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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM16–22–000; Order No. 847]

Coordination of Protection Systems for Performance During Faults and Specific Training for Personnel Reliability Standards

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) approves Reliability Standards PRC–027–1 (Coordination of Protection Systems for Performance During Faults) and PER–006–1 (Specific Training for Personnel) submitted by the North American Electric Reliability Corporation (NERC).

DATES: This rule will become effective August 13, 2018.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Order No. 847

Final Rule

(Issued June 7, 2018)

1. Pursuant to section 215 of the Federal Power Act (FPA), the Commission approves Reliability Standards PRC–027–1 (Coordination of Protection Systems for Performance During Faults) and PER–006–1 (Specific Training for Personnel).[1] The North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization (ERO), submitted Reliability Standards PRC–027–1 and PER–006–1 for approval. As discussed below, we determine that Reliability Standard PRC–027–1, which is designed to maintain the coordination of protection systems installed to detect and isolate faults on bulk electric system elements, such that those protection systems operate in the intended sequence during faults, and PER–006–1, which is intended to ensure that personnel are trained on specific topics essential to reliability to perform or support real-time operations of the bulk electric system, improve upon the currently-effective Reliability Standards. In addition, based on the record before us, we do not adopt the NOPR proposal to direct NERC to modify Reliability Standard PRC–027–1 to require an initial protection system coordination study to ensure that applicable entities will perform (or have performed), as a baseline, a study demonstrating proper coordination of its protection systems.

2. The Commission also approves the associated violation risk factors, violation severity levels, implementation plans, and effective dates proposed by NERC for Reliability Standards PRC–027–1 and PER–006–1. The Commission further approves the retirement of currently-effective Reliability Standard PRC–001–1.1(ii) (System Protection Coordination) as proposed by NERC. Finally, the Commission approves new and revised definitions submitted by NERC for incorporation in the NERC Glossary for the following terms: (1) ''protection system coordination study;'' (2) ''operational planning analysis;'' and (3) ''real-time assessment.''[2]

I. Background

A. Section 215 and Mandatory Reliability Standards

3. Section 215 of the FPA requires a Commission-certified ERO to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval.[3] Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight or by the Commission independently.[4] In 2006, the Commission certified NERC as the ERO pursuant to section 215 of the FPA.[5]

B. Order No. 693

4. On March 16, 2007, the Commission issued Order No. 693, approving 83 of the 107 Reliability Standards filed by NERC, including Reliability Standard PRC–001–1.[6] In addition, the Commission directed NERC to develop modifications to Reliability Standard PRC–001–1 that:

(1) correct the references for Requirements, and [*sic*]

(2) include a requirement that upon the detection of failures in relays or protection system elements on the Bulk-Power System that threaten reliable operation, relevant transmission operators must be informed promptly, but within a specified period of time that is developed in the Reliability Standards development process, whereas generator operators must also promptly inform their transmission operators; and (3) clarifies that, after being informed of failures in relays or protection system elements that threaten reliability of the Bulk-Power System, transmission operators must carry out corrective control actions, *i.e.,* return a system to a stable state that respects system requirements as soon as possible and no longer than 30 minutes after they receive notice of the failure.[7]

C. NERC Petition and Reliability Standards PRC–027–1 and PER–006–1

5. On September 2, 2016, NERC submitted a petition seeking Commission approval of Reliability Standards PRC–027–1 and PER–006–1.[8]

[1] 16 U.S.C. 824o (2012).

[2] NERC Glossary of Terms Used in NERC Reliability Standards (NERC Glossary).

[3] *Id.* 824o(c), (d).

[4] *Id.* 824o(e).

[5] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *order on compliance,* 118 FERC ¶ 61,190, *order on reh'g,* 119 FERC ¶ 61,046 (2007), *aff'd sub nom. Alcoa Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[6] *Mandatory Reliability Standards for the Bulk-Power System,* Order No. 693, FERC Stats. & Regs. ¶ 31,242 at PP 1433–1449, *order on reh'g,* Order No. 693–A, 120 FERC ¶ 61,053 (2007).

[7] Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 1449.

[8] Reliability Standards PRC–027–1 and PER–006–1 are not attached to this Final Rule. The Reliability Standards are available on the Commission's eLibrary document retrieval system in Docket No. RM16–22–000 and are posted on the NERC website, *http://www.nerc.com.*

NERC stated that the Reliability Standards, new and revised NERC Glossary terms, and the retirement of Reliability Standard PRC–001–1.1(ii) satisfy the Commission's criteria in Order No. 672 and are just, reasonable, not unduly discriminatory or preferential, and in the public interest.[9] NERC explained that the intent of the submitted Reliability Standards and changes to the NERC Glossary are to maintain the coordination of protection systems installed to detect and isolate faults on bulk electric system elements and require registered entities to provide training to their relevant personnel on protection systems and remedial action schemes. NERC asserted that the submitted Reliability Standards are an improvement over currently-effective Reliability Standard PRC–001–1.1(ii) and will ensure that appropriate personnel are trained on protection systems and that protection systems are appropriately studied, coordinated, and monitored.

1. Reliability Standard PER–006–1

6. NERC stated that Reliability Standard PER–006–1 requires generator operators to use a systematic approach to develop and implement training for dispatch personnel at centrally-located dispatch centers.[10] NERC explained that Reliability Standard PER–006–1 will also cover plant personnel who are responsible for real-time control of a generator. NERC maintained that it is appropriate to train plant personnel in the functionality of protection systems and remedial action schemes. NERC observed that Reliability Standard PER–006–1 replaces the phrase ''purpose and limitations'' used in Reliability Standard PRC–001–1(ii) with the phrase ''operational functionality'' to clearly identify the objective of the training.[11] NERC also noted that Reliability Standard PER–006–1 replaces the phrase ''applied in its area'' in Reliability Standard PRC–001–1.1(ii) with the phrase ''that affect the output of the generating facility(ies) it operates'' to properly tailor the scope of the required training. NERC noted that Reliability Standard PER–006–1 does not specify a periodicity for the required training.

2. Reliability Standard PRC–027–1

7. NERC asserted that Reliability Standard PRC–027–1:

provides a clear set of Requirements that obligate entities to (1) implement a process for establishing and coordinating new or revised Protection System settings, and (2) periodically study Protection System settings that could be affected by incremental changes in Fault current to ensure the Protection Systems continue to operate in their intended sequence.[12]

According to NERC, Reliability Standard PRC–027–1, Requirement R1 mandates that each transmission owner, generator owner, and distribution provider establish a process for developing new and revised protection system settings for bulk electric system elements.[13]

8. NERC stated that Reliability Standard PRC–027–1, Requirement R2 mandates that every six years, applicable entities must either: (1) Perform a protection system coordination study to determine whether the protection systems continue to operate in the intended sequence during faults; (2) compare present fault current values to an established fault current baseline and, only if the comparison identifies a 15 percent or greater deviation in fault current values (either three phase or phase to ground) at a bus to which the bulk electric system is connected, perform a protection system coordination study; or (3) use a combination of Options 1 and 2.[14]

9. NERC explained that Reliability Standard PRC–027–1, Requirement R3 will require applicable entities to use the process established under Reliability Standard PRC–027–1, Requirement R1 for the development of any new or revised protection system settings.

3. Retirement of Reliability Standard PRC–001–1.1(ii)

10. NERC stated that Reliability Standard PRC–001–1.1(ii) includes six requirements that are either addressed by Reliability Standards approved by the Commission or by Reliability Standards PER–006–1and PRC–027–1. Specifically, NERC explained that Reliability Standard PRC–001–1.1(ii), Requirement R1 has been partially replaced by Reliability Standards PER–003–1 and PER–005–2. NERC continued that Reliability Standard PER–006–1 and the revised definitions of operational planning analysis and real-time assessment will replace the remaining portions of Reliability Standard PRC–001–1.1(ii), Requirement R1. NERC asserted that Reliability Standard PRC–001–1.1(ii), Requirement R2 has been addressed by Reliability Standards IRO–001–4, IRO–008–2, IRO–010–2, TOP–001–3, and TOP–003–3, which the Commission approved in Order No. 817.[15] NERC stated that Reliability Standard PRC–027–1 will replace Reliability Standard PRC–001–1.1(ii), Requirements R3 and R4. NERC also explained that Reliability Standard PRC–001–1.1(ii), Requirement R5 has been replaced with several Reliability Standards developed after Reliability Standard PRC–001–1(ii) became effective.[16] NERC further stated that Reliability Standard PRC–001–1.1(ii), Requirement R6 has been replaced with Reliability Standards TOP–001–3 and TOP–003–3.

D. Notice of Proposed Rulemaking

11. On November 16, 2017, the Commission issued a Notice of Proposed Rulemaking proposing to approve Reliability Standards PRC–027–1 and PER–006–1.[17] The NOPR proposed to determine that Reliability Standards PRC–027–1 and PER–006–1 improve upon the currently-effective Reliability Standards. However, the NOPR observed that Reliability Standard PRC–027–1, Requirement R2, Option 2 does not appear to ensure coordination of all bulk electric system elements with protection system functions because it does not require an initial protection system coordination study. Accordingly, the NOPR also proposed to direct NERC, pursuant to section 215(d)(5) of the FPA, to submit modifications to Reliability Standard PRC–027–1 within 12 months of the effective date of this Final Rule to require an initial protection system coordination study to ensure that applicable entities will perform (or have performed), as a baseline, a study demonstrating proper coordination of its protection systems.[18]

12. In addition, the NOPR proposed to approve the associated violation risk factors and violation severity levels, implementation plan, and effective date proposed by NERC.[19] The NOPR also proposed to approve the revised definitions for inclusion in the NERC

[9] NERC Petition at 10.

[10] *Id.* at 13.

[11] *Id.* at 15.

[12] *Id.* at 26.

[13] *Id.* at 27.

[14] *Id.* at 26.

[15] *Id.* at 5 (citing *Transmission Operations Reliability Standards and Interconnection Reliability Operations and Coordination Reliability Standards,* Order No. 817, 153 FERC ¶ 61,178 (2015)).

[16] *Id.* at 6.

[17] *Coordination of Protection Systems for Performance During Faults and Specific Training for Personnel Reliability Standards,* Notice of Proposed Rulemaking, 82 FR 55535 (Nov. 22, 2017), 161 FERC ¶ 61,159, at P 12 (2017) (NOPR). The NOPR was erroneously published a second time in the **Federal Register** on November 28, 2017, which changed the comment date to January 29, 2018. 82 FR 56759 (Nov. 30, 2017); 82 FR 56186 (Nov. 28, 2017).

[18] NOPR, 161 FERC ¶ 61,159 at PP 14, 24.

[19] *Id.* P 13.

Glossary.[20] Further, the NOPR proposed to approve the retirement of Reliability Standard PRC–001–1.1(ii), as requested by NERC.[21]

13. In response to the NOPR, the Commission received fifteen sets of comments. We address below the issues raised in the NOPR and comments. The Appendix to this Final Rule lists the entities that filed comments in response to the NOPR.

II. Discussion

14. Pursuant to section 215(d)(2) of the FPA, we approve Reliability Standards PER–006–1 and PRC–027–1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest, as both Reliability Standards improve on currently-effective Reliability Standard PRC–001–1.1(ii) in important ways.[22] As discussed below, we do not adopt the NOPR proposal to direct NERC to modify Reliability Standard PRC–027–1 to require coordination of all bulk electric system elements with protection system functions.

15. Reliability Standard PRC–027–1 improves on currently-effective Reliability Standard PRC–001–1.1(ii) by: (1) Modifying the applicability section to include the appropriate functional entity types with the responsibilities, resources, and skill sets to conduct the studies required to coordinate protection systems, and (2) listing the protection system functions on all bulk electric system elements that require coordination. Reliability Standard PER–006–1, along with existing formal training requirements in the Personnel Performance, Training, and Qualifications (PER) group of Reliability Standards, also improves upon Reliability Standard PRC–001–1.1(ii), Requirement R1 by ensuring that the necessary personnel are familiar with and understand the purpose and limitations of protection systems schemes while providing more precise and auditable requirements.

16. In addition, we approve NERC's associated violation risk factors, violation severity levels, implementation plans, and effective dates. We also approve the revised definitions for inclusion in the NERC Glossary. Further, we approve the retirement of Reliability Standard PRC–001–1.1(ii), as requested by NERC.

[20] *Id.*

[21] *Id.*

[22] 16 U.S.C. 824o(d)(2).

Initial Protection System Coordination Study

NOPR

17. The NOPR proposed to direct that NERC develop modifications to Reliability Standard PRC–027–1 to ensure coordination of all bulk electric system elements with protection system functions by requiring that applicable entities perform an initial protection coordination study under Requirement R2, Option 2.

