy and obtain an explanation for the order, with the reason given being either that the order was under the CSL (because Respondent counted the orders on a calendar-month basis) or that the order was supported by the dispensing levels shown on the UR, which had not been obtained since early October. Respondent did not report any of the orders as suspicious. Based on Respondent's failure to investigate the orders and the information it had obtained regarding the pharmacy's dispensing levels, I hold that the orders were suspicious.

Moreover, while a March 24, 2010 SOMS note states that the CSL was 22,500 du, on March 27 (a Saturday), City View placed two orders totaling 20,000 du, resulting in its rolling 30-day orders being 61,200 du, nearly three times the CSL listed in the note. While the evidence shows that Respondent contacted the pharmacist and was told that he placed the second order to be released on April 1, there is no evidence that Respondent questioned him as to why City View's orders during March had increased by 70 percent from the previous month. Instead, it approved the first order on the ground that the ''UR supports release-places CSL @ 51,200 for current period,'' even though it had not obtained a new UR in more

[184] The SOMS notes show that multiple orders were placed on October 12. GX 19, at 119. However, only one of the entries lists the name of a reviewer and a reason for why the order was shipped and the note does not state what drug was ordered. As for the October 20 order, the SOMS notes do not list a reviewer and a reason, thus suggesting that the order was not held for review.

[185] While on the Pharmacy Evaluation form, the questions which asked for the percentage of controlled drugs and the percentage of schedule II drugs, followed the questions: ''What is the average number of prescriptions filled per day?'' the Site Visit Recommendation form simply states: ''Control/Non-control ratio of 30%.''

than five months. Nor did it report the order as suspicious. Here again, I hold that the order was suspicious for the reasons stated above. Moreover, this was another example of the CSL having been increased based on Respondent's having filled orders even though it failed to properly review those orders.

As found above, on seven occasions during April, Respondent filled orders by City View which placed its rolling 30-day total at between 61,200 and 64,000 du (depending on the date), when its CSL was 51,200. With the exception of the April 26 (the last April) order, when it finally obtained a new UR, Respondent did not even contact City View, let alone obtain an explanation for the orders. And even with respect to the April 26 order, there is no evidence that Respondent obtained an explanation for the order.

Here again, Respondent's records show that the orders were approved, the typical reason being that the UR (from seven months earlier) supported the order, although in one instance (April 1), the reason given was that the order was ''within csl for period,'' GX 19, at 114, and in the instance of the April 5 order, there is no evidence that the order was even held for review. *Id.*

As for the UR, which it finally obtained on April 26, it showed that during the period of March 1–30, 2010, City View had dispensed 93,943 du of oxycodone 30, an amount which was nearly double what it had dispensed during September 2009. Indeed, City View's dispensings of oxycodone 30 alone now comprised more than 52.5 percent of its total dispensings. Moreover, the UR showed that City View's dispensings of alprazolam 2 mg, another drug highly sought after by drug abusers for use as a part of a drug cocktail with narcotics such as oxycodone, totaled 19,738 du, more than double the amount (9,722) it dispensed during September 2009.

Aside from the fact that the April 26 order placed City View's orders at 64,000 du on a rolling 30-day basis and nearly 13,000 du above the CSL and was not properly investigated, I find that the March 2010 UR alone created a strong suspicion that City View was engaging in illegitimate dispensing practices and rendered the April 26 order suspicious. I further find that Respondent failed to report the order as suspicious.

Although this UR alone establishes that all of City View's subsequent orders through the termination of the account—nearly eight months later—were suspicious, the evidence establishes that City View continued to place oxycodone orders which were held by the SOMS and were not properly investigated. Nor were any of the orders reported as suspicious. These include orders on May 10 and 18 which placed City View's orders at 65,000 du, thus exceeding the 51,200 du CSL set by the compliance committee, both of which were released, with the reasons given that the orders were either within or under the CSL.

While on May 18, 2010, Respondent conducted a due diligence survey by telephone, during which City View again represented that its dispensing ratio was 30 percent controlled to 70 percent non-controlled, there is no evidence that Respondent compared this statement with the recent UR as its inspector had previously recommended.[186] Nor is there any evidence that it compared the UR with the information DEA had previously published and provided during the August 2009 briefing as to the dispensing ratio.

Although City View also stated that it was servicing two small nursing homes and was near a medical center, Respondent did not even obtain the names of the homes, let alone inquire as to how many residents they had and the types and quantities of various controlled substance prescriptions the pharmacy claimed it was filling for their residents. In short, these superficial explanations do nothing to dispel the strong suspicion created by the March UR.

On June 28, 2010, Respondent performed another site visit at City View. While City View's pharmacist reported a dispensing ratio consistent with what he had previously told Respondent, I hold that this does not dispel the strong suspicion created by the amounts of oxycodone 30 and alprazolam 2 being dispensed by the pharmacy. Nor do I find the inspector's notations that City View was two blocks from a hospital and that there were pain clinics in the area sufficient to dispel the strong suspicion created by the UR that the pharmacy was engaged in illegitimate dispensing practices.

On July 7, 2010, Respondent reviewed the site visit and lowered City View's CSL to 28,700 du; it also placed it on compliance hold pending the receipt of an updated UR. However, Respondent did not obtain a new UR until December. Yet on July 13, it removed the compliance hold. That same day, it filled an order for 10,000 du of oxycodone 30, bringing City View's rolling 30-day total to 37,000 du. While this order placed City View at more than 8,000 du above the new CSL, the explanation provided in the SOMS merely states: ''rwr order sitevisit [sic] and ur on fiel'' [sic]. Here again, I conclude that Respondent failed to obtain an explanation for the order. Based on both the information provided by the UR, and the fact that the order was placed on hold because it was of unusual size and Respondent failed to properly investigate the order, I conclude that the order was suspicious. However, the order was not reported.

Later, on July 28, Respondent edited an oxycodone order to meet the CSL. Here again, there is no evidence that Respondent obtained an explanation for the order (and a new UR) and it failed to report the order. For the same reasons as stated above, I hold that the order was suspicious but was not reported.

On September 28, Respondent filled an order for 5,000 du of oxycodone 30 and 1,600 du of oxycodone 15, bringing the total of its filled orders to 34,700 on a rolling 30-day basis and exceeding the CSL of 28,700 du. Likewise, on five different dates in October, Respondent filled orders which brought City View's rolling 30-day total to between 34,900 and 35,900 du, again exceeding the CSL which remained at 28,700. GX 19, at 117 (SOMS note entry for 10/26/10).

With respect to each of these orders, Respondent failed to obtain an explanation from the pharmacy and a new UR. Here again, the orders were typically filled with Respondent documenting the reason as the orders were under the CSL, even though they were not. As explained previously, I hold that the orders were suspicious and should have been reported but were not.