Comments

18. NERC does not support the proposed directive because it believes that the proposed directive is unduly burdensome and unsupported by the materials cited in the NOPR. NERC contends that while the ''proposed directive could potentially help reduce misoperations caused by coordination issues . . . [it] would also impose a significant burden on industry . . . requiring a substantial expenditure of resources.'' [23] NERC also states that it ''expects that many entities will choose to do a full Protection System Coordination Study . . . for their more impactful [bulk electric system] Elements'' and that ''it is highly likely that the overwhelming majority of entities have already conducted coordination studies for their Protection Systems.'' [24] While NERC agrees with the goal of reducing protection system misoperation rates on the bulk electric system, it contends that recent misoperation rates demonstrate that mis-coordination of existing protection systems ''does not present a widespread risk to [bulk electric system] reliability that would necessitate the expenditure of resources required to conduct full Protection System Coordination Studies for every [bulk electric system] element with a Protection System.'' [25]

19. In addition, NERC and other commenters contend that the materials cited in the NOPR do not support the proposal to modify Reliability Standard PRC–027–1.[26] NERC, EEI and Tri-State contend that the Arizona Southern California September 8, 2011 Outage Report is unsupportive because it addresses mis-coordination of remedial action schemes and not protection systems.[27] NERC and Tri-State assert that the NERC System Protection Control Task Force Report addressed issues specific to generation transmission interfaces and did not apply broadly to all bulk electric system elements with protection systems.[28] NERC and Tri-State also contend that the 2009 letter from the NERC President to the NERC board of Trustees and stakeholders is no longer relevant because mis-coordination issues are now responsible for a smaller percentage of events and that mis-coordination has not recently caused any significant system disturbances.[29] NERC and Tri-State claim that Reliability Standard PRC–004 now requires applicable entities to mitigate the effects of misoperations by implementing a corrective action plan that has reduced misoperations.[30]

20. Further, while NERC agrees with the 2013 Misoperations Report that reducing misoperations, including mis-coordination events, is an important priority for bulk electric system reliability, NERC contends that the report does not indicate that requiring protection system coordination studies for all applicable elements, as proposed in the NOPR, is the only or optimal way to reduce mis-coordination events.[31] EEI also contends that the 2013 Misoperations Report shows that human error and lack of training are responsible for a significant portion of misoperations.[32]

21. NERC, EEI, and Tri-State explain that the 2014 incident identified in the ''lessons learned'' document on ''Generation Relaying—Underfrequency Protection Coordination'' was unrelated to protection system coordination.[33]

22. Finally, NERC states that while the 2016 State of Reliability Report highlights the continued need to reduce misoperations, the report does not indicate that there is a need to require entities to perform a protection system coordination study for every bulk electric system element with a protection system.[34] NERC also contends that the 2017 State of Reliability Report observes a continuing decline in misoperation rates, but that misoperations are a priority for NERC.[35] NERC states that the misoperations rate within the Texas Reliability Entity Region observed in the 2016 State of Reliability Report was mitigated by the

[23] NERC Comments at 4.

[24] *Id.* at 5–6.

[25] *Id.* at 6.

[26] *See generally* NERC Comments; EEI Comments; Tri-State Comments; Entergy Comments; ITC Comments.

[27] NERC Comments at 7; EEI Comments at 7; Tri-State Comments at 7–8.

[28] NERC Comments at 7–8; Tri-State Comments at 8–9.

[29] NERC Comments at 8; Tri-State Comments at 9–10.

[30] NERC Comments at 8; Tri-State Comments at 9.

[31] NERC Comments at 9.

[32] EEI Comments at 7.

[33] NERC Comments at 10; EEI Comments at 8; Tri-State Comments at 10.

[34] NERC Comments at 10.

[35] *Id.* at 9.

time NERC issued the 2017 State of Reliability Report.[36] NERC claims that this reduction in misoperation events is evidence that requiring entities to perform protection system coordination studies is unnecessary because the entities will address the misoperation events without specific requirements in Reliability Standards.[37]

23. Other commenters do not support the proposal to direct NERC to develop modifications to Reliability Standard PRC–027–1 because they generally contend that the proposed directive is not necessary and would impose a burden without a proportional reliability benefit.[38] Hydro One estimates that it will need approximately 30,000 hours of work to perform an initial protection system coordination study.[39] Tri-State estimates that it would take an engineer at least twenty hours to perform a protection system coordination study at each of its approximately 700 terminals.[40] Tri-State estimates that the actual cost to all applicable entities could be more than $120 million.[41] PG&E estimates a cost to industry ''greatly in excess of $100 million'' and asserts that the proposed directive would require PG&E to perform coordination studies for 95 percent of the PG&E bulk electric system at a cost of $3.5 million in engineering labor.[42]

24. Entergy requests that the Commission find that NERC's approach for requiring protection system coordination studies achieves the Reliability Standard's ''reliability goals effectively and efficiently.'' [43] Entergy opines that, by adopting NERC's proposal without modification, the Commission appropriately would give ''due weight'' to the technical expertise of the ERO. Entergy asserts that NERC properly supported Requirement R2 by setting forth evidence of the frequency of coordination events over a four-year period, which shows that only 11 percent of misoperation events (17 events out of 151) and only 2.9 percent of total events (17 out of 574) involved Protection System coordination issues. Further, Entergy claims that, in proposing the Reliability Standard, NERC was aware of the possibility that some bulk electric system elements may never undergo a Protection System Coordination Study and that ''NERC does not afford this possibility the same risk as the Commission.'' [44] According to Entergy, ''NERC has properly balanced the implementation costs and reliability benefits of the proposed PRC–027–1 Reliability Standard and determined that Option 2 is sufficient to ensure reliability'' and the Commission should defer to NERC's expertise, or otherwise provide more support to justify a deviation from NERC's proposal.

25. In addition, some commenters expressed concern that applicable entities may not have maintained sufficient documentation to substantiate prior protection system coordination studies and, as result, entities would have to perform new protection system coordination studies purely for compliance purposes.[45]

26. As an alternative to the proposed directive, NERC and other commenters suggest that Reliability Standard PRC–027–1 be modified so that it requires an applicable entity to conduct an initial baseline protection system coordination study on a certain subset of its bulk electric system elements (*i.e.,* based on a higher voltage or higher risk protection systems).[46] NERC and other commenters also request that the Commission permit NERC to allow more than 6 years to complete the initial baseline protection system coordination studies (*i.e.,* 10 or 12 years) if the Commission directs NERC to modify Reliability Standard PRC–027–1.[47] EEI recommends that if the Commission continues to have concerns about Reliability Standard PRC–027–1, Requirement R2, Option 2, as an alternative to the proposed directive, a final rule should direct NERC ''to assess the effectiveness of Option 2 after the implementation of the proposed Reliability Standard and if necessary make technical recommendations to improve the efficiency and effectiveness as appropriate.'' [48]

27. Idaho Power supports the proposed directive.[49] Idaho Power supports eliminating Reliability Standard PRC–027–1, Requirement R2, Option 2 because it contends that Option 1 is a more robust option explaining that it is ''preferable because it is more likely to address miscoordinations.'' [50]

Commission Determination

28. Based on the record before us, we do not adopt the directive proposed in the NOPR. The record in this proceeding supports the NOPR's conclusion that mis-coordination of protection systems may pose a potential reliability risk and, as currently drafted, Reliability Standard PRC–027–1, Requirement R2, Option 2 permits applicable entities to forego protection system coordination studies under certain circumstances.[51] However, we are persuaded by the statements from NERC and other commenters that applicable entities generally perform, or will choose to perform for their significant facilities, protection system coordination studies even in the absence of a Reliability Standard requirement.[52] We also recognize the concern raised by commenters regarding the burden of compliance. Specifically, we recognize the concern that were the NOPR directive adopted, applicable entities could be required to re-run protection system coordination studies for the sole purpose of generating compliance documentation, even if such entities already performed protection

[36] NERC Comments at 11; *see also* Entergy Comments at 8.

[37] NERC Comments at 11.

[38] APPA/TAPS Comments at 3; EEI Comments at 3; El Paso Electric Comments at 4; Entergy Comments at 4; Hydro One Comments at 1–2; ITC Comments at 3; LPPC Comments at 2; NPPD Comments at 1; NRECA/ELCON Comments at 5; Oncor Comments at 1; PG&E Comments at 2; SCE&G Comments at 1; Tri-State Comments at 4.

[39] Hydro One Comments at 1.

[40] *Id.* at 13.

[41] *Id.*

[42] PG&E Comments at 3.

[43] Entergy Comments at 5.

[44] *Id.* at 9–10.

[45] ITC Comments at 4; Entergy Comments at 1; NPPD Comments at 1; PG&E Comments at 3.

[46] NERC Comments at 11–12; El Paso Electric Comments at 2; Entergy Comments at 12; NRECA/ELCON Comments at 6–7.

[47] NERC Comments at 12; El Paso Electric Comments at 2–3; Entergy Comments at 12–13; NRECA/ELCON Comments at 6–7. Separately, El Paso Electric contends that the six-year cycle proposed by NERC in Reliability Standard PRC–027–1, Requirement R2 is too short and directs resources away from ''other activities that have a greater likelihood of improving reliability outcomes in a demonstrable way.'' El Paso Electric Comments at 2. We disagree. NERC recognized the potential burden imposed by Requirement R2 and determined that six years ''balance[d] the resources required to perform Protection System Coordination Studies and the potential reliability impacts created by incremental changes of Fault current over time.'' NERC Petition at 40. Moreover, during the standard drafting process, some commenters indicated that six years was too long an interval. *See, e.g.,* NERC Petition, Exhibit G (Summary of Development History and Record of Development) at 1479 of pdf (ReliabilityFirst recommending a 24-month period to conduct protection system coordination study), 2169 of pdf (Texas RE stating that six years is too long of a time period between studies of fault currents).

[48] EEI Comments at 6.

[49] Idaho Power Comments at 1–2.

[50] *Id.* at 2.

[51] *See, e.g.,* NERC Comments at 6 (''NERC and the standard drafting team concluded that Protection System coordination did not present a prevalent enough risk to the reliable operation of the [bulk electric system] to warrant imposing the burden of requiring applicable entities to perform a full Protection System Coordination Study for every [bulk electric system] Element with a Protection System.''); Entergy Comments at 9 (''In proposing the Reliability Standard, NERC was aware of the possibility that some bulk electric system elements may never undergo a Protection System Coordination Study.'').

[52] *See, e.g.,* NERC Comments at 5; NPPD Comments at 1; Tri-State Comments at 10; ITC Comments at 4.

system coordination studies that remain valid but lack documentation to substantiate compliance. Accordingly, pursuant to 215(d)(2) of the FPA, we approve Reliability Standard PRC–027–1 and do not direct modifications to the Reliability Standard.[53]

III. Information Collection Statement

29. The collections of information addressed in this Final Rule are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.[54] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[55] Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of a rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

30. The Commission solicited public comments in the NOPR on the need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques. The Commission did not receive comments regarding the burden estimates for the Reliability Standards approved herein (*i.e.,* Reliability Standards PRC–027–1 and PER–006–1).[56]

31. The information collection requirements in this Final Rule in Docket No. RM16–22–000 are associated with FERC–725A, FERC–725G, and FERC–725Y, as discussed below.[57]

32. *Public Reporting Burden:* The number of respondents below is based on an examination of the NERC compliance registry on December 1, 2017, for transmission owners, generator owners, generator operators, and distribution providers within the United States and an estimate of how many such entities from that registry will be affected by the Reliability Standards in this Final Rule for adoption and implementation. As of December 1, 2017, 337 transmission owners, 971 generator owners, 944 generator operators, and 419 distribution providers in the United States were registered in the NERC compliance registry. However, under NERC's compliance registration program, entities may be registered for multiple functions, so these numbers incorporate some double counting. We note that many generation sites share a common generator owner or generator operator. The following table provides the estimated annual burden and cost related to information collection requirements in this Final Rule.[58]

CHANGES DUE TO THE FINAL RULE IN DOCKET NO. RM16–22–000

Respondent category and requirement[59]	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of annual responses (1) * (2) = (3)	Average burden hours and cost per response[60] (4)	Annual burden hours and total annual cost (rounded)[61] (3) * (4) = (5)
FERC–725G (Reliability Standard PRC–027–1)[62]					
TO; Reporting Reqs. R1, R2, & R3	337	1	337	60 hrs.; $3,941.40	20,220 hrs.; $1,328,252.
TO; Recordkeeping Reqs	337	1	337	40 hrs.; $1,565.60	13,480 hrs.; $527,607.
GO; Reporting Reqs. R1, R2, & R3	971	1	971	10 hrs.; $656.90	9,710 hrs.; $637,830.
GO; Recordkeeping Reqs	971	1	971	10 hrs.; $391.40	9,710 hrs.; $380,049.
DP; Reporting Reqs. R1, R2, & R3	419	1	419	10 hrs.; $656.90	4,190 hrs.; $275,241.
DP; Recordkeeping Reqs	419	1	419	10 hrs.; $391.40	4,190 hrs.; $163,997.
Sub-Total for Reporting Reqs. for FERC–725G					34,120 hrs.; $2,241,323.
Sub-Total for Recordkeeping Reqs. for FERC–725G					27,380 hrs.; $1,072,653.
Total Increase for FERC–725G					61,500 hrs.; $3,313,976.
FERC–725Y (Reliability Standard PER–006–1)[63]					
GOP; Reporting Req. R1	944	1	944	5 hrs.; $328.45	4,720 hrs.; $310,057.
GOP; Recordkeeping Req	944	1	944	10 hrs.; $391.40	9,440 hrs.; $369,482.
Total Increase for FERC–725Y					14,160 hrs.; $679,539.
Reductions to FERC–725A (retirement of Reliability Standard PRC–001–1.1)[64]					
GOP; Reporting Req	944	1	944	40 hrs.; $2,627.60	37,760 hrs.; $2,480,454.
GOP; Recordkeeping Req	944	1	944	50 hrs.; $1,957.00	47,200 hrs.; $1,847,408.
TOP; Reporting Req	176	1	176	60 hrs.; $3,941.40	10,560 hrs.; $693,686.
TOP; Recordkeeping Req	176	1	176	70 hrs.; $2,739.80	12,320 hrs.; $482,205.
BA; Reporting Req	99	1	99	32 hrs.; $2,102.08	3,168 hrs.; $208,106.
BA; Recordkeeping Req	99	1	99	20 hrs.; $782.80	1,980 hrs.; $77,497.
Reduction Sub-Total Reporting Reqs. for FERC–725A					51,484 hrs.; $3,382,246.
Reduction Sub-Total Recordkeeping Reqs. for FERC–725A.					61,500 hrs.; $2,407,110.
Reduction Sub-Total for FERC–725A					112,984 hrs.; $5,789,356 (reduction).