Finally, in November 2010, Respondent filled oxycodone orders on four separate dates, each of which placed City View's orders over its CSL on a rolling 30-day basis. On November 2 and 9, City View's orders totaled 36,300 du, and on November 18, its orders totaled 37,000 du. For both the November 2 and 18 orders, Ms. Seiple noted only ''rwr'' as the reason for releasing them. As for the November 9 order, Ms. Seiple noted that the order was ''being released with reservation'' and that the oxycodone was ''within buying pattern'' and ''under [the] CSL.'' Here again, I conclude that Respondent failed to obtain an explanation from the pharmacy for each of the orders and a new UR. And as explained previously, I hold that the orders were suspicious and should have been reported but were not.

On December 2, Respondent finally obtained another UR, eight months after

[186] Of note, this question did not refer to the percentage of prescriptions. Rather, the question simply stated: ''What is your Daily ratio of controlled to non-controls?'' GX 19, at 38.

it had obtained the previous UR. However, the UR was incomplete. Nonetheless, on December 6, Respondent filled orders for 8,000 du of oxycodone 30 and 1,000 du of oxycodone 15, before placing City View on compliance hold three days later. While it is unclear whether these orders were held by the SOMS, I hold that the orders were suspicious based on the information provided by the previous UR. However, Respondent failed to report the orders.

On or about December 15, 2010, City View placed a further order for controlled substances which, based on the various notes made by Ms. Seiple, was likely for oxycodone. Respondent placed the order on hold, with Ms. Seiple documenting that she had called the PIC and her ''concerns regarding # of doses dispensed as opposed to noncontrols'' and how the pharmacy made a profit (apparently because insurance did not reimburse at a high enough rate given the cost of the drugs). RX 2D, at 2. The following day, Ms. Seiple noted that she had spoken to City View ''on phone multiple times regarding ratio of controls & noncontrols,'' as well as ''in regards to ratio cash vs. insurance,'' and that the pharmacy was ''placed in noncontrolled status due to customer indicating cash in OXY.'' *Id.* While Respondent apparently deleted the December 15 order, it did not report the order as suspicious. I hold that the order was suspicious.

Significantly, Respondent had information that the ratio of controlled to non-controlled drugs being dispensed by City View was suspiciously high well before April 1, 2009, and each of the URs it obtained thereafter corroborated this. This information alone was enough to establish a strong suspicion as to the legitimacy of City View's dispensing practices.[187]

As for Ms. Seiple's declaration, none of the reasons she offered dispelled the strong suspicion created by the information Respondent had obtained. While Ms. Seiple asserted that City View's business model involved marketing to nursing homes, hospice programs, and in-patient medical facilities, at the time of 2008 site visit, the pharmacy did not identify any actual customer and nearly two years later, the pharmacy reported that it serviced only two small nursing homes with 20 to 30 beds; Respondent also obtained no information as to how many of the nursing homes residents were being prescribed oxycodone 30. Although Ms. Seiple also asserted that City View was located within two blocks of two hospitals, Respondent produced no evidence as to why this justified the pharmacy's dispensing levels of oxycodone and other highly abused drugs relative to non-controlled drugs.

To be sure, City View also reported that it filled prescriptions for patients from several pain clinics. While this undoubtedly accounted for both the large volume of pain medications and the high percentage of oxycodone dispensed by City View, this does not establish that the dispensings were legitimate. Indeed, notwithstanding that Respondent's CEO had earlier decided to cut off sales to pain physicians in Florida who were engaged in direct dispensing, it conducted no further investigation into the qualifications of the physicians that were identified by the pharmacy as writing the oxycodone prescriptions. It did not even verify if they were licensed by the State, let alone whether they had any training or board certification in pain management or another related specialty. Nor did it ask the pharmacy as to the nature of the prescriptions that these physicians were writing and whether they included such cocktails as oxycodone and alprazolam.

Moreover, putting aside Ms. Seiple's misleading statement that after City View's account was approved, the SOMS held any order that met the suspicious order criteria and that these orders were released only after review, the evidence shows that while numerous orders were held, Respondent rarely, if ever, contacted the pharmacy and obtained an explanation for the order, which it then independently verified. Also, Ms. Seiple did not address why Respondent failed to obtain a new UR whenever an order was held, nor did she explain why Respondent ignored the information which showed that City View's dispensings of oxycodone 30 had nearly doubled between September 2009 and March 2010. And finally, while Ms. Seiple asserted that Respondent terminated City View after it developed concerns over the pharmacy's dispensing volumes and ratio of controlled to non-controlled drugs, the same concerns were present well before April 1, 2009. I thus conclude that none of Ms. Seiple's explanations refute the conclusion that the various orders were suspicious.

Medical Plaza Pharmacy

On March 24, 2009, Respondent conducted a due diligence survey for Medical Plaza's request to purchase controlled substances. During the survey, the PIC reported that 35 to 40 percent of the prescriptions filled by the pharmacy were for schedule II controlled substances but that he was unsure of the percentage of dispensings comprised by all controlled substances. He also represented that 70 to 80 percent of the prescriptions he filled were paid for by insurance.

Thereafter, Respondent approved Medical Plaza to purchase controlled substances, and while the date of this decision is unclear, the evidence shows that Respondent filled the pharmacy's orders for oxycodone 30 as early as April 10, 2009. Notably, Respondent approved Medical Plaza without having performed a site visit or having obtained a UR.

On June 18, 2009, Respondent finally performed a site visit. As found above, prior to the site visit, Respondent had filled orders for 14,800 du of oxycodone 30. During the site visit, Respondent's inspector noted that the pharmacy did not fill prescriptions for physicians who were primarily engaged in pain management. Yet the inspector also noted that schedule II drugs comprised 20 percent and all controlled substances comprised 60 percent of the pharmacy's prescriptions, this being the second time that Respondent had received information that Medical Plaza's dispensing ratio of controlled to non-controlled drugs was suspicious. He also noted that 25 percent of the prescriptions were paid for with cash.

Nonetheless, Respondent did not obtain a UR until August 11, after Medical Plaza sought an increase in the amount of controlled substances it could purchase, apparently after orders for 5,000 oxycodone 15 and 3,600 oxycodone 10/325 were held by the SOMS. Prior to this date, Respondent had filled orders for 19,800 du of 30 mg tablets.[188] Given the acknowledgement of Respondent's CEO and former Vice-President that they were aware of the oxycodone abuse crisis ongoing in Florida during this time period, as well

[187] Given that the record does not contain evidence as to how much Respondent charged City View for the drugs and how much City View was paid by insurers, I do not address whether the concern as to how City View could make a profit on its oxycodone dispensings was present prior to December 2010.

[188] It is noted that under Respondent's Policies and Procedures, it did not bind itself to obtaining a UR prior to selling controlled substances to a new customer. *See* RX 78, at 30–31 (Policy 6.1). Moreover, while its Policy mandates the performance of additional due diligence in various circumstances including where there are ''[i]ndications that the customer is or may be diverting controlled drugs,'' even then its Policy does not require that a UR be obtained. *Id.* at 30–31 (''Additional due diligence may include any or all of the following steps, as determined by a Compliance Manager: i. Drug Utilization Records.'').

as the information Medical Plaza provided the pharmacy during the March 2009 survey, which included that schedule II drugs comprised 35 to 40 percent of the prescriptions it dispensed, I conclude that Respondent's failure to obtain a UR prior to approving Medical Plaza to purchase controlled substances was reckless and a breach of its due diligence duty to conduct a meaningful investigation of its customer. *Southwood,* 72 FR at 36,498–99.

As for the UR, which covered the month of July, it showed that Medical Plaza had dispensed 61,130 du of oxycodone 30 and 27,122 du of oxycodone 15, out of the pharmacy's total dispensings of 201,445 du. Thus, oxycodone 30 alone accounted for more than 30 percent of Medical Plaza's dispensings and the combined dispensings of oxycodone 30 and 15 accounted for nearly 44 percent of its dispensings. Also, as found above, Medical Plaza's dispensings of all oxycodone products accounted for more than 51 percent of its total dispensings. Thus, even ignoring that during the June 2009 site visit, Medical Plaza had changed its story (from what it told during the March 2009 due diligence survey) regarding the level of its schedule II dispensings, the level of the pharmacy's oxycodone dispensings was more than sufficient to create a strong suspicion as to the illegitimacy of the pharmacy's dispensing practices.

The UR also provided other indicia that Medical Plaza was engaged in illegitimate dispensing activity. As found above, whether by looking at the number of prescriptions or the quantity of dosage units, even a cursory review of the UR shows that controlled substances were predominant among the most highly dispensed drugs. Also, as found above, Medical Plaza blacked out the financial data (which included its costs and profits) for nearly all of the controlled substances it dispensed. Yet Medical Plaza had previously represented that 70 to 80 percent of the prescriptions it filled were paid for by insurance and Respondent's former Vice-President testified that ''DEA advised us to focus on whether a customer had a high percentage of cash for controlled substance prescriptions (as compared to third-party insurance payments) [and] refused to accept insurance for the payment of controlled substance prescriptions.'' GX 51B, at 4 ¶ 12. In short, the blacked-out financial data begged the question, which Respondent did not ask until seventeen months later (when it ignored the answer anyway), what was the pharmacy hiding? I hold, however, that the blacked-out data provided an additional basis of suspicion as to the legitimacy of Medical Plaza's dispensing practices.[189]

As noted above, on August 11, Medical Plaza placed orders for 5,000 du of oxycodone 15 and 3,600 du of Endocet 10, thus triggering holds by the SOMS. While the notations on a form (used to review requests to increase a customer's controlled substances purchasing limits) state that Medical Plaza was ''[i]n a medical building of 60 doctors, and next to a hospital,'' Respondent conducted no further inquiry into the practice specialties of these physicians and whether they would be prescribing such powerful narcotics as oxycodone 30 in the course of their medical practices.

While this review prompted Respondent to obtain a UR, the following day Respondent filled the orders. Moreover, while Ms. Seiple documented that Medical Plaza's request to increase its purchasing limit was to be reviewed by the Compliance Committee, Respondent filled the orders before the review was even conducted. For the reasons explained above, I hold that the information Respondent obtained provided multiple grounds to suspect that Medical Plaza was engaged in illegitimate dispensing practices and that the two orders were suspicious and should have been reported. Respondent did not, however, report the orders. It also failed to report various orders placed by Medical Plaza in October, including an order for 10,000 du of oxycodone 30.

On November 17, Medical Plaza placed orders for 7,000 du of oxycodone 30; 3,000 du of oxycodone 15; 1,200 du of OxyContin 80; 1,200 du of Endocet 10/325; and 200 du of Endocet 5/325. As found above, these orders placed Medical Plaza's oxycodone orders at 23,600 du on a rolling 30-day basis, which was 5,000 du over its CSL. While Respondent filled the orders for OxyContin and Endocet, it held the orders for the 30 and 15 mg tablets.

The next day, Respondent conducted a new due diligence survey. Respondent's representative noted that Medical Plaza's ''primary customer base'' was as a community pharmacy and did not check the form's boxes for either pain management or workers compensation. Respondent's representative also noted that Medical Plaza did not do any institutional or closed-door business. Medical Plaza further represented that its ''ratio of controls [sic] to non controls [sic]'' [190] was ''40/60'' and that ''70 to 80'' percent of the prescriptions were paid by insurance.

There is, however, no evidence that Respondent questioned why Medical Plaza was dispensing the quantities of oxycodone as shown on the last UR (July 2009) or why the ratio of controlled to non-controlled dispensings reported by the pharmacy was double the level discussed in the August 2009 briefing.

Moreover, there is no evidence that Respondent's employee obtained an explanation for the orders and it also failed to obtain a new UR. However, Respondent filled the orders, noting that they were shipped with reservation and that an updated UR was requested. Based on the various information Respondent had obtained, which raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices, as well as the fact that these orders were held by the SOMS because they were of unusual size and yet Respondent failed to obtain an explanation for the orders and a new UR, I conclude that the orders were suspicious and should have been reported but were not.

On December 14, Medical Plaza placed an order for 15,000 du of oxycodone, which placed it over CSL by 9,000 du on a rolling 30-day basis. As found above, while Respondent obtained a new UR, it failed to obtain an explanation for the order. Moreover, as explained previously, while Respondent did not fill the order, it was nonetheless required to report it, because it was suspicious based on both the information Respondent had obtained regarding Medical Plaza's dispensing practices and because the order was held by the SOMS based on its unusual size.

As for the UR, which covered the month of November, it showed that Medical Plaza's dispensings of oxycodone 30 had increased by 31,274 du (51 percent) from the level of the previous UR to 92,404 du. The UR also showed that Medical Plaza's dispensings of oxycodone 15 had increased by 16,929 (62.4 percent) from the previous level to 44,051 du. Thus, Medical Plaza's dispensings of oxycodone 30 amounted to 37.5 percent,

[189] It also noted that the pharmacy had represented that it did not fill prescriptions for physicians who were primarily engaged in pain management. The pharmacy's representation and the quantity of oxycodone and other narcotics it was dispensing begged the questions of who were the physicians writing these prescriptions and what were their practice specialties? There is, however, no evidence that Respondent asked these questions.

[190] Here again, the question did not refer to percentages of prescriptions but was simply phrased as: ''What is your daily ratio of controls [sic] to non controls [sic]?''

its dispensings of the 15 mg tablets amounted to 17.9 percent, and its dispensings of all oxycodone products amounted to 63 percent of its total dispensings for all drugs (246,255 du).

Moreover, the UR again showed that controlled substance were predominant among the most dispensed drugs, whether this was determined by the number of prescriptions or quantity of dosage units, with only carisoprodol being among the top 15 drugs dispensed. And once again, the financial data for the most highly dispensed controlled substances were blacked out.

In sum, the UR provided nothing to dispel the strong suspicion that Medical Plaza was engaged in illegitimate dispensing activities. Indeed, as it showed that the pharmacy's dispensing of oxycodone had increased by a large margin from the previous UR, it should have reinforced this conclusion. Yet Respondent failed to report the December 14 order as suspicious.

Thereafter, Respondent did not ship any more oxycodone until February 24, 2010, when Medical Plaza placed orders for 3,600 du of 30 mg and 6,000 du of 15 mg. As Respondent had not obtained any new information since the previous UR, I find that these orders, which were not reported, were suspicious.