[53] 16 U.S.C. 824o(d)(2).

[54] 44 U.S.C. 3507(d) (2012).

[55] 5 CFR 1320.11 (2017).

[56] As discussed above, several commenters addressed the potential burden of a new version of Reliability Standard PRC–027–1 modified, pursuant to the Commission's directive, to require initial protection system coordination studies. *See, e.g.,* Tri-State Comments at 12. However, those comments are not relevant to the burden estimates contained in this Final Rule because, herein, the Commission only approves Reliability Standards PRC–027–1 and PER–006–1.

[57] In the NOPR in Docket No. RM16–22–000, some of the reporting requirements were included under FERC–725G6 (OMB Control No. 1902–0300), a temporary place holder, because FERC–725G was pending review at OMB in an unrelated action. As indicated below, those reporting requirements are now included under FERC–725G (OMB Control No. 1902–0252). When the NOPR in Docket No. RM16–22–000 was issued, another unrelated item affecting FERC–725A was pending OMB review. Burden estimates were provided in order to solicit public comments, but the burden reduction to FERC–725A was not submitted to OMB at that time. The burden reduction to FERC–725A for this Final Rule will be submitted to OMB for review.

[58] TO = transmission owner; TOP = transmission operator; GO = generator owner; GOP = generator operator; DP = distribution provider; and BA = balancing authority.

CHANGES DUE TO THE FINAL RULE IN DOCKET NO. RM16–22–000—Continued

Respondent category and requirement [59]	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of annual responses (1) * (2) = (3)	Average burden hours and cost per response [60] (4)	Annual burden hours and total annual cost (rounded) [61] (3) * (4) = (5)
NET TOTAL REDUCTION FOR CHANGES IN RM16–22–000.	.....	.....	.....	.....	37,324 hrs.; $1,795,841 (reduction).

Titles: FERC–725A (Mandatory Reliability Standards for the Bulk-Power System), FERC–725G (Reliability Standards for the Bulk Power System: PRC Reliability Standards) and FERC–725Y (Mandatory Reliability Standards: Operations Personnel Training).

Action: Revisions to existing collections.

OMB Control Nos.: 1902–0244 (FERC–725A); 1902–0252 (FERC–725G) and 1902–0279 (FERC–725Y).

Respondents: Business or other for profit, and not for profit institutions.

Frequency of Responses: Annual recordkeeping and reporting requirements, with some reporting requirements being at least once every six years.

Necessity of the Information: Reliability Standards PRC–027–1 and PER–006–1 set forth requirements for coordination of protection systems and personnel training on specific topics essential to reliability. The Commission approves Reliability Standards PRC–027–1 and PER–006–1, which will replace Commission-approved Reliability Standard PRC–001–1.1(ii). Reliability Standards PRC–027–1 and PER–006–1 improve upon existing Reliability Standard PRC–001–1.1(ii) because the Reliability Standards assign responsibilities to entities with more appropriate resources and skill sets to conduct studies required to coordinate protection systems. The approved Reliability Standards also provide additional clarity to applicable entities.

Internal review: The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

IV. Environmental Analysis

33. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[65] The action here falls within the categorical exclusion in the Commission's regulations for rules that are clarifying, corrective or procedural, for information gathering, analysis, and dissemination.[66]

V. Regulatory Flexibility Act

34. The Regulatory Flexibility Act of 1980 (RFA) generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities.[67] The Small Business Administration (SBA) defines which utilities are small businesses based on the number of employees that a utility and its affiliates employ.[68]

35. Reliability Standard PRC–027–1 (included in FERC–725G) will apply to approximately 1,727 entities (337 transmission owners, 971 generator owners, and 419 distribution providers) in the United States.[69] Pursuant to SBA regulations, the small business threshold for Electric Bulk Power Transmission and Control is 500 employees. For generator owners, the small generator threshold ranges from 250 to 750 employees (depending on the fuel source). For Electric Power Distribution, the small business threshold is 1,000 employees. We estimate that the annual cost for each entity will be $1,048 for each generator owner and distribution provider and $5,507 for each transmission owner.

36. Reliability Standard PER–006–1 (included in FERC–725Y) will apply to approximately 944 generator operators in the United States. Pursuant to SBA regulations the small business threshold for generator operators ranges from 250 to 750 employees (depending on the fuel source). We estimate that the annual cost for each generator operator will be $719.

37. The retirement of Reliability Standard PRC–001–1.1(ii) (included in FERC–725A) will decrease the annual estimated cost for 944 generator operators by $4,585 each, for 176 transmission operators by $6,681 each, and for 99 balancing authorities by $2,885 each. For the generator operators affected by this retirement and approval of Reliability Standard PER–006–1, the net annual effect would be a decrease of $3,866 each.

38. We estimate the net annual cost of this Final Rule would vary, by type of entity, from an annual decrease of $6,681 (for each transmission operator) to an annual increase of $5,507 (for each transmission owner). We view this as a minimal economic impact for each entity. Accordingly, we certify that this Final Rule will not have a significant economic impact on a substantial number of small entities.

VI. Document Availability

39. In addition to publishing the full text of this document in the **Federal**

[59] For each Reliability Standard, the Measure shows the acceptable evidence for the associated Reporting Requirement, and the Compliance section details the related Recordkeeping Requirement.

[60] The estimates for cost per hour are based on May 2016 wage figures from the Bureau of Labor Statistics (BLS, *https://www.bls.gov/oes/current/naics2_22.htm*) and BLS benefits information from March 20, 2018 (for December 2017, *https://www.bls.gov/news.release/ecec.nr0.htm*). The estimated hourly cost, for wages plus benefits, are: (a) $68.12/hour, for electrical engineer, Occupation Code 17–2071, and (b) $39.14/hour, for information and record clerk, Occupation Code 43–4199.

The hourly cost for an electrical engineer is used for the reporting requirements; the hourly cost for a record clerk is used for the recordkeeping requirements.

[61] For display purposes, the cost figures in column 5 have been rounded.

[62] Some of the reporting requirements are required at least every six calendar years. In this table, the Commission assumes that respondents might work on some of their elements each year; the annual burden estimate shown is one sixth of the burden associated with one complete six-year cycle. For example, for each transmission owner: (a) The annual reporting burden associated with Requirements R1, R2, and R3 is shown as 60 hours per year, and (b) the burden for the six-year cycle would be six times that, or a total of 360 hours.

[63] In order to provide improved information on the Reliability Standard and associated burden, FERC–725Y (rather than FERC–725A) will cover the burden required by PER–006–1.

[64] The estimates for average annual burden hours per response are based on figures in Order No. 693. Order No. 693, FERC Stats. & Regs. ¶ 31,242, at PP 1906–1907. The numbers of respondents and estimated hourly costs are based on current figures.

[65] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[66] 18 CFR 380.4(a)(2)(ii) (2017).

[67] 5 U.S.C. 601–612 (2012).

[68] 13 CFR 121.201, Subsector 221 (2017).

[69] Many respondents serve multiple roles in the NERC compliance registry, so there is likely double counting in the estimates.

Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

40. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

41. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at 202–502–8371, TTY 202–502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

42. The Final Rule is effective August 13, 2018. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. This Final Rule is being submitted to the Senate, House, and Government Accountability Office.

By the Commission.

Issued: June 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

List of Commenters

APPA/TAPS	American Public Power Association and Transmission Access Policy Study Group
EEI	Edison Electric Institute.
El Paso Electric.	El Paso Electric Company.
Entergy	Entergy Services, Inc.
Hydro One	Hydro One Networks Inc.
Idaho Power	Idaho Power Company.
ITC	International Transmission Company d/b/a ITC Transmission, Michigan Electric Transmission Company, LLC, ITC Midwest LLC and ITC Great Plains, LLC.
LPPC	Large Public Power Council.
NPPD	Nebraska Public Power District.
NERC	North American Electric Reliability Corporation.
NRECA/ELCON.	National Rural Electric Cooperative Association and the Electricity Consumers Resource Council.
Oncor	Oncor Electric Delivery.
PG&E	Pacific Gas and Electric Company.
SCE&G	South Carolina Electric and Gas Company.
Tri-State	Tri-State Generation and Transmission Association, Inc.

[FR Doc. 2018–12663 Filed 6–12–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2018–0445]

Safety Zone; Wendell Family Fourth of July Fireworks Display, Rockport, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Wendell Family Fourth of July Fireworks Display on July 4, 2018, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event in Rockport, TX. During the enforcement periods, entry into these zones is prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative.

DATES: The regulations in 33 CFR 165.801, Table 4, Line 7 will be enforced from 8 p.m. through 9:30 p.m. on July 4, 2018.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Kevin Kyles, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5125, email *Kevin.L.Kyles@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.801, Table 4, Line 7, for the Wendell Family Fourth of July Fireworks Display regulated area from 8 p.m. through 9:30 p.m. on July 4, 2018. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801, specifies the location of the regulated area for the Wendell Family Fourth of July Fireworks which encompasses portions of Little Bay and Rockport Beach Park. As reflected in §§ 165.23 and 165.801(a), if you are the operator of a vessel in the regulated area you must comply with directions from the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. Persons or vessels desiring to enter the zones must request permission from the COTP or a designated representative. They can be reached on VHF FM channel 16 or by telephone at (361) 939–0450. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative. In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notice to Mariners (BNM), Local Notices to Mariners (LNM), Marine Safety Information Broadcasts (MSIBs), and/or through other means of public notice as appropriate at least 24 hours in advance of each enforcement.

Dated: June 6, 2018.

E.J. Gaynor,

Captain, U.S. Coast Guard, Captain of the Port Sector Corpus Christi.

[FR Doc. 2018–12645 Filed 6–12–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0535]

RIN 1625–AA00

Safety Zone; Lewis River, Ridgefield, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Lewis River near Ridgefield, WA. This action is necessary

to provide for the safety of life on these navigable waters during a fireworks display on June 30, 2018. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Columbia River or a designated representative.

DATES: This rule is effective from 9:15 p.m. to 11:45 p.m. on June 30, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0535 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Laura Springer, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, email *msupdxwwm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

Pekin Ferry will be conducting a fireworks display from 10:15 p.m. to 10:45 p.m. on June 30, 2018, to commemorate Independence Day. The fireworks are to be launched from a barge in the Lewis River in the vicinity of Pekin Ferry in Ridgefield, WA. Hazards from firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Columbia River (COTP) has determined that potential hazards associated with the fireworks to be used in this display will be a safety concern for anyone within a 450-yard radius of the barge.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it would be impracticable to complete a notice-and-comment rulemaking by the date of the fireworks display, June 30, 2018.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because an enforcement regulation is needed on June 30, 2018, to respond to the potential safety hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Columbia River (COTP) has determined that potential hazards associated with the fireworks display on June 30, 2018, will be a safety concern for anyone within a 450-yard radius of the launch site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a safety zone from 9:15 p.m. until 11:45 p.m. on June 30, 2018. The safety zone will cover all navigable waters of the Lewis River within 450 yards of a barge located at 45°52′07″ N, 122°43′53″ W, in vicinity of Pekin Ferry in Ridgefield, WA. The duration of the zone is intended to ensure the safety of vessels and these navigable waters an hour before, during, and an hour after the scheduled 10:15 p.m. to 10:45 p.m. fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of the Lewis River for approximately 2 and ½ hours when vessel traffic is normally low. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 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 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.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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** section.

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.

C. 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).

D. Federalism and Indian Tribal Governments

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 have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. 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.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (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 a safety zone lasting approximately 2 and ½ hours that will prohibit entry within 450 yards of a fireworks barge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. 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.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 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, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–0535 to read as follows:

§ 165.T13–0535 Safety Zone; Lewis River, Ridgefield, WA.

(a) *Safety zone.* The following area is designated a safety zone: Waters of the Lewis River, within a 450-yard radius of the fireworks barge located at 45°52′07″ N, 122°43′53″ W in vicinity of Pekin Ferry in Ridgefield, WA.