In March 2010, Medical Plaza's oxycodone orders increased dramatically, with Respondent filling orders placed on six dates totaling 49,000 du of oxycodone 30 and 31,500 du of oxycodone. Significantly, the highest monthly total of orders filled during the previous six months was 12,600 du (November 2009), and with each successive order from March 18 through March 25, Medical Plaza's orders on a rolling 30-day basis exceeded the CSL by a factor which increased from three to seven times.

While each of these orders was held by the SOMS because it exceeded the CSL, with the possible exception of the March 16 order (the notes for which refer to problems with AR [191]), in each other instance there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. Nor did it obtain a UR on reviewing any of the March orders. Indeed, the orders were typically released with the explanation being that the UR supported the order. Based on both the information Respondent had obtained regarding Medical Plaza's dispensing practices and the fact that the orders were held by the SOMS because they were of unusual size and were not properly investigated, I conclude that the orders were suspicious and should have been reported but were not.

As found above, in April, Medical Plaza continued to place orders, which, even if the CSL was increased based on the March orders (notwithstanding that they were not properly reviewed), still exceeded the CSL on a rolling 30-day basis. Indeed, on April 15, Medical Plaza placed orders for 42,000 du of oxycodone 30 and 10,000 du of oxycodone 15, bringing its rolling 30-day total to 138,200 du, which was nearly 58,000 du over the CSL. As with the previous orders (April 1 and 8), Respondent approved the orders but did not obtain an explanation for the orders and a new UR. Instead, the justification for filling the orders was that they were within the CSL (April 1 order), the size was ''not excessive'' (April 8 orders) and that the ''ur supports order'' (April 15). None of these orders were reported as suspicious. For the same reasons as stated above, I conclude that these orders were suspicious.

On April 23, Medical Plaza placed an order for 15,000 du of oxycodone 30 and 15,000 du of oxycodone 15, thus bringing its rolling 30-day total to 140,700 du, more than 60,000 over the March shipments. Respondent contacted the pharmacy, and was initially told that the order was placed because of price, that the pharmacy's business was about the same, and that the pharmacy was stocking up. While Respondent asked for a new UR, Respondent's PIC replied that ''nothing changed'' and did not provide a new UR. (Indeed, Respondent did not obtain a new UR until August 19). Moreover, in a subsequent phone call, Medical Plaza now claimed that it was promoting its business.

While Respondent deleted the orders, it failed to report them as suspicious. I hold that they were suspicious based on the information Respondent had obtained regarding Medical Plaza's controlled substance dispensing levels. I further hold that the orders were suspicious because they were clearly of unusual size and Medical Plaza's pharmacist gave inconsistent explanations for the orders.

On May 3, Medical Plaza placed orders for 30,000 oxycodone 30 and 20,000 oxycodone 15, thus bringing its rolling 30-day total of orders to 115,700 du, 40,000 du over its CSL (notwithstanding that the SOMS would recalculate the CSL based on the filled orders which were never properly reviewed). While Respondent documented having called the pharmacy, it is unclear whether it ever obtained an explanation for the order. What is clear is that it did not obtain a new UR. And while the evidence shows that Respondent reduced both orders to 10,000 du, it did not report the orders as suspicious. For the reasons stated previously, I hold that the orders were suspicious.

Thereafter, Respondent did not fill any oxycodone orders until June 28, when it shipped 14,000 oxycodone 30 to Medical Plaza. According to a SOMS note, Respondent had reduced Medical Plaza's CSL to 14,000 du. RX 2F, at 4 (MFR entry for June 28). Yet this order had actually been for 20,000 du and while Respondent called the pharmacy, there is no evidence as to what explanation Medical Plaza provided and it did not obtain a new UR. Moreover, three days later on July 1, Medical Plaza placed another order for 20,000 du. Thus, on a rolling 30-day basis, Medical Plaza had placed orders that were more than double its CSL. Here again, while Respondent edited the order to 14,000 du, it did not obtain an explanation for the order and a new UR. Moreover, it did not report the orders.

Notwithstanding that the June 28 and July 1 orders were substantially less than Medical Plaza's orders during March and April, I nonetheless hold that the orders were suspicious based on Respondent's failure to properly investigate the orders (by obtaining an explanation and a new UR), as well as the information it had previously obtained which raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices.

While on July 22, Ms. Seiple documented that she had requested an updated UR, on July 30, Respondent filled an order for 10,300 du of oxycodone 30 even though it had not obtained a new UR. As found above, the order again placed Medical Plaza over its CSL by 10,000 du and yet no explanation was obtained from the pharmacy.[192] *See* GX 22, at 145 (SOMS note of 8/17/2010 indicating that CSL was still 14,000). And only four days later, Respondent filled an order for 12,200 du of oxycodone 30, which again resulted in Medical Plaza exceeding its CSL by more than 8,000 du. Yet according to the SOMS, the order was

[191] While this may be an abbreviation for accounts receivable, the record does not establish this.

[192] The SOMS notes for this date indicate that this order was not held for review. *See* GX 22, at 145. According to a note in the Ship to Memos, the July 1 order was returned. *Id.* at 141. However, according to the materials Respondent provided on the SOMS, ''[t]he rolling 30 day invoice history will include invoices and credit memos from the past 30 days.'' RX 78, at 60. Thus, even if the July 1 order was returned, it still should have been counted in determining whether Medical Plaza's orders placed it over the CSL.

not even held for review. *Id.* Respondent did not report either order as suspicious. For the reasons as discussed above, I hold that the July 30 and August 3 orders were suspicious.

On August 17, 2010, Medical Plaza placed an order for 20,000 du of oxycodone 30. While Respondent deleted the order, the order placed Respondent at 42,500 du, more than three times (and more than 28,000 du over) its CSL as reflected in the SOMS notes of the same date. While Respondent called the PIC and requested a new UR, told him that the order was being deleted but that he could re-order after the UR was reviewed, Respondent failed to obtain an explanation for the order and it did not report the order as suspicious. For the reasons discussed above, I hold that the order was suspicious.

On August 19, Medical Plaza finally provided a new UR (eight months after the previous UR), which covered the month of July 2010. The UR showed that the pharmacy had dispensed 118,908 du of oxycodone 30 and 41,160 du of oxycocodone 15; its total dispensings of all prescription products were 285,977.85 du. Thus, oxycodone 30 amounted to 41.6 percent of its total dispensings, its dispensing of oxycodone 15 comprised 14.4 percent, and its dispensings of all oxycodone products were 63.58 percent. Also, as with the previous UR, controlled substances were predominant among the most highly dispensed drugs (the only exception in the top ten being carisoprodol) and once again, Medical Plaza had blacked out the financial data for oxycodone 30 and 15, as well as alprazolam 2. As with the previous URs, the July 2010 UR raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices which Respondent ignored.

The same day, Medical Plaza place an order for 20,000 du of oxycodone 30, bringing its rolling 30-day total to 42,500 du, again exceeding the CSL (as noted in the 8/17 SOMS note) by a factor of three. Respondent edited the order to 6,400 du, thus bringing the total filled orders to 28,900 du. Respondent did not, however, obtain an explanation for the order. Nor did it report the order, which I hold was suspicious.

As found above, Respondent filled orders on September 1 (10,000 du) and 7 (8,600 du), as well as October 1 (16,800 du), each of which placed Medical Plaza over its CSL, even if the CSL had been recalculated based on the July orders. Respondent did not obtain an explanation for any of these orders or a new UR. According to the SOMS notes, the September 1 order was released because it was within the ''monthly buying pattern'' and the order left 8,600 du which could be filled. However, with the September 1 order, Medical Plaza's orders came to 28,600 du on a rolling 30-day basis. Moreover, Respondent did not report the order as suspicious.

As for the September 7 order, the SOMS note shows that it was ''edited to meet CSL,'' even though upon filling the order, Medical Plaza's filled orders on a rolling 30-day basis came to 25,000 du.[193] Here again, the order was not reported as suspicious. And on filling the October 1 order, Medical Plaza's filled orders totaled 25,400 du on a rolling 30-day basis. Yet the only entries in the SOMS note which could correspond with this order merely states ''rwr,'' an abbreviation for release with reservation. Respondent did not report the order as suspicious. Based on the information Respondent had obtained which raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices, as well the evidence showing that each of these three orders exceeded the CSL and was held by the SOMS but that Respondent failed to investigate the orders, I hold that the orders were suspicious.

Thereafter, Respondent filled Medical Plaza's orders for oxycodone 30 each month through March 4, 2011, shipping 16,800 du each month with the exception of November (when it shipped only half this amount). While the evidence supports a finding that each of these orders was suspicious based on the information provided by the URs alone, several of the orders were held by the SOMS. Here again, however, the evidence shows that the orders were released without Respondent obtaining an explanation for the orders. None of the orders was reported as suspicious.

More specifically, the December 1 orders brought Medical Plaza's rolling 30-day total to 25,200 du. Yet according to a note in the MFR, Medical Plaza's oxycodone CSL was still at 14,000 du. As for why the orders were released, the SOMS notes merely include the abbreviation for release with reservation.

In January, Medical Plaza ordered 20,000 du. Respondent edited the order to 16,800. MFR notes show that Respondent contacted the pharmacy and was told that the pharmacy ''use[s] quite a bit of insurance on oxy,'' prompting Ms. Seiple to question how the pharmacy could be making a profit when insurance reimbursed at a lower rate ($32) than what Master's charged for oxycodone ($39) and then noting that the pharmacy would be ''losing money.''

The same day, Respondent obtained a new UR from Medical Plaza. While that UR showed that Medical Plaza's dispensing of oxycodone had declined from the previous UR, in contrast to the previous URs, the financial data for the oxycodone and other highly abused drugs were not blacked out. Tellingly, the data showed that far from ''losing money'' on its oxycodone 30 dispensings, Medical Plaza was making profits that were approximately three times its acquisition costs. Yet even then, Respondent failed to report Medical Plaza's order as suspicious. I hold that the order was suspicious.

Moreover, on February 1 (10,000 du) and 2 (6,800 du), Respondent filled more orders by Medical Plaza. Remarkably, the most recent UR contains a handwritten note by Ms. Seiple which indicates that she reviewed the UR on ''2–2–11,'' and in an MFR note of the same date, Ms. Seiple wrote that ''63K of 190K dispensing is 33% of sales is oxy 30 & 15 mg.'' Yet the same day, Respondent's compliance committee released the order for 6,800 du. Here again, Respondent failed to report the orders as suspicious. I hold that both orders were suspicious.

Finally, on March 2, Medical Plaza placed an order for 16,800 du. While an MFR note of March 3 states that the account was placed on compliance hold pending the pharmacy providing a physician's list and the performance of a site visit, Respondent filled the order the next day. Respondent did not, however, report the order as suspicious. I hold that it was. And I further hold that Respondent repeatedly violated 21 CFR 1301.74(b) by failing to report suspicious orders.

As for Ms. Seiple's assertions that Respondent did not report Medical Plaza's orders because the pharmacy was located in a medical center with 60 physicians and was adjacent to a medical center, and that this accounted for the large of volume of pain medication being dispensed and the percentage of oxycodone being dispensed relative to other drugs, Respondent's inspector specifically noted that pharmacy did not fill prescriptions for physicians who were primarily engaged in pain management. So too, in a subsequent survey, Respondent's representative did not document that Medical Plaza's primary customer based was comprised of either

[193] As found above, whether the CSL was recalculated based on the July orders (including the one that was returned) or based on the August orders, the September order still exceeded the CSL.

workers compensation or pain management patients.

As explained above, the mere presence of 60 doctors in the same building, without any investigation into their specialties and the drugs they would prescribe in the course of their respective medical practices does not remotely justify either the volume of pain medications or the percentage of oxycodone being dispensed by Medical Plaza relative to other drugs. Indeed, while a pharmacy's presence in a building with a large number of doctor's offices might explain why a pharmacy dispenses a larger volume of *all* prescription products than a pharmacy not located in the building, unexplained is why this would render the pharmacy more likely to dispense a much greater percentage of controlled substances, especially of oxycodone 30, a drug highly sought after by drug abusers, than any other pharmacy.

As for Ms. Seiple's statement regarding the SOMS, even ignoring that her statement misleadingly suggests that all of Medical Plaza's orders post-April 1 were reviewed, the evidence shows that there were numerous instances in which orders were held by the SOMS but were released without Respondent obtaining an explanation for the order, which it independently verified, as well as a new UR. Moreover, while Medical Plaza represented that 70 to 80 percent of the prescriptions it filled were paid for with insurance, Ms. Seiple entirely failed to address why she did not question Medical Plaza as to why the financial data for its controlled substance dispensings were blacked out on the URs. And she also failed to address why Respondent continued selling oxycodone to Medical Plaza even after she questioned how the pharmacy could be making a profit on oxycodone given that insurance paid less than the cost of the product and the UR she then obtained showed that Medical Plaza was obviously making substantial profits.

Temple Terrace Pharmacy D/B/A Superior Pharmacy

In June 2008, Respondent conducted a due diligence survey in response to Superior's request for an increase in the amount of solid dose oxycodone it could purchase. Notably, the answers provided by Superior were not indicative of illegitimate dispensing practices as Superior represented that twenty (20) percent of the prescriptions it filled were for controlled substances, and that 90 to 95 percent of the prescriptions were paid for by insurance. Superior also apparently represented that it did not have ''relationships with specific doctors/clinics,'' and maintained that it had a variety of policies in place to prevent diversion. Yet even in this period, Superior began to present various indicia that it was not all that it claimed to be.

Specifically, while Respondent requested a complete UR showing its dispensings of both controlled and non-controlled drugs, Superior provided a report showing only the top 100 drugs it dispensed. Moreover, during a site visit conducted several weeks later, Respondent's consultant found that the pharmacy shared its waiting area with a clinic that specialized in pain management and weight loss and that ''[m]any of their prescriptions originate within the clinic.'' The consultant's report also included two photographs showing the signage on the pharmacy's storefront. On top, the sign read: ''SUPERIOR PHARMACY • WALK IN CLINIC''; below that the sign read: ''Pain Management & Weight Loss.''