(b) *Regulations.* In accordance with § 165.23, no person may enter or remain in this safety zone unless authorized by the Captain of the Port Columbia River or his designated representative. Also in accordance with § 165.23, no person may bring into, or allow to remain in this safety zone any vehicle, vessel, or object unless authorized by the Captain of the Port Columbia River or his designated representative.

(c) *Enforcement period.* This section will be enforced from 9:15 p.m. to 11:45 p.m. on June 30, 2018.

Dated: June 6, 2018.

D.F. Berliner,

Captain, U.S. Coast Guard, Acting Captain of the Port, Sector Columbia River.

[FR Doc. 2018–12659 Filed 6–12–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0536]

RIN 1625–AA00

Safety Zone; Columbia River, The Dalles, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Columbia River near The Dalles, OR. This action is necessary to provide for the safety of life on these navigable waters during a fireworks display on June 30, 2018. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Columbia River or a designated representative.

DATES: This rule is effective from 9 p.m. to 11:30 p.m. on June 30, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0536 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Laura Springer, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, email *msupdxwwm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Dalles Main Street will be conducting a fireworks display from 10 p.m. to 10:30 p.m. on June 30, 2018, to commemorate Independence Day. The fireworks are to be launched from a barge in the Columbia River in The Dalles, OR. Hazards from firework displays include accidental discharge, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Columbia River (COTP) has determined that potential hazards associated with the fireworks to be used in this display will be a safety concern for anyone within a 450-yard radius of the barge.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because to do so would be impracticable to complete a notice-and-comment rulemaking prior to the effective rule by June 30, 2018.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because action is needed on June 30, 2018, to respond to the potential safety hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Columbia River (COTP) has determined that potential hazards associated with the fireworks display on June 30, 2018, will be a safety concern for anyone within a 450-yard radius of the launch site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a safety zone from 9 p.m. until 11:30 p.m. on June 30, 2018. The safety zone will cover all navigable waters of the Columbia River within 450 yards of a barge located at 45°36′18″ N, 121°10′23″ W, in vicinity of The Dalles, OR. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 10 p.m. to 10:30 p.m. fireworks display. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of the Columbia River for approximately 2 and a ½ hours during the evening when vessel traffic is normally low. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 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 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.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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** section.

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.

C. 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).

D. Federalism and Indian Tribal Governments

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 have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. 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.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (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 a safety zone lasting approximately two and a half hours that will prohibit entry within 450 yards of a fireworks barge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. 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.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 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, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–0536 to read as follows:

§ 165.T13–0536 Safety Zone; Columbia River, The Dalles, OR.

(a) *Safety zone.* The following area is designated a safety zone: Waters of the Columbia River, within a 450-yard radius of the fireworks barge located at 45°36′18″ N, 121°10′23″ W in vicinity of The Dalles, OR.

(b) *Regulations.* In accordance with § 165.23, no person may enter or remain in this safety zone unless authorized by the Captain of the Port Columbia River or his designated representative. Also in accordance with § 165.23, no person may bring into, or allow to remain in this safety zone any vehicle, vessel, or object unless authorized by the Captain of the Port Columbia River or his designated representative.

(c) *Enforcement period.* This section will be enforced from 9 p.m. to 11:30 p.m. on June 30, 2018.

Dated: June 6, 2018.

D.F. Berliner,

Captain, U.S. Coast Guard, Acting Captain of the Port, Sector Columbia River.

[FR Doc. 2018–12658 Filed 6–12–18; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 18–143, 10–90, 14–58; FCC 18–57]

The Uniendo a Puerto Rico Fund and the Connect USVI Fund, Connect America Fund, ETC Annual Reports and Certifications

AGENCY: Federal Communications Commission.

ACTION: Final action.

SUMMARY: In this document, the Federal Communications Commission (Commission) establishes the Uniendo a Puerto Rico Fund and the Connect USVI Fund to rebuild, improve and expand voice and broadband networks in Puerto Rico and the U.S. Virgin Islands. Through the Uniendo a Puerto Rico Fund, the Commission will make available up to $750 million of funding to carriers in Puerto Rico, including an immediate infusion of $51.2 million for restoration efforts in 2018. Through the Connect USVI Fund, the Commission will make available up to $204 million of funding to carriers in the U.S. Virgin Islands, including an immediate infusion of $13 million for restoration efforts in 2018. As a result of these Funds, as well as the Commission's decision not to offset more than $65 million in advance payments it made to carriers last year, it will make available up to $256 million in additional high-cost support for rebuilding, improving, and expanding broadband-capable networks in Puerto Rico and the Virgin Islands.

DATES: This action is effective June 13, 2018.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order in WC Docket Nos. 18–143, 10–90, 14–58; FCC 18–57, adopted on May 8, 2018 and released on May 29, 2018. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW, Washington, DC 20554 or at the following internet address: *https://docs.fcc.gov/public/attachments/FCC-18-57A1.pdf.*

I. Introduction

1. The 2017 hurricane season caused widespread devastation to Puerto Rico and the U.S. Virgin Islands, destroying thousands of homes and causing near total destruction of critical infrastructure. Hurricane Maria, the strongest storm to hit Puerto Rico in almost a century, ripped through the island as a Category 4 storm with 155-mph winds. Following on the heels of Hurricane Irma, Maria's damage to the communications network proved particularly devastating. The government of Puerto Rico estimates that the two hurricanes caused approximately $1.5 billion of damage to the communications network. Similarly, Maria ''decimat[ed] the communications and power grid'' across St. Croix, the largest of the U.S. Virgin Islands. And the ''[t]wo other main islands, St. John and St. Thomas, [had been] pummeled by Hurricane Irma just 14 days earlier.'' Recovery of the communications networks in Puerto Rico and the U.S. Virgin Islands has proven especially challenging, particularly compared to other locations in the United States impacted by this season's hurricanes,

due to their isolation from the mainland, which has caused logistical difficulties and contributed to ongoing electrical power outages.

2. Restoring communications networks is a critical element of recovery. The Commission establishes the Uniendo a Puerto Rico Fund and the Connect USVI Fund to rebuild, improve and expand voice and broadband networks in Puerto Rico and the U.S. Virgin Islands.

3. Through the Uniendo a Puerto Rico Fund, the Commission will make available up to $750 million of funding to carriers in Puerto Rico, including an immediate infusion of $51.2 million for restoration efforts in 2018. Of the remainder, the Commission anticipates that about $444.5 million would be made available over a 10-year term for fixed voice and broadband (an $84 million increase over current funding levels) and that about $254 million would be made available over a 3-year term for 4G Long-Term Evolution (LTE) mobile voice and broadband (a $16.8 million increase).

4. Through the Connect USVI Fund, the Commission will make available up to $204 million of funding to carriers in the U.S. Virgin Islands, including an immediate infusion of $13 million for restoration efforts in 2018. Of the remainder, the Commission anticipates that about $186.5 million would be made available over a 10-year term for fixed broadband (a $21 million increase) and that about $4.4 million would be made available over a 3-year term for 4G LTE mobile voice and broadband (a $4.2 million increase).

5. As a result of these Funds, as well as the Commission's decision not to offset more than $65 million in advance payments it made to carriers last year, the Commission will make available up to $256 million in additional high-cost support for rebuilding, improving, and expanding broadband-capable networks in Puerto Rico and the Virgin Islands. The Commission intends to target high-cost support over the next several years in a tailored and cost-effective manner, using competitive processes where appropriate.

II. Order: No Offset of Advance Payments

6. At the outset, the Commission now declines to offset the approximately $65.8 million in emergency high-cost support provided immediately following the hurricanes against future payments. Although the Commission had previously anticipated offsetting the advance payments against future support, it no longer believes that to be a prudent course. The continuing difficulties in bringing service and power back to Puerto Rico and the U.S. Virgin Islands have impeded and delayed restoration efforts so that conditions on the islands have not improved sufficiently to justify reducing future support payments. Restoration efforts are still ongoing rather than largely complete and persistent power outages and other logistical challenges have made the continued operation of restored networks more expensive than some expected. As such, requiring the offset of advance payments would substantially delay, if not prevent, further restoration efforts—and the Commission finds that the public interest is best served by allowing carriers to continue their critical work to restore their communications networks. The Commission therefore declines to offset future payments against the emergency relief granted by the *2017 Hurricane Funding Order.*

7. As a result, the Commission will continue in 2018 to provide, at a minimum, current levels of high-cost support to carriers in Puerto Rico and the U.S. Virgin Islands. This means that in Puerto Rico, the fixed carrier (PRTC) will continue to receive approximately $3 million each month (or $36 million annualized) and mobile carriers (Centennial Puerto Rico Operations Corp., Suncom Wireless Puerto Rico Operating Co., Cingular Wireless, Puerto Rico Telephone Company, PR Wireless Inc., and Worldnet Telecommunications, Inc.) will continue to receive approximately $6.6 million each month (or $79.2 million annualized) in frozen support in the near term. In the U.S. Virgin Islands, the fixed carrier (Viya) will continue to receive approximately $1.4 million each month (or $16.5 million annualized) and the mobile carrier (Choice Communications, LLC) will continue to receive approximately $5,600 each month (or $67,000 annualized) in frozen support in the near term.

8. Also as a result of this decision, the advance payments should be considered a new, one-time source of high-cost support provided in the immediate aftermath of the hurricanes. The same rules and accountability measures as currently govern the frozen high-cost support these carriers receive will continue to apply. The Commission will also apply its accounting and audit rules to prevent waste, fraud, and abuse. For the reasons given in section III, paras. 22–23 in the following, the Commission finds good cause to forego the usual notice-and-comment procedure for this Order.

III. The Uniendo A Puerto Rico Fund and the Connect USVI Fund

9. The Commission will establish the Uniendo a Puerto Rico Fund and the Connect USVI Fund in two stages. In stage one, the Commission makes $51.2 million in new funding available to Puerto Rico and $13 million to the U.S. Virgin Islands to help restore voice and broadband service. The Commission provides this immediate relief to allow impacted carriers to rebuild more quickly in 2018 and set the stage for the longer-term plan. In stage two, the Commission intends to make about $699 million available in the Uniendo a Puerto Rico Fund and about $191 million available in the Connect USVI Fund to rebuild, improve, and expand voice and broadband networks on the islands in the longer term.

10. The Commission finds that it is in the public interest to provide new funding in the short term to restore service in Puerto Rico and the U.S. Virgin Islands. Given the devastation wrought by these two back-to-back hurricanes, which collectively were unprecedented in their severity and in the protracted duration of damage they caused, the Commission decides to make available up to $64.2 million of new funding—roughly equal to the amount it has decided not to offset against existing support payments—to bolster the ability of existing carriers to restore their facilities across the islands. This additional support should help restore and maintain service as quickly as possible for as many people as possible during that interim period.

11. Specifically, the Commission directs a one-time infusion of $51.2 million through the Uniendo a Puerto Rico Fund and $13 million through the Connect USVI Fund to support any facilities-based providers of voice and broadband services even if they have not previously received universal service support. The Commission finds this allocation of support (in addition to existing support streams) to be likely sufficient to cover the short-term costs of restoration while the Commission considers further reforms and funding over the longer term. In so finding, the Commission takes into account, among other factors, differences in landmass, geography, topography, and population between Puerto Rico and the U.S. Virgin Islands, the significant financial and operational challenges faced by carriers in both areas, and the past and current availability of high-cost support to carriers.

12. The Commission distributes the Stage 1 funding for each territory through a three-step process. First, any

facilities-based provider of voice and broadband internet access service may elect to participate in this opportunity for new restoration funding. To participate, a facilities-based provider must submit a certification regarding the number of subscribers (voice or broadband internet access service) it served in the territory as of June 30, 2017 (before the hurricanes), along with accompanying evidence, to the Commission within 14 days of the publication of this Order. A voice-only subscriber, a broadband-only subscriber, and a voice-and-broadband subscriber each count as one subscriber. For mobile network operators, each line in a multi-line plan counts as one subscriber. For fixed network operators, each enterprise location served counts as one subscriber; such treatment reflects the high fixed costs of deploying service to any one location as well as the higher revenue potential of enterprise customers. The Commission uses the same definition of voice and broadband subscribers as applies to FCC Form 477 reporting. Providers also must file a copy of the certification and accompanying evidence through the Commission's Electronic Comment Filing System (ECFS) as well as email a copy to *ConnectAmerica@fcc.gov.* The Commission will then verify eligibility using various data sources, including FCC Form 477 data.

13. Second, the Commission allocates 60 percent of the funding available to the territory to fixed network operators and 40 percent to mobile network operators. The Commission does so for two reasons. For one, allocating more to fixed service providers is appropriate in light of the relatively higher costs of restoring fixed services. For another, the Commission expects that restoring and improving the fixed network will facilitate more reliable and faster backhaul for the mobile services. In other words, new funding for fixed networks may in fact decrease at least some of the need for funding of mobile networks.

14. Third, the Commission directs the Wireline Competition Bureau (WCB) and the Wireless Telecommunications Bureau (WTB) to allocate these amounts among qualifying providers of each territory and type according to the number of subscribers (voice or broadband internet access service) each served as of June 30, 2017. The Bureaus shall make public these allocations via a Public Notice as soon as practicable.