Moreover, within days of the site visit, Respondent visited Superior's Web page. As found above, the Web page included blurbs promoting Superior as both a pain management clinic (''Don't live in pain. Trust the medical professionals at Superior Pain Clinic to help you enjoy life again!'') and weight loss clinic, as well as a pharmacy.

As found above, Respondent's owner/CEO testified that in early 2009, he had decided to cut off sales to Florida pain management physicians who were engaged in the direct dispensing of controlled substances, in part because of his putative concern over their unethical marketing practices. Yet here was a pharmacy and pain clinic occupying the same space and Respondent's compliance department failed to investigate the relationship between the two. This was all the more remarkable given that during the due diligence survey conducted by Respondent in June 2008, its employee had entered scribble in the answer blank with regard to the question of whether the pharmacy had ''[r]elationships with specific doctors/clinics,'' thus suggesting that there were no such relationships. Indeed, the evidence suggests that Respondent did not even inquire as to the relationship between the pharmacy and the pain clinic until November 2009.

Thus, as of April 1, 2009, Respondent had obtained substantial information which raised a strong suspicion as to the legitimacy of Superior's dispensing practices. As found above, in April 2009, Respondent filled various orders totaling 28,800 du of oxycodone products; in May 2009, it filled orders totaling 25,000 du of oxycodone 30; and in June, it filled orders totaling 65,000 du of oxycodone products (of which 55,000 du were for oxycodone 30) and which included a June 24 order for 30,000 du of 30 mg, as well as 5,000 du of both 15 mg and 10/325 mg. Respondent did not report any of these orders as suspicious. Based on the information Respondent had previously obtained, I hold that these orders were suspicious.

Moreover, six days before it filled the June 24 order, Respondent finally obtained a second UR from Superior. Notably, with the exception of carisoprodol, each of the top twenty-five drugs dispensed was a controlled substance under the CSA and three of the top four drugs were different manufacturers' oxycodone 30 products. Also among the most dispensed drugs were the stronger formulations of alprazolam (1 and 2 mg) and diazepam (5 and 10 mg), as well as other narcotics including oxycodone 15 and combination hydrocodone drugs. The UR further showed that Superior's dispensings of oxycodone 30 alone totaled more than 60,000 du, nearly 29 percent of its total dispensings, and combined with its dispensings of oxycodone 15 and Endocet 10, these three products alone accounted for more than 37 percent of its total dispensings.

Also, on June 23, Respondent conducted a due diligence assessment by phone during which the pharmacy was asked about its primary customer base and denied that it was comprised of pain management or bariatric patients. Yet during the site visit conducted a year earlier, Respondent's consultant had noted that ''many of the prescriptions originate within the clinic.'' Moreover, during the assessment, Superior apparently acknowledged that controlled substances comprised 50 percent of its dispensings.

Superior also provided the names of two physicians (written as a Dr. Mercedes and Dr. Hubang) who were working at the Superior Pain Clinic. While Respondent obtained a printout from the Florida DOH's license verification Web page, the printout was for a Dr. Merced, whose address was listed as being in North Carolina, and not a Dr. Mercedes. Moreover, there is no evidence that Respondent verified the licensure status of a Dr. Hubang, or of any of the doctors previously identified by its consultant as being pain management physicians whose prescriptions were being filled at Superior. While several months later, Respondent eventually determined that the doctor's name was actually Dr.

Mubang, there is no evidence that Respondent verified the latter's licensure status.[194]

Even putting aside the substantial information Respondent had acquired regarding the suspicious nature of Superior's dispensings, Superior's June orders were 40,000 du (and 2.6 times) above its May orders and its purported 25,000 du purchasing limit (as well as 36,000 du greater than its April orders). The June orders were thus of unusual size, and therefore suspicious for this reason as well. Yet the orders were not reported to the Agency.

As for the oxycodone orders Superior placed in July (totaling 65,000 oxycodone 30 and 65,200 total du of oxycodone) and August (totaling 75,000 oxycodone 30), I hold that aside from whether the orders were of unusual size, pattern or frequency, the circumstances surrounding the Superior's operation establishes that the orders were suspicious. The orders were not, however, reported as suspicious.

The next month, Respondent filled an order (September 14) for 30,000 du of oxycodone 30 but did not report the order as suspicious. Moreover, as found above, on September 24, Superior placed orders for another 30,000 oxycodone 30 and 5,000 Endocet 10. While the latter order was filled, the former order triggered a compliance hold which was conducted by Ms. Seiple. Of note, Ms. Seiple documented that she had reviewed the file and noted that the pharmacy was located inside the clinic and that she had called the pain clinic and been told that if she came in, there was a pharmacy inside the clinic. Ms. Seiple then documented that the orders for 30,000 oxycodone 30 were being deleted ''per Web site'' and the photographs. Yet even then, Respondent failed to report the orders as suspicious. And of further note, Respondent had known for fourteen months that the pharmacy and pain clinic shared the same space and jointly marketed themselves as a sort of one-stop shop.

As found above, Respondent did obtain a new UR for the previous month. Notably, the UR showed that Superior's dispensings of oxycodone 30 alone accounted for 33 percent of its total dispensings, and 19 of the top 25 drugs dispensed were controlled under the CSA. Moreover, while notations in Ms. Seiple's September 24 note indicated that Superior had either been placed on non-controlled status or had its oxycodone limit reduced to 25,000 du, on September 30, Respondent filled three orders totaling 30,000 du of oxycodone. Yet the orders were not even held by the SOMS for review and Respondent provided no explanation for why the orders were shipped. I find, however, that the orders were suspicious and that Respondent violated the suspicious order rule when it failed to report the orders.

Respondent continued to fill numerous orders placed by Superior for oxycodone (as well as other controlled substances) through December 7, 2009. Indeed, on November 30, Respondent filled two orders for 20,000 du of oxycodone 30 and on December 2, it filled an additional order for 10,000 du, even though it had determined on November 19 that Superior's pharmacist owned both the pharmacy and the pain clinic.

Based on the circumstances presented by Superior, I find that each of these orders was suspicious and that Respondent violated 21 CFR 1301.74(b) by failing to report the orders. As for Ms. Seiple's proffered explanations for why Superior's orders were not reported, as explained in my factual findings, I reject her explanations and find it especially noteworthy that she entirely failed to address why, in light of the information she had obtained as early as June 2008, which showed, *inter alia,* that the pharmacy and pain/weight loss clinic were located in the same space and that Superior marketed itself as both a pharmacy and pain/weight management clinic, Respondent continued to distribute oxycodone and other controlled substances to it thereafter. Indeed, Ms. Seiple's statement that the ''weight-loss and pain management facility [were] located in an adjacent office'' is downright misleading.

Ms. Seiple further asserted that the volume and percentage of Superior's dispensings of controlled substances and oxycodone were accounted for (in part) because Superior was ''filling prescriptions for a juvenile in-patient facility.'' However, Respondent obtained no information as to the type of treatment being provided by the facility, the number of patients it had, and whether its patients would even be treated with drugs such as oxycodone 30. Indeed, this is just another example of Respondent's willingness to accept any superficial explanation which it believed would justify its continued filling of the pharmacies' oxycodone orders.