15. The Commission notes that to be eligible for funding, the provider must be willing at the time of certification to be designated an eligible telecommunications carrier (ETC) by the relevant commission, must in fact become an ETC and submit that designation to the Universal Service Administrative Company (USAC) before receiving any funding, and must remain an ETC for at least one year after first receiving funding. Given the importance of conducting restoration operations as quickly as possible, the Commission expects local regulators and providers to work together to designate ETCs as quickly as possible. If a provider has not been designated an ETC within 60 days of the Bureaus' announcement of support allocations, the Commission reserves the right to redirect that provider's allocation toward other universal service purposes, such as increasing the funding available for long-term rebuilding of voice and broadband-capable networks in Puerto Rico and the U.S. Virgin Islands.

16. The Commission reminds providers that section 254(e) of the Act and § 54.7 of the Commission's rules provide that carriers receiving federal universal service support ''shall use that support only for the provision, maintenance, and upgrading of facilities and services for which the support is intended.'' Carriers must therefore use this additional funding to help restore and improve coverage and service quality to pre-hurricane levels and to help safeguard their equipment against future natural disasters. Appropriate uses include repairing, removing, reinforcing or relocating network elements damaged during the hurricanes; repairing or restoring customer premise equipment; replacing, rebuilding, and reinforcing the physical outside plant (poles, fiber, nodes, coaxial cables, and the like); hardening networks against future disasters; and increasing network resiliency to power outages or other potential service interruptions due to natural disasters. To help ensure that support is targeted towards short-term restoration and rebuilding expenses, the Commission limits eligible expenditures to those incurred through June 30, 2019, beginning from the date that the affected areas were declared a disaster by the Federal Emergency Management Agency following Hurricanes Irma and Maria. Carriers will be required to certify both at the time of acceptance of support and after support is spent that all support was used for the intended purpose. The Commission also notes that, during the short term when networks are still being restored, backhaul from fixed-service providers is essential to the provision of mobile services and it requires providers seeking restoration funding to offer backhaul to all interested parties on nondiscriminatory terms for a period of one year after first receiving funds. Failure to abide by these conditions may result in the loss of some or all restoration funding. The Commission reminds Puerto Rico and the U.S. Virgin Islands that the Act prohibits the territories from adopting regulations related to funding that are ''inconsistent with the Commission's rules to preserve and advance universal service.''

17. To protect against duplicative recovery and guard against waste, fraud, and abuse, carriers may not use this support for costs that are (or will be) reimbursed by other sources of funding inclusive of federal or local government aid or insurance reimbursements. Moreover, carriers are prohibited from using Stage 1 support for other purposes, such as the retirement of company debt unrelated to eligible expenditures, or other expenses not directly related to hurricane restoration and improvement. The Commission reminds carriers that high-cost support recipients ''are subject to random compliance audits and other investigations to ensure compliance with program rules and orders.'' Carriers must retain for at least ten years the records required to demonstrate that their use of this support complied with this Order and other Commission rules. The Commission directs USAC to initiate audits of Stage 1 disbursements in conjunction with its 2018 audits.

18. The Commission acknowledges that they are not allocating the new funding in proportion to frozen high-cost support. That is in large part because those frozen allocations were by and large established at least seven years ago and do not necessarily reflect the costs of providing or restoring service or the extent of today's networks. Indeed, if the Commission were to follow such allocation, wireless carriers in Puerto Rico would receive approximately 1,177 times the support of such carriers in the U.S. Virgin Islands—a strange result given that Puerto Rico is only 33 times larger than the U.S. Virgin Islands. And networks owned by those not historically universal-service recipients would be entirely excluded—despite the damage they incurred from the hurricanes. Instead, the Commission believes the relative size of each network, coupled with a recognition that fixed service networks generally require greater funding for restoration efforts and the need to provide non-contiguous service in the U.S. Virgin Islands, better reflect the likely costs of restoration.

19. The Commission finds that using notice and comment procedures for this interim and one-time relief, and thereby

delaying its effectiveness by at least several months, would be impracticable and contrary to the public interest. The good cause exception to the notice and comment procedures of the Administrative Procedures Act ''excuses notice and comment in emergency situations, or where delay could result in serious harm.''

20. Given the emergency situation and the devastation to communications networks caused by the hurricanes, the sooner providers receive additional funds, the sooner service can be restored to the people of Puerto Rico and the U.S. Virgin Islands. As noted above, Hurricane Maria was a once-in-a-century storm that caused devastating damage. Even after months of recovery efforts, ''the majority of citizens in Puerto Rico lack access to continuous and reliable telecommunications services.'' Similarly, ''only a small percentage of Viya's wireline customers have had their voice, broadband, and cable service restored, and there are still significant gaps in Viya's USVI wireless coverage.'' Voice and broadband-capable networks, of course, serve important public safety goals (including allowing the public to quickly notify first responders of emergencies). And the next hurricane season commences on June 1, 2018. Delaying these funds could result in serious harm if carriers are not able to restore and fortify their service before the start of the next hurricane season. Such efforts will take significant time, and the Commission wishes to help the carriers proceed as rapidly as possible.

21. The Commission is also concerned that some carriers might choose cheaper restoration plans that leave equipment vulnerable to another hurricane over more costly restoration plans that better protect against future natural disasters. Further, unlike other affected areas, Puerto Rico and the U.S. Virgin Islands have struggled to restore electrical power. One provider explains that ''[t]he principal cause of communications outages and network unreliability in Puerto Rico undoubtedly has been the continued lack of commercial power and long-term reliance on backup generators.'' Based on these unique circumstances, the Commission finds that the need for rapid action provides good cause for forgoing the usual administrative procedures in this unique situation.

22. The Commission further finds good cause to make this relief effective immediately upon publication in the **Federal Register**. ''In determining whether good cause exists, an agency should 'balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.' '' This interim relief imposes no regulatory burden on any carrier but merely offers funds to help their restoration efforts. The Commission therefore does not believe it would violate fundamental fairness to make the action effective immediately, particularly given the substantial need for immediate implementation of the relief, which only exists during calendar year 2018. Indeed, waiting 30 days to make this relief available ''would undermine the public interest by delaying'' restoration of service in hurricane-ravaged areas.

23. Finally, given the urgent need to bring service back to pre-hurricane levels as soon as possible, the Commission finds good cause to extend its previous waiver of § 54.313(c)(4) of the Commission's rules, which requires carriers receiving frozen support to certify that all support is used ''to build and operate broadband-capable networks used to offer the provider's own retail broadband service in areas substantially unserved by an unsubsidized competitor.''

IV. Procedural Matters

A. Paperwork Reduction Act

24. This document does not contain new information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

B. Congressional Review Act

25. The Commission will send a copy of this Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

26. *Final Regulatory Flexibility Certification.* Because the Order relies upon the good cause exception to notice and comment procedures, no final regulatory flexibility analysis is required under 5 U.S.C. 604.

V. Ordering Clauses

27. Accordingly, *it is ordered*, pursuant to the authority contained in sections 4(i), 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 214, 254, 303(r), and 403, and §§ 1.1, 1.3, and 1.412 of the Commission's rules, 47 CFR 1.1, 1.3, and 1.412, that this Order *is adopted*. The Order is effective upon publication in the **Federal Register**.

28. *It is further ordered* that, pursuant to § 1.3 of the Commission's rules, 47 CFR 1.3, that § 54.313(c)(4) of the Commission's rules, 47 CFR 54.313(c)(4), *is waived* to the extent described in this document.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2018–12488 Filed 6–12–18; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG285

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Using Jig Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels using jig gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2018 Pacific cod total allowable catch apportioned to vessels using jig gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), June 10, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish

fisheries appear at subpart B of 50 CFR part 680.

The 2018 Pacific cod total allowable catch (TAC) apportioned to vessels using jig gear in the Central Regulatory Area of the GOA is 61 metric tons (mt), as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the 2018 Pacific cod TAC apportioned to vessels using jig gear in the Central Regulatory Area of the GOA is necessary to account for the incidental catch in other anticipated fisheries. Therefore, the Regional Administrator is establishing a directed fishing allowance of 0 mt and is setting aside the remaining 61 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels using jig gear in the Central Regulatory Area of the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod by vessels using jig gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of June 7, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 8, 2018.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–12702 Filed 6–8–18; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 114
Wednesday, June 13, 2018

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 JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–482]

Schedules of Controlled Substances: Temporary Placement of N-Ethylpentylone in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Proposed amendment; notice of intent.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is publishing this notice of intent to issue an order temporarily scheduling *N*-1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (*N*-ethylpentylone, ephylone) in schedule I. This action is based on a finding by the Acting Administrator that the placement of *N*-ethylpentylone in schedule I is necessary to avoid an imminent hazard to the public safety. When it is issued, the temporary scheduling order will impose regulatory requirements under the Controlled Substances Act (CSA) on the manufacture, distribution, reverse distribution, possession, importation, exportation, research, and conduct of instructional activities, and chemical analysis of *N*-ethylpentylone, as well as administrative, civil, and criminal remedies with respect to persons who fail to comply with such requirements or otherwise violate the CSA with respect to *N*-ethylpentylone.

DATES: June 13, 2018.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: This notice of intent is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug Enforcement Administration (DEA) intends to issue a temporary order (in the form of a temporary amendment) placing *N*-ethylpentylone in schedule I of the Controlled Substances Act (CSA).[1] The temporary scheduling order will be published in the **Federal Register** on or after July 13, 2018.

Legal Authority

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance permanently are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA.[2] The Acting Administrator transmitted notice of his intent to place *N*-ethylpentylone in schedule I on a temporary basis to the Acting Assistant Secretary for Health of HHS by letter dated November 22, 2017. The Acting Assistant Secretary responded to this notice of intent by letter dated December 13, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no active investigational new drug applications or approved new drug applications for *N*-ethylpentylone. The Acting Assistant Secretary also stated that the HHS has no objection to the temporary placement of *N*-ethylpentylone in schedule I of the CSA. *N*-Ethylpentylone is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for this substance under section 505 of the FDCA, 21 U.S.C. 355.

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

N-Ethylpentylone

Around 2014, the synthetic cathinone, *N*-ethylpentylone, emerged in the United States' illicit drug market after the scheduling of other popular synthetic cathinones (*e.g.,* ethylone, 4-methyl-*N*-ethylcathinone (4–MEC), mephedrone, methylone, pentylone, and 3,4-methylenedioxymethamphetamine (MDPV)). The identification of *N*-ethylpentylone in forensic evidence and overdose deaths indicates that this substance is being misused and abused. Law enforcement encounters include those reported to the National Forensic

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

Laboratory Information System (NFLIS), a DEA sponsored program that systematically collects drug identification results and associated information from drug cases analyzed by Federal, State, and local forensic laboratories, the System to Retrieve Information from Drug Evidence (STRIDE), a federal database for the drug samples analyzed by DEA forensic laboratories, and STARLiMS (a web-based, commercial laboratory information management system that replaced STRIDE in 2014). Forensic laboratories have analyzed drug exhibits received from State, local, or Federal law enforcement agencies that were found to contain *N*-ethylpentylone.[3] NFLIS registered over 6,000 reports from state and local forensic laboratories identifying this substance in drug-related exhibits for a period from January 2013 to December 2017 from 41 states. *N*-Ethylpentylone was first identified in NFLIS in May 2014. STRIDE/STARLiMS registered over 300 reports from DEA forensic laboratories from January 2013 to December 2017. *N*-Ethylpentylone was first reported to STRIDE/STARLiMS in December 2015. Additionally, encounters of *N*-ethylpentylone have occurred by the U.S. Customs and Border Protection (CBP).

N-Ethylpentylone, like other synthetic cathinones, is a designer drug of the phenethylamine class and it is pharmacologically similar to schedule I synthetic cathinones (*e.g.,* cathinone, methcathinone, mephedrone, methylone, pentylone, and MDPV) and well-known schedule I and II sympathomimetic agents (*e.g.,* methamphetamine, 3,4-methylenedioxymethamphetamine (MDMA), and cocaine). *N*-ethylpentylone, similar to these substances, causes stimulant related psychological and somatic effects. Consequently, there have been documented reports of emergency room admissions and numerous deaths associated with the abuse of *N*-ethylpentylone. No approved medical use has been identified for this substance, nor has it been approved by the FDA for human consumption.

Available data and information for *N*-ethylpentylone, summarized below, indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–482.

Factor 4. History and Current Pattern of Abuse

N-Ethylpentylone is a synthetic cathinone of the phenethylamine class and it is structurally and pharmacologically similar to cathinone, methcathinone, mephedrone, methylone, pentylone, MDPV, methamphetamine, MDMA, and other schedule I and II substances. Thus, it is highly likely that *N*-ethylpentylone is abused in the same manner and by the same users as these substances. That is, *N*-ethylpentylone, like these substances, is most likely ingested by swallowing capsules or tablets or snorted by nasal insufflation of the powder tablets. Products containing *N*-ethylpentylone, similar to schedule I synthetic cathinones, are likely to be falsely marketed as ''research chemicals,'' ''jewelry cleaner,'' ''stain remover,'' ''plant food or fertilizer,'' ''insect repellants'' or ''bath salts,'' sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations, and purchased on the internet. Like those seen with commercial products that contain synthetic cathinones, the packages of products that contain *N*-ethylpentylone also probably contain the warning ''not for human consumption,'' most likely in an effort to circumvent statutory restrictions for these substances. Demographic data collected from published reports and mortality records suggest that the main users of *N*-ethylpentylone, similar to schedule I synthetic cathinones and MDMA, are young adults.

Available evidence suggests that the history and pattern of abuse of *N*-ethylpentylone parallels that of MDMA, methamphetamine, or cocaine and that *N*-ethylpentylone has been marketed as a replacement for these substances. *N*-Ethylpentylone has been identified in law enforcement seizures that were initially suspected to be MDMA. In addition, there are reports that abusers of *N*-ethylpentylone thought they were using MDMA or another illicit substance but toxicological analysis revealed that the psychoactive substance was *N*-ethylpentylone. Toxicology reports also revealed that *N*-ethylpentylone is being ingested with other substances including other synthetic cathinones, common cutting agents, or other recreational substances. Consequently, products containing synthetic cathinones, including *N*-ethylpentylone, are distributed to users, often with unpredictable outcomes. Thus, the recreational abuse of synthetic cathinones, including *N*-ethylpentylone, is a significant concern.

Factor 5. Scope, Duration and Significance of Abuse

N-Ethylpentylone is a popular recreational drug that emerged on the United States' illicit drug market after the scheduling of other popular synthetic cathinones (*e.g.,* ethylone, mephedrone, methylone, pentylone, and MDPV) (*see* DEA 3-Factor Analysis for a full discussion). Forensic laboratories have confirmed the presence of *N*-ethylpentylone in drug exhibits received from state, local, and federal law enforcement agencies. Law enforcement data show that *N*-ethylpentylone first appeared in the illicit drug market in 2014 with one encounter and began increasing thereafter.[4] In 2015, NFLIS registered five reports from three states regarding *N*-ethylpentylone. However, in 2016, there were 2,074 reports from 39 states and, in 2017, there were 3,955 reports from 39 states related to this substance registered in NFLIS. *N*-Ethylpentylone represented 60% of all synthetic cathinones encountered by local law enforcement agencies and reported to NFLIS in 2017. From January 2013 to December 2017, NFLIS registered 6,035 reports from state and local forensic laboratories identifying this substance in drug-related exhibits from 41 states. STRIDE/STARLiMS registered over 338 reports from DEA forensic laboratories during January 2013 to December 2017. Additionally, seizures of *N*-ethylpentylone have occurred by the U.S. Customs and Border Protection (CBP) beginning in 2016. Concerns over the continuing abuse of synthetic cathinones have led to the control of many synthetic cathinones.

Factor 6. What, if Any, Risk There Is to the Public Health

The identification of *N*-ethylpentylone in toxicological samples associated with fatal and non-fatal overdoses have been reported in the medical and scientific literature, forensic laboratory reports, and public health documents. Like schedule I synthetic cathinones, *N*-ethylpentylone has caused acute health problems leading to emergency department (ED) admissions, violent behaviors causing harm to self or others, and/or death. Adverse health effects associated with the abuse of *N*-ethylpentylone include a number of stimulant-like adverse health

[3] NFLIS and STRIDE/STARLiMS databases were queried on February 8, 2018.

[4] NFLIS and STRIDE/STARLiMS databases were queried on February 8, 2018.

effects such as diaphoresis, insomnia, mydriasis, hyperthermia, vomiting, agitation, disorientation, paranoia, abdominal pain, cardiac arrest, respiratory failure, and coma. In addition, *N*-ethylpentylone has been involved in deaths of many individuals. The DEA is aware of approximately 151 overdose deaths involving *N*-ethylpentylone abuse reported in the United States between 2014 and 2018. Thus, the abuse of *N*-ethylpentylone, like that of the abuse of schedule I synthetic cathinones and stimulant drugs, poses significant adverse health risks. Furthermore, because abusers of synthetic cathinones obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent. These unknown factors pose an additional risk for significant adverse health effects to the end user.

Based on information received by the DEA, the misuse and abuse of *N*-ethylpentylone has led to, at least, the same qualitative public health risks as schedule I synthetic cathinones, MDMA, and methamphetamine. The public health risks attendant to the abuse of synthetic cathinones, including *N*-ethylpentylone, are well established and have resulted in large numbers of ED visits and fatal overdoses.

Finding of Necessity of Schedule I Placement To Avoid an Imminent Hazard to the Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information, summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and/or abuse of *N*-ethylpentylone resulting from the lack of control of this substance poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for *N*-ethylpentylone indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated November 22, 2017, notified the Acting Assistant Secretary of the DEA's intention to temporarily place this substance in schedule I.

Conclusion

This notice of intent provides the 30-day notice pursuant to section 201(h) of the CSA, 21 U.S.C. 811(h), of DEA's intent to issue a temporary scheduling order. In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Acting Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule *N*-ethylpentylone in schedule I of the CSA, and finds that placement of *N*-ethylpentylone in schedule I of the CSA on a temporary basis is necessary in order to avoid an imminent hazard to the public safety.

The temporary placement of *N*-ethylpentylone in schedule I of the CSA will take effect pursuant to a temporary scheduling order, which will not be issued before July 13, 2018. Because the Acting Administrator hereby finds that it is necessary to temporarily place *N*-ethylpentylone in schedule I to avoid an imminent hazard to the public safety, the temporary order scheduling this substance will be effective on the date that order is published in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). It is the intention of the Acting Administrator to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this notice. Upon publication of the temporary order, *N*-ethylpentylone will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession of a schedule I controlled substance.

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. In the alternative, even assuming that this notice of intent might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although the DEA believes this notice of intent to issue a temporary scheduling order is not subject to the notice and comment requirements of section 553 of the APA, the DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Acting Administrator took into consideration comments submitted by the Acting Assistant Secretary in response to notice that DEA transmitted to the Acting Assistant Secretary pursuant to section 811(h)(4).

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553

of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not 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. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(36) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(36) *N*-Ethylpentylone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: ephylone, *N*-1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone) ..... (7543)

* * * * *

Dated: June 6, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018–12669 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2018–6; Order No. 4635]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is noticing a recent filing requesting that the Commission initiate an informal rulemaking proceeding to consider changes to an analytical method for use in periodic reporting (Proposal Three). This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 29, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Proposal Three
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IV. Ordering Paragraphs

I. Introduction

On June 1, 2018, the Postal Service filed a petition pursuant to 39 CFR 3050.11, requesting that the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports.[1] The Petition identifies the proposed analytical changes filed in this docket as Proposal Three.

II. Proposal Three

Background. The Commission adopted the use of incremental costs as the basis for class-level and product-level attributable costs in September of 2016.[2] In FY 2017, the methodology was fully applied for the first time.[3] Proposal Three seeks to revise two incremental costing procedures in accordance with this methodological change.

The first proposed revision concerns the Postal Service's method for calculating incremental costs for competitive products collectively. Under current analytical principles, the Postal Service calculates these costs using a so-called ''hybrid'' approach. The Postal Service first calculates the incremental costs of competitive domestic products (including group specific costs for these products) and then adds it to the volume variable and product specific costs of competitive international products. This ''hybrid'' approach blends an estimate of competitive domestic incremental costs with a proxy estimate of competitive international incremental costs.

The second proposed revision relates to estimating inframarginal costs for products with insufficient data at the cost pool level. The Postal Service states that this revision primarily concerns negotiated service agreements (NSAs), because NSAs are classified as independent products, which can have low volumes. Petition, Proposal Three at 1. Furthermore, the Postal Service contends that NSAs create practical issues in calculating incremental costs, in part because the Postal Service's data systems do not distinguish between NSA and non-NSA mailpieces. *Id.* at 13. This prevents the Postal Service from creating the standard cost drivers for NSAs (*e.g.* volume, weight, cubic volume), which are necessary for calculating incremental costs. *Id.*

Proposal. As discussed above, the Postal Service proposes two procedures to revise its calculation of incremental costs.

Under procedure one, the Postal Service seeks to replace the ''hybrid'' approach to calculating aggregate incremental costs, which relies on a proxy for international costs, with a direct estimation of those costs. *Id.* at 4. Due to improvements suggested in the FY 2016 Annual Compliance Determination, in conjunction with corresponding analytical improvements, the Postal Service states that it can now directly estimate the actual incremental costs of international mail. *Id.* at 6.

Under procedure two, the Postal Service proposes thresholds for calculating inframarginal costs and an alternative methodology for approximating the appropriate cost driver ratios for NSAs. *Id.* at 8. Specifically, the Postal Service suggests that it should not have to calculate the incremental costs if an NSA has less than 0.3 percent of the product type's (*e.g.* Priority Mail, Parcel Select) volume variable cost or less than $8 million in volume variable cost. *Id.* at 11. The Postal Service also seeks to use the ratio of NSA volume variable costs to product type volume variable costs as a proxy cost driver to calculate the incremental cost of NSA products. *Id.* at 12–20.

Rationale and impact. The Postal Service contends that procedure one will allow it ''to rely upon the best available information'' because the

[1] Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Three), June 1, 2018 (Petition).

[2] Docket No. ACR2017, Annual Compliance Report, December 29, 2017, at 4–6.

[3] Docket No. ACR2017, Annual Compliance Determination, March 29, 2018, at 8.

procedure replaces the hybrid approach's proxy incremental costs with actual estimation of the incremental costs of international products. *Id.* at 7. The Postal Service comments that ''[t]his alone constitute[s] a clear improvement over past practice.'' *Id.* at 6. Furthermore, the Postal Service notes that the change will allow ''the incremental cost model to directly estimate the costs of producing all competitive products simultaneously, and thus provide exactly the information needed to fully conduct the cross-subsidy test as intended.'' *Id.* at 7.

The Postal Service estimates that the impact of procedure one would be to raise competitive product incremental costs by 0.2 percent. *Id.* at 7–8. The Postal Service estimates that amount to be approximately $25 million. *Id.*

The Postal Service argues that procedure two's proposed thresholds are appropriate because its testing suggests that NSAs ''have no appreciable inframarginal costs'' below these thresholds. *Id.* at 11. The Postal Service argues that ''when a product has a very small volume relative to the other products handled in the activity or cost pool, the product's volume variable cost and incremental cost will virtually be the same.'' *Id.* at 9. For that reason, the Postal Service avers that ''the calculation of incremental costs for the hundreds of domestic NSA's with minimal volumes would require a material amount of scarce Postal Service resources, and the resulting incremental cost estimates for those products would not be practically different from their volume variable costs.'' *Id.* at 12. The Postal Service concludes that it and the Commission ''are better served when the Postal Service expends those resources on other, critical, costing issues.'' *Id.*

With regard to procedure two's proposed cost driver change, the Postal Service states that it ''is not possible . . . to generate the required cost driver proportions for specific NSA products.'' *Id.* at 13. For this reason, the Postal Service proposes to use ''the volume variable cost ratio as a proxy for the unknown true variable, the ratio of the cost drivers.'' *Id.* at 17. In the Postal Service's view ''the approximation used for the missing driver ratios should reflect the characteristics of the missing information as well as possible.'' *Id.* at 13.

The Postal Service states that the impacts associated with procedure two are ''less clear cut'' than procedure one because ''there is no intuitive baseline against which to compare [results].'' *Id.* at 20. The Postal Service explains that ''[i]n theory, the logical baseline would be actual inframarginal costs calculated using actual data at the cost pool level.'' *Id.* However, ''since the very reason we must rely on the approximation is because such actual data at that level do not exist, that theoretical baseline does not exist either.'' *Id.*

III. Notice and Comment

The Commission establishes Docket No. RM2018–6 for consideration of matters raised by the Petition. More information on the Petition may be accessed via the Commission's website at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Three no later than June 29, 2018. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2018–6 for consideration of the matters raised by the Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Three), filed June 1, 2018.

2. Comments by interested persons in this proceeding are due no later than June 29, 2018.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Katalin K. Clendenin to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–12646 Filed 6–12–18; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Ch. I

[EPA–HQ–OA–2018–0107; FRL–9979–41–OP]

RIN 2010–AA12

Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: EPA promulgates regulations under authority provided in the federal environmental statutes such as the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), and many others. Most statutory provisions require or allow some consideration of cost and benefits when setting pollution standards, but there is variation in terminology and specificity provided in each law regarding the nature and scope of the cost and benefit considerations. In this advance notice of proposed rulemaking (ANPRM), EPA is soliciting comment on whether and how EPA should promulgate regulations that provide a consistent and transparent interpretation relating to the consideration of weighing costs and benefits in making regulatory decisions in a manner consistent with applicable authorizing statutes. EPA is also soliciting comment on whether and how these regulations, if promulgated, could also prescribe specific analytic approaches to quantifying the costs and benefits of EPA regulations. This ANPRM does not propose any regulatory requirements.