Morrison's

Prior to April 1, 2009, Respondent had acquired substantial information that raised a strong suspicion as to the legitimacy of Morrison's dispensing practice. As early as its initial due diligence survey, Morrison's had reported that 60 percent of the prescriptions it filled were for controlled substances and 35 percent of the prescriptions were for schedule II drugs. Moreover, while the UR obtained in the spring of 2008 showed that Morrison's was dispensing an average of 63,315 du of oxycodone 30 per month (which accounted for 38 percent of the dispensings), the next UR (which was obtained on January 30, 2009) showed that the pharmacy's monthly dispensings had nearly doubled to 111,705 du.[195] Yet there is no evidence that Respondent found this to be suspicious.

In April 2009, Respondent filled Morrison's orders for 171,700 du of oxycodone 30 as well as its orders for 37,200 du of oxycodone 15 mg; in total, Respondent shipped to Morrison's nearly 218,000 du of oxycodone products. There is no evidence that Respondent questioned Morrison's as to why it was ordering 60,000 du more of oxycodone 30 than its average monthly dispensing level and it did not report the orders as suspicious. Based on the circumstances presented, I conclude that the orders were suspicious and should have been reported.

In May, Respondent obtained another UR. While the UR covered the period of January 1 through May 6, 2009, it showed that Morrison's was dispensing an average of 81,726 du per month of oxycodone 30. Yet during the month of May, Respondent shipped 141,200 du of oxycodone 30, 59,000 du more than the pharmacy's average monthly dispensing of the drug.

Here again, there is no evidence that Respondent questioned Morrison's as to why it was ordering this quantity and it did not report the orders as suspicious. Moreover, this was the second month in a row in which Morrison's had ordered substantially more oxycodone that what it was dispensing on a monthly basis. Based on the circumstances presented, I conclude that the orders were suspicious and should have been reported.

[194] Ms. Seiple also asserted that ''[b]ased on [Respondent's] extensive investigation, it determined that the orders it shipped to Superior were not suspicious.'' RX 103, at 75. Notwithstanding that Superior was also operating a pain clinic, Respondent's ''extensive investigation'' apparently did not uncover that Dr. Mubang had been criminally charged by the State of Florida with trafficking in prescription drugs, even though a Google Search would likely have revealed this.

[195] As found above, the UR obtain in the spring of 2008 covered the period of January 1 to April 1, 2008; the UR obtained on Jan. 30, 2009, covered the period of November 1, 2008 through January 30, 2009.

The UR also showed that Morrison's was dispensing an average of 19,463 du per month of oxycodone 15. While in June, Respondent filled orders totaling only 81,600 du of oxycodone 30, it also filled orders totaling 39,900 du of oxycodone 15, more than double the amount of its average monthly dispensings of this dosage. Here again, there is no evidence that Respondent questioned Morrison's regarding the quantity of oxycodone 15 it was ordering, and it did not report the orders as suspicious.

In July, Respondent filled orders totaling 141,300 du of oxycodone 30 and 48,000 du of oxycodone 15. Notwithstanding that Morrison's orders for the 30 mg dosage were 61,000 du (76 percent) larger and the orders for oxycodone 15 were nearly 2.5 times larger than its average monthly dispensings per the previous UR, Respondent failed to report the orders for either dosage as suspicious. Moreover, this was the third month in the last four in which Morrison's oxycodone 30 orders had exceeded its monthly dispensings by 60,000 du, and yet Respondent did not report the orders as suspicious.

As found above, on or about August 1, 2009, the SOMS became operational. *See* RX 78, at 59. While Respondent would eventually terminate Morrison's on or about August 18, the day after the DI identified it as a customer whose oxycodone orders were of concern, during the first seventeen days of the month, Respondent had filled orders totaling 101,600 du of oxycodone 30 and 39,600 du of oxycodone 15. Moreover, the SOMS notes establish that between August 5 and 14, multiple orders were held by the SOMS for review. GX 23, at 151. Yet in each instance the orders were released, with such reasons given as that the UR supported the order, the order was under the current size limit, or the order was ''ok to ship per'' Ms. Seiple.

Notably, in no instance did Respondent contact Morrison's and obtain an explanation for the order, and it did not obtain a new UR until the same day the DI identified Morrison's as a customer whose oxycodone orders were concerning. Nor did it report any of these orders as suspicious even though the purpose of the SOMS was to identify orders of unusual size, pattern or frequency.

As for the UR, it showed that during July 2009, Morrison's dispensings of oxycodone 30 had more than doubled to 196,069 du of oxycodone 30 (at an average prescription size of 195 du), an increase of more than 114,000 du from the average monthly dispensings per the previous UR. The UR also showed that Morrison's dispensings of oxycodone 15 had more than tripled to 63,658 du.

The next day, Morrison's placed orders for 8,400 du of oxycodone 30 and 1,200 du of oxycodone 15, as well as Endocet and methadone. While Respondent placed Morrison's on compliance hold and deleted the orders, it did not report the orders as suspicious. As explained above, deleting or refusing to fill an order does not excuse a distributor from its obligation to report a suspicious order.

As with the other pharmacies, Ms. Seiple offered the same set of unresponsive explanations as she did for the other pharmacies, even going so far as to declare under oath that ''after Morrison's account was approved, [the] SOMS system identified and held any orders for controlled substances placed by Morrison's that deviated from its typical volume pattern or frequency'' when the SOMS was not even operational during the months of April through July 2009. As explained previously, I do not find persuasive her explanations as to why Respondent failed to report the multiple suspicious orders placed by Morrison's.

Summary

The evidence shows that Respondent failed to report hundreds of suspicious orders placed by these pharmacies. With respect to each of the seven pharmacies, prior to April 1, 2009, Respondent had obtained information which created a strong suspicion that the pharmacies were engaged in dispensing illegitimate prescriptions, and while Respondent obtained additional information from the pharmacies at various points throughout the course of its dealings with them, this information corroborated rather than dispelled the already existing suspicion.[196] Indeed, in several cases, even after Ms. Seiple documented her concerns as to the legitimacy of a pharmacy's dispensing practices, those concerns were either ignored or discounted for months thereafter.

Moreover, even after the SOMS became operational and the pharmacies' orders were held because they exceeded one of the criteria set forth in 21 CFR 1301.74(b) (typically, because they were of unusual size), the evidence shows that Respondent rarely investigated any of the orders. Rather, the evidence shows that those orders were frequently released without contacting the pharmacy and obtaining an explanation for the order, let alone independently verifying that explanation. Indeed, those orders were frequently released with the justification being that the order was supported by the UR, even though the URs invariably reflected dispensing levels of oxycodone and other controlled substances that were highly suspicious.