DATES: Comments must be received on or before July 13, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA–2018–0107 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. 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 *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: For further information on this document, please contact Elizabeth Kopits,

National Center for Environmental Economics, Office of Policy, 1200 Pennsylvania Avenue NW, Mail Code 1809T, Washington, DC 20460, Phone: (202) 566–2299; *kopits.elizabeth@epa.gov.*

SUPPLEMENTARY INFORMATION: This notice is organized as follows:

I. Background
II. Topics for Which EPA Is Seeking Input
A. The Nature of Potential Problems of Inconsistency and Lack of Transparency
B. Possible Approaches for Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process
C. Potential for Issuing Regulations To Govern EPA's Approach in Future Rulemakings
III. Statutory and Executive Order Review

I. Background

EPA promulgates regulations to protect public health and the environment under authority provided in the federal environmental statutes that it implements, such as the CAA, CWA, SDWA, and many others. The specific authorities given to the Administrator are established in various sections and subsections of each statute, which range from broad authority (*e.g.,* to protect public health with an adequate margin of safety) to detailed requirements that specify standards or require that standards be at least as stringent as the best controlled similar source. In addition to legislative direction, regulatory agencies also take direction from the President and the Office of Management and Budget within the Executive Office of the President regarding what type of formal regulatory evaluation should be performed during rulemaking. For decades, Presidents have issued orders providing instruction to agencies concerning the consideration of benefits and costs in regulatory analysis.[1] Executive Order 12866, *Regulatory Planning and Review,* requires an assessment of benefits and costs for all significant regulatory actions—with benefits and costs expressed in quantitative terms to the extent feasible—and instructs agencies that, to the extent permitted by law, regulatory actions should have benefits that justify their costs (58 FR 51735, October 4, 1993).[2]

OMB's *Circular A–4* [3] and EPA's *Guidelines for Preparing Economic Analyses* [4] provides the Agency with peer-reviewed guidance on how to conduct the analysis of regulatory actions to comply with E.O. 12866 and other executive orders and statutory requirements (*e.g.,* Small Business Regulatory Enforcement Fairness Act of 1996 considerations). EPA's *Guidelines* establish a scientific framework for analyzing the benefits, costs, and economic impacts of regulations and policies, including assessing the distribution of costs and benefits among various segments of the population. They incorporate recent advances in theoretical and applied work in the field of environmental economics.[5] In this ANPRM, EPA is taking comment on the role that regulatory analysis or aspects of that analysis play in decision making consistent with statutory direction, not what these existing guidance documents recommend about how best to conduct the underlying analysis of regulatory actions.

Most statutory provisions require or allow some consideration of cost and benefits when setting regulatory standards to achieve public health and environmental benefits, but there can be a significant variation in terminology and specificity provided in each law regarding the nature and scope of cost and benefit considerations. For example, Section 301 of the CWA instructs the Administrator to select the ''best available technology economically achievable'' (33 U.S.C. 1311(b)(2)(A)), and then requires EPA to take into account the cost of achieving effluent reductions when assessing best available technology (33 U.S.C. 1314(b)(2)(B)). Section 111 of the CAA, however, requires the Administrator to set ''standards of performance'' for reducing air pollution (42 U.S.C. 7411), defined as ''the best system of emission reduction which (taking into account the cost of achieving such reduction and any non-air quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated'' (42 U.S.C. 111(a)(1)). Other provisions may only implicitly direct EPA to consider costs, alone or in conjunction with benefits and other factors, or be silent on whether costs should or may be considered.

Virtually all environmental statutes leave the specifics on *how* costs and benefits are to be considered to EPA. The Agency interprets the terms used in the relevant statute and decides how best to weigh costs against benefits and other factors in making regulatory decisions. A few statutory provisions require that specific metrics (*e.g.,* particular price changes) be included among the ''costs'' to be considered (see *e.g.,* Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 6(b)),[6] but in most provisions ''costs'', ''economic factors'', and similar terms remain undefined and are included as one item of unspecified weight among a list of multiple factors that EPA is required to consider (*e.g.,* CWA, 33 U.S.C. 304(b)(2)(B); CWA, 33 U.S.C. 1314(b)(2)(B); CAA, 42 U.S.C. 111(b)(1)(B) and 42 U.S.C. 111(a)(1) [7]). Even when Congress does include statutory language to indicate how EPA should weigh cost considerations against benefits and other relevant factors, there is considerable variation in the language used and the statutory instruction provides little, if any, direction on what constitutes ''appropriate consideration'', ''reasonableness'', ''practicable'',

[1] This became more formalized in 1981 with Executive Order 12291 which required executive agencies to perform a cost-benefit analysis for all major rules and centralized the regulatory review process by directing the Office of Management and Budget (OMB) to serve as a central clearinghouse for the review of agency regulations.

[2] Over the past decade, the estimated costs and benefits resulting from EPA regulations have been the highest within the federal government. *See* Table 1–1 of the Office of Information and Regulatory Affairs' (OIRA) 2017 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with Unfunded Mandates Reform Act.

[3] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

[4] *https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses.*

[5] All chapters undergo an external peer review prior to finalization, either through the EPA's Science Advisory Board Environmental Economics Advisory Committee or through independent reviews by external experts. OMB's Circular A4 also underwent extensive review before being finalized. *Circular A–4* was subject to public comment, interagency review and external expert peer review.

[6] FIFRA section 6(b) elaborates on the costs to be taken into account in cancellation of agricultural pesticide registrations by making clear that ''the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice *on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.*'' (Emphasis added.)

[7] CWA Section 304(b)(2)(B), 33 U.S.C. 1314(b)(2)(B), states that ''Factors relating to the assessment of best available technology shall take into account the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, *the cost of achieving* such effluent reduction, non-water quality environmental impact (including energy requirements), and such other factors as the Administrator deems appropriate.'' (Emphasis added.) CAA Section 111(b)(1)(B), 42 U.S.C. 7411(b)(1)B), requires EPA to set standards of performance for certain categories of new stationary sources, where Section 111(a)(1), *id.* § 7411(a)(1), defines ''standard of performance'' as ''a standard for emissions of air pollutants which reflects the degree of emission limitation achievable through the application of the best system of emission reduction which (*taking into account the cost* of achieving such reduction and any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated.'' (Emphasis added.)

''achievable'', a ''feasible'' threshold, and related terms.

This has resulted in a variety of concepts of 'costs' that may be considered across statutes and even under the same statute. These concepts include many different metrics that estimate financial impacts to the regulated entity, *e.g.,* direct costs for compliance activities incurred by a regulated entity, compliance cost per ton of pollutant reduced, the number of regulated facilities that may go out of business as a result of the proposed regulation, or compliance cost as a percent of firm revenues. EPA's Regulatory Impact Analyses (RIAs), as guided by its *Economic Guidelines,* typically also quantify the standard economic measure of cost used in benefit-cost analysis –*i.e.,* the broader concept of the ''social cost'' of the regulation (the sum of all opportunity costs incurred as a result of a regulation)—and ultimately reach an estimate of ''net benefits'' (social benefits minus social costs).

For many of EPA's regulatory programs, the courts have weighed in on the scope of costs to be considered during the development of a regulation. For example, in *Michigan* v. *EPA,* 135 S. Ct. 2699, 192 L.Ed.2d 674 (2015), the Supreme Court held that EPA is required to consider costs when determining whether it is ''appropriate and necessary'' to regulate power plants under CAA section 112 (42 U.S.C. 7412(n)(1)(A)), and indicated that ''cost'' can extend well beyond financial outlays by regulated entities to include all of the negative repercussions of this action, whether economic or otherwise (135 S. Ct. at 2707). Many court rulings acknowledge the discretion provided to the agency in how relevant factors are measured and weighed. For example, in 2009, the US Supreme Court ruled in *Entergy Corporation et al.* v. *Riverkeeper, Inc.* that EPA may use cost-benefit analysis in setting standards and issuing permits under Section 316(b) of the CWA.

Many technical and practical factors play a role in how EPA implements statutory instruction related to cost considerations in regulatory decisions. Any assessment of costs (and benefits) is limited by the state of scientific and economic modeling, quantification methods, and available data—all of which change over time and across industries and sectors of the economy. Similarly, statutory authority to collect information from regulated industries varies, and in some cases EPA may choose not to exercise that authority in order to reduce the costs of data collection to the regulated entity (relying instead on voluntary provision of information or publicly-available data, or simply doing without data where the burden appears to outweigh the data's anticipated utility). In these instances, EPA may be limited in what cost metrics can be used for a specific regulatory decision and may not be able to use identical cost considerations across rules. A lack of data and a lack of a regular process for ongoing or retrospective review after rules have been implemented [8] also inhibits EPA's ability to gain insights about the realized costs and benefits of actions that may help inform how it considers costs and other factors in future rulemakings. Finally, industry or sector specific factors may play a role, as some metrics may be more or less relevant to the affected industries, sectors, or question at hand. For example, potential plant closures is a metric sometimes used to measure a potential impact and inform stakeholders about regulatory actions on some industries (*e.g.,* manufacturing industries dominated by privately-owned businesses), but this may not be an appropriate or viable measure of a potential financial impact for other types of regulated entities (*e.g.,* some wastewater treatment plants, or electric power plants that are not otherwise economical must still operate to ensure adequate reliability of the system).

EPA regularly receives much public comment related to how costs and benefits are considered in decision making. On April 13, 2017, in accordance with Executive Order 13777, ''Enforcing the Regulatory Reform Agenda,'' EPA issued a request for comment on regulations that may be appropriate for repeal, replacement, or modification.[9] While that solicitation was broad in scope and generated comments on a myriad of regulatory reform issues, one common theme in many industry comments related to how the Agency considers cost in developing its regulations. For example, some commenters argued that the approach of considering compliance cost divided by the total emission reductions (*i.e.,* summing across pollutants) resulted in controls that appear cost-effective that may not have been deemed cost-effective if each pollutant was considered separately. Such a situation arose in in consideration of the best system of emissions reductions (BSER) for the Oil and Natural Gas NSPS (81 FR 35823, June 3, 2016). Other commenters argued in past rulemakings the Agency has justified the stringency of a standard based on the estimated benefits from reductions in pollutants not directly regulated by the action (*i.e.,* ''ancillary benefits'' or ''co-benefits'').[10] For example, in the Mercury and Air Toxics Standards (MATS) rule (77 FR 9304, February 16, 2012), the monetized benefits from one of the pollutants being directly regulated (*i.e.,* mercury) were significantly lower than the estimated costs of the rule, and the quantified benefits in the regulatory impact analysis outweighed the costs because of the benefits from reductions in ambient fine particulate matter (82 FR 16736, April 6, 2017). Similar criticisms have been made regarding the extent to which EPA has considered key uncertainties, baseline assumptions, and other analytical factors in quantifying both benefits and costs relevant to decision making.

The purpose of this ANPRM is to request more information about the nature and extent of issues raised by stakeholders regarding EPA practices in considering costs and benefits in the rulemaking process, and to solicit comment on potential approaches that would provide improved consistency and transparency. EPA specifically seeks comment on whether, and if so, how EPA should promulgate regulations

[8] Many previous administrations have periodically undertaken programs of retrospective review or issued executive orders urging agencies to reassess existing regulations and eliminate, modify, or strengthen those regulations that have become outmoded in light of changed circumstances. Agencies are also subject to some limited regulatory lookback requirements mandated by statute, but for the most part retrospective review has not become institutionalized practice within EPA nor other regulatory agencies as has prospective review (such as ex ante benefit-cost analysis conducted under Executive Order 12866).

[9] See **Federal Register** notice: Evaluation of Existing Regulations (82 FR 17793). The comment period closed on May 15, 2017 and EPA received over 460,000 comments. All public comments are accessible online in our docket on the *Regulations.gov* website identified by Docket ID No. EPA–HQ–OA–2017–0190.

[10] OMB Circular A–4 defines ancillary benefit as ''a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking (*e.g.,* reduced refinery emissions due to more stringent fuel economy standards for light trucks) while a countervailing risk is an adverse economic, health, safety, or environmental consequence that occurs due to a rule and is not already accounted for in the direct cost of the rule (*e.g.,* adverse safety impacts from more stringent fuel-economy standards for light trucks). You should begin by considering and perhaps listing the possible ancillary benefits and countervailing risks . . . . Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis. In some cases the mere consideration of these secondary effects may help in the generation of a superior regulatory alternative with strong ancillary benefits and fewer countervailing risks . . . . Like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks.'' (OMB 2003).

that specify how the Agency will approach its consideration of costs and benefits in setting pollution standards, consistent with statutory direction.

II. Topics for Which EPA Is Seeking Input

EPA is requesting comments regarding perceived inconsistency and lack of transparency in how the Agency considers costs and benefits in rulemaking, potential approaches for addressing these concerns, and the scope for issuing regulations to govern EPA's approach in future rulemakings. Questions pertaining to each of these topics are provided below. EPA invites comments on all aspects of this ANPRM. Comments should provide enough detail and contain sufficient supporting information (*e.g.,* citations to published studies and or data related to your comments) in order for the Agency to understand the issues raised and give them the fullest consideration.