Moreover, Respondent represented to the Agency that the SOMS would determine whether a pharmacy's orders were of unusual size by counting the orders on a rolling 30-day basis. While the evidence shows that in numerous instances, the SOMS held an order because it resulted in the pharmacy's orders exceeding its CSL on a rolling 30-day basis, many of the orders were subsequently filled because Respondent then counted the pharmacy's orders on a calendar-month basis. And again, Respondent filled the orders without obtaining an explanation from the pharmacy. Whether the orders were filled because they were supported by the UR, or because Respondent counted them on a calendar-month basis, this also frequently resulted in the CSL being increased even though Respondent had entirely failed to investigate whether there was a legitimate basis for the increase in the orders. This resulted in an even greater amount of oxycodone being shipped without being held by the SOMS for review.

So too, the evidence shows that in other instances, an order which placed a pharmacy over its CSL was entirely deleted. Respondent thus treated the order as if it had never existed rather than report it as suspicious and the SOMS did not include it in calculating the rolling 30-day total. And in still other instances, Respondent edited an order by reducing its size so that the pharmacy's orders did not place it over its CSL. Here again, Respondent failed to report these orders.

It is true—as the ALJ noted—that under 21 CFR 1301.71(b), ''[s]ubstantial compliance with the standards set forth in [21 CFR 1301.72–.76] may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the . . . registrant.'' R.D. at 199–201. Nor do I dispute the ALJ's conclusion that perfection is not the standard for assessing Respondent's compliance with 21 CFR 1301.74(b). *Id.*

[196] It is acknowledged that Respondent inquired as to the pharmacies' policies to prevent diversion. Certainly doing so is a necessary component of a distributor's due diligence obligations. However, even assuming that Respondent's inquiries were adequate, whether the pharmacies were actually following their policies is a totally different matter. Given the evidence discussed above, I hold that even assuming each of the pharmacies had adequate policies to prevent diversion, in no case did this dispel the strong suspicion that each of the pharmacies was engaged in illegitimate dispensing practices.

at 201 (''one minor oversight does not render the entire system ineffective'').

Here, however, the evidence with respect to the seven pharmacies establishes a wholesale failure on Respondent's part to comply with the regulation, both as to the manner in which Respondent actually operated its SOMS (including the manner in which it followed Policy 6.2) and in its failure to report hundreds of suspicious oxycodone orders.[197] As for the numerous suspicious order reports it did submit, Respondent produced no evidence explaining the circumstances which led it to file those reports, and as one of its former employees testified, ''the customers who were easily suspended or terminated from purchasing controlled substances from [it] were not the big money accounts.'' GX 52, at 7.

I thus conclude that Respondent has not substantially complied with 21 CFR 1301.74(b). I further conclude that the Government has proved that Respondent ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' [198]

Sanction

Where, as here, the Government has met its *prima facie* burden of showing that a registrant has committed acts which ''render [its] registration . . . inconsistent with the public interest'' and thus subject to suspension or revocation, a respondent must come forward with '' ''sufficient mitigating evidence'' '' to show why it can continue to be entrusted with its registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller,* 53 FR 21,931, 21,932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23,853; *John H. Kennedy,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels,* 60 FR 62,884, 62,887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination).

Nor are these the only factors DEA considers in setting the appropriate sanction. *See, e.g., Southwood Pharmaceuticals, Inc.,* 72 FR 36,487, 36,504 (2007); *Joseph Gaudio,* 74 FR 10,083, 10,094 (2009). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *Cf. Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *see also Paul H. Volkman,* 73 FR 30,630, 30,644 (2008); *Gregory D. Owens,* 74 FR 36,751, 36,757 n.22 (2009).

Also, the Agency has held repeatedly that '' '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked,' '' or whether an application should be denied. *Gaudio,* 74 FR at 10,094 (quoting *Southwood,* 72 FR at 36,504 (2007)); *see also Robert Raymond Reppy,* 76 FR 61,154, 61,158 (2011); *Michael S. Moore,* 76 FR 45,867, 45,868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10,094 (quoting *Southwood,* 71 FR at 36,504). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

As found above, Respondent stipulated that it ''does not accept responsibility for any alleged wrongdoing in this matter'' and that ''any evidence . . . of changes, modifications, or enhancements [it] made to its internal Policies and Procedures in the ordinary course of business,'' whether of ''its own accord'' or ''based on alleged guidance or communications from [DEA] does not constitute evidence of remedial measures.'' ALJ Ex. 8. Respondent's failure to acknowledge its misconduct is reason alone to revoke its registration, especially given the evidence which shows that Respondent's failure to report suspicious orders placed by the seven pharmacies was both extensive and egregious. *See Holiday CVS,* 77 FR at 62,323; *see also MacKay* v. *DEA,* 664 F.3d 808, 820 (10th Cir. 2011); *Chein* v. *DEA,* 533 F.3d 828, 837 (D.C. Cir. 2007).

Indeed, the egregiousness of Respondent's misconduct is exacerbated by the acknowledgement of its senior officials that they were well aware of the oxycodone epidemic then ongoing in the State of Florida. It also exacerbated by the evidence which strongly supports the conclusion that with respect to the seven pharmacies, its Policies and Procedures for detecting and reporting suspicious orders were rarely, if ever, followed. And finally, I conclude that revocation is further supported by the Agency's interest in deterring future misconduct on the part of both Respondent, which retains a second distributor's DEA registration, and the community of registrants. *See Southwood,* 71 FR at 36,503 (citing *Butz* v. *Glover Livestock Comm'n Co., Inc.,* 411 U.S. 182, 187–88 (1973)).

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(4) and 823(b), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration RD0277409, issued to Masters Pharmaceuticals, Inc., be, and it hereby is, revoked. I further order that any application of Masters Pharmaceuticals, Inc., to renew or modify this registration be, and it hereby is, denied. This Order is effective October 15, 2015.

Dated: September 8, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–23038 Filed 9–14–15; 8:45 am]

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[197] Throughout this proceeding, Respondent has argued that because it is tertiary distributor, it lacks the data to ''reliably compar[e] either its oxycodone distribution[s] to other wholesalers' distributions or the oxycodone volumes purchased by a particular pharmacy to the volumes purchased by an average Florida pharmacy.'' RX 102, at 9–10; *see also* RX 104, at 8 (testimony of Respondent's owner that its ''business model tends to make its customers' purchasing patterns more difficult to predict and more variable than they would be if [it] were a full-line wholesaler''). Unexplained by Respondent is why it could not have obtained the information through the URs it acquired from all of its customers.

In the December 27, 2007 letter, the Deputy Assistant Administrator explained that ''[t]he determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base.'' GX 4, at 1. The SOMS, however, did not compare a pharmacy's orders with those of Respondent's other customers, and thus does not appear to be a system that complies with 21 CFR 1301.74(b). Because the Government did not challenge the adequacy of Respondent's SOMS on this basis, I do not consider it.

[198] As explained above, I hold that the ALJ's pre-hearing order barring the Government from asserting any evidence of Respondent's failure to report suspicious orders between April 1, 2009 and the Compliance Review was error. However, even were the Court of Appeals to disagree, the scope of Respondent's failure to report suspicious orders following the compliance review is so extensive and egregious that I would come to the same conclusion that the revocation of Respondent's registration is warranted to protect the public interest.

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