A. The Nature of Potential Concerns Regarding Perceived Inconsistency and Lack of Transparency

EPA requests more information about the nature and extent of the concerns relating to possible inconsistency and lack of transparency in considering costs and benefits in the rulemaking process. The most helpful comments would provide specific examples with context and specify relevant statutory provisions. What impact could greater consistency or transparency have on regulated entities, states, tribes, and localities, and the public?

B. Potential Approaches for Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process

EPA requests comment on approaches for increasing consistency and transparency when and how EPA considers cost and benefits in setting pollution standards, consistent with statutory direction.

1. What would increased consistency look like?

a. Given statutory constraints, how could EPA more consistently adhere to existing guidance on benefit-cost analysis principles, definitions and analytical techniques whether across the entire agency or specific programs? For example, to what extent, if any, should EPA develop a regulatory action that commits the Agency to following its existing peer-reviewed guidance documents on risk assessment [11] and *Guidelines for Preparing Economic Analysis* [12] when developing future rulemakings?

b. Should EPA consider adopting uniform definitions of specific terms used in statutes—*e.g.,* ''cost,'' ''benefit,'' ''economic factors,'' ''reasonable,'' ''appropriate,'' and ''weight of scientific evidence''—and specifying ex ante how they will be factored into subsequent regulatory decisions?'' How should EPA approach the scope of the uniformity of these definitions (*e.g.,* within a particular regulatory program; within statute; across statutes)?

c. To what extent should standard benefit-cost analysis principles (*e.g.,* setting a standard to maximize net benefits) guide the selection of specific statutorily required metrics and thresholds (*e.g.,* ''reasonableness'') against which to measure the effects of a proposed regulation?

d. What improvements would result from a general rule that specifies how the Agency will factor the outcomes or key elements of the benefit-cost analysis into future decision making? For example, to what extent should EPA develop a general rule on how the Agency will weigh the benefits from reductions in pollutants that were not directly regulated (often called ''co-benefits'' or ''ancillary benefits'') or how it will weigh key analytical issues (*e.g.,* uncertainty, baseline assumptions, limited environmental modeling, treatment of regulating multiple pollutants within one regulatory action) when deciding the stringency of future regulations? In addition, frequently scientific understanding is not adequate either to quantify or to monetize the effects of some pollutants or other impacts. How should these potentially important but non-quantified and/or non-monetized effects be included in decision making?

e. To what extent would it be helpful for EPA to require consideration of cumulative regulatory costs and benefits of multiple regulations during the rulemaking process, including how such consideration may affect the design or implementation of a regulation (*i.e.,* longer or different compliance timeframes)?

2. What would improved transparency look like?

a. How might the documentation of how EPA considered costs and benefits in a regulatory decision be improved from current practices?

b. In what ways can EPA increase transparency about the decision-making process in cases where the decision was based on information that is barred from release by law?

3. To what extent would requiring a systematic retrospective review element in new regulations help to provide ongoing consistency and transparency in how regulatory decision making will adapt over time to new information? Such a requirement might provide a more regular and systematic approach to ex-post (*i.e.* after regulations have been promulgated and become effective) evaluation of the costs and benefits of EPA regulations, as compared with the periodic regulatory reviews the EPA has historically conducted.[13] This might help identify needed revisions, inform future regulatory approaches, and improve methods of ex ante analysis.

a. What are the opportunities and challenges associated with issuing regulations to require retrospective analysis and the concomitant need to collect data in order to conduct a meaningful retrospective analysis? Would it be more challenging under some provisions of key environmental statutes? If so, which ones?

b. What criteria should EPA use to determine when retrospective review is needed? For example, should selection criteria be tied to the estimated impacts of the regulation, the degree of uncertainty at the time of ex ante analysis, the extent to which retrospective analysis will be feasible/successful?

c. How specific should prospective plans for such a review be? For example, should plans specify the methodology that will be used, the coverage or scope of the analysis, the data that will be used and data collection plans?

C. Potential for Issuing Regulations To Govern EPA's Approach in Future Rulemakings

EPA requests comment on opportunities and challenges associated with promulgating regulations to govern EPA's approach to cost and benefit considerations in future rulemakings. EPA is soliciting comment on whether and how best to develop such regulations.

1. What are the most pressing economic or legal considerations that should be taken into account when deciding the appropriate level of specificity (all activities, by statute, by specific statutory provision) at which to formulate regulations?

2. What are the opportunities and challenges with issuing regulations to govern EPA's practice when statutory provisions do not mention costs or imply these are factors to be considered alongside benefits and other factors when setting pollution standards?

3. How can EPA best promote more consistency and predictability while still leaving room for consideration of regulatory context and for flexibility to adapt to new information and methodological advances?

4. In cases where current EPA practice reflects prior judicial decisions, a change in course may come with significant burden to the Agency. Is there a way to address this concern in regulations governing the consideration of costs and benefits?

5. Are there ways to improve consistency and transparency using methods other than a regulatory approach (*e.g.,* additional guidance)? What are the opportunities and challenges associated with these approaches?

6. Are any of the opportunities and challenges identified above specific to a

[11] *https://www.epa.gov/risk/risk-assessment-guidelines.*

[12] *https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses.*

[13] It would also supplement existing statutory requirements for periodic review of the adequacy of standards or guidelines (*e.g.,* CAA 42 U.S.C. § 109(d)(1); CWA 33 U.S.C. § 304(b)).

particular statute or statutes? If so, please provide examples.

III. Statutory and Executive Order Reviews

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this is a ''significant regulatory action'' because the action raises novel legal or policy issues. Accordingly, EPA has submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. Because this action does not propose or impose any requirements, and instead seeks comments and suggestions for the agency to consider in possibly developing a subsequent proposed rule, the various statutes and Executive Orders that normally apply to rulemaking do not apply in this case. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statues and Executive Orders as applicable to that rulemaking.

Dated: June 7, 2018.

E. Scott Pruitt,

Administrator.

[FR Doc. 2018–12707 Filed 6–12–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 18–143, 10–90, 14–58; FCC 18–57]

The Uniendo a Puerto Rico Fund and the Connect USVI Fund, Connect America Fund, ETC Annual Reports and Certifications

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on how best to structure the second stage of the Uniendo a Puerto Rico and Connect USVI Funds to speed longer-term efforts to rebuild fixed and mobile voice and broadband networks in the territories and harden them against future natural disasters. The Commission intends to target high-cost support over the next several years in a tailored and cost-effective manner, using competitive processes where appropriate.

DATES: Comments are due on or before July 5, 2018 and reply comments are due on or before July 18, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this document, you should advise the contact listed in the following as soon as possible.

ADDRESSES: You may submit comments, identified by WC Docket Nos. 18–143, 10–90 and 14–58, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's website: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking (Notice) in WC Docket Nos. 18–143, 10–90, 14–58; FCC 18–57, adopted on May 8, 2018 and released on May 29, 2018. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th St. SW, Washington, DC 20554 or at the following internet address: *https://docs.fcc.gov/public/attachments/FCC-18-57A1.pdf.* The Order that was adopted concurrently with the Notice is published elsewhere in the **Federal Register**.

I. Introduction

1. Through the Uniendo a Puerto Rico Fund, the Commission will make available up to $750 million of funding to carriers in Puerto Rico, including an immediate infusion of $51.2 million for restoration efforts in 2018. Of the remainder, the Commission proposes that about $444.5 million would be made available over a 10-year term for fixed voice and broadband (an $84 million increase over current funding levels) and that about $254 million would be made available over a 3-year term for 4G Long-Term Evolution (LTE) mobile voice and broadband (a $16.8 million increase).

2. Through the Connect USVI Fund, the Commission will make available up to $204 million of funding to carriers in the U.S. Virgin Islands, including an immediate infusion of $13 million for restoration efforts in 2018. Of the remainder, the Commission proposes that about $186.5 million would be made available over a 10-year term for fixed broadband (a $21 million increase) and that about $4.4 million would be made available over a 3-year term for 4G LTE mobile voice and broadband (a $4.2 million increase).

3. As a result of these Funds, as well as the Commission's decision not to offset more than $65 million in advance payments it made to carriers last year, it will make available up to $256 million in additional high-cost support for rebuilding, improving, and expanding broadband-capable networks in Puerto Rico and the Virgin Islands. The Commission seeks comment on how best to structure the second stage of these Funds to speed longer-term efforts to rebuild fixed and mobile voice and broadband networks in the territories and harden them against future natural disasters. The Commission intends to target high-cost support over the next several years in a tailored and cost-effective manner, using competitive processes where appropriate.

II. Notice: Stage 2 Funding for Long-Term Rebuilding

4. The Commission recognizes that a longer-term solution is needed to rebuild, improve, and expand service in Puerto Rico and the U.S. Virgin Islands given the widespread devastation to communications networks caused by the hurricanes. In this Notice, the Commission proposes to establish second stages for the Uniendo a Puerto Rico Fund and the Connect USVI Fund—one that would make available about $699 million through the Uniendo a Puerto Rico Fund and about $191 million through the Connect USVI Fund.

5. As background, the USF currently directs approximately $36 million each year to fixed services in Puerto Rico and $16 million each year to fixed services in the U.S. Virgin Islands, along with $79.2 million each year to mobile services in Puerto Rico and only $67,000 each year to mobile services in the U.S. Virgin Islands. However, none of this funding is tied to specific, accountable build-out targets. The Commission now seeks comment on revisiting that spending to ensure there is sufficient support for the long-term

rebuilding of the territories and that such support is distributed in a cost-efficient manner.

6. Based on the Commission's analysis, it proposes to spend up to an additional $126 million through the second stages of the Uniendo a Puerto Rico Fund and the Connect USVI Fund. Specifically, the Commission would increase funding for fixed services by $10.5 million per year over ten years and for mobile services by $7 million per year over three years to ensure that carriers have sufficient funds to rebuild and improve the voice and broadband-capable networks, both where the hurricanes destroyed existing infrastructure and in rural areas that have not yet been served. As result, the Uniendo a Puerto Rico Fund would make available about $444.5 million over a decade for fixed broadband (an $84 million increase over current funding levels) and about $254 million over 3 years for 4G LTE mobile broadband (a $16.8 million increase). And the Connect USVI Fund would make available about $186.5 million over a decade for fixed broadband (a $21 million increase) and about $4.4 million over a 3-year term for 4G LTE mobile broadband (a $4.2 million increase).

7. The Commission expects that this support will provide meaningful relief to carriers in the storm-ravaged territories in a targeted and cost-effective manner. The Commission seeks comment on whether this budget is appropriate and whether additional support beyond current levels of high-cost support is necessary to rebuild, improve, and expand service in these areas. Does the Commission's proposed allocation of additional high-cost support between fixed and mobile providers accurately reflect the costs that each will face in restoring, improving and expanding service? The Commission also seeks comment on whether and how to incorporate any unclaimed restoration funding into its long-term plan. Commenters are requested to provide specific information to substantiate their views.

8. The proposal for different terms of support for fixed and mobile providers reflects the Commission's distinct goals of providing longer-term support for fixed services and restoring a competitive environment for mobile providers. And because the Commission's proposed long-term plan treats fixed and mobile services in different ways, it seeks more detailed comment in the following on the particulars of the plan for each type of service.

9. More generally, the Commission seeks comment on how to ensure that service is rebuilt quickly and efficiently, while improving networks where feasible and protecting critical communications networks against future natural disasters. Recognizing that access to reliable communications services is essential, particularly in times of emergency, the Commission also explores options to expand service to areas that were unserved prior to the hurricanes. The Commission invites comment on how to balance its competing objectives of rebuilding and improving service, ensuring network resiliency, and expanding coverage. At the same time, the Commission is mindful of its responsibility as stewards of the USF to ensure that support is spent efficiently and seek comment on appropriate safeguards to ensure accountability. Similar to Stage 1 funding, the Commission reminds Puerto Rico and the U.S. Virgin Islands that the Act prohibits the territories from adopting regulations related to Stage 2 funding that are ''inconsistent with the Commission's rules to preserve and advance universal service.''

10. The long-term rebuilding, improvement, and hardening of fixed voice and broadband service is critical in helping Puerto Rico and the U.S. Virgin Islands recover from the devastation caused by the hurricanes. The Commission believes that authorizing up to $105 million in additional funds for rebuilding while distributing all high-cost funding for fixed networks through an incentive-based mechanism will best ensure that networks are rebuilt, improved, and expanded across the territories in an efficient manner.

11. The Commission first notes that present circumstances require them to revisit the Commission's past treatment of high-cost support for fixed networks in Puerto Rico and the U.S. Virgin Islands. In the *December 2014 Connect America Fund Order,* 80 FR 4446, January 27, 2015, the Commission decided to allow price-cap carriers in insular areas to elect to continue receiving frozen high-cost support amounts in exchange for accepting tailored service obligations to be adopted at a later date. Although PRTC (in Puerto Rico) and Viya (in the U.S. Virgin Islands) elected to receive frozen support, the Commission has yet to establish specific service obligations for either carrier. Moreover, the hurricanes and their aftermath wrought havoc upon these existing networks—so much so that each of these carriers has claimed that multiples of their current annual support amounts are necessary for restoration and rebuilding. The Commission seeks comment on the view that changed circumstances require them to revisit funding for fixed networks in these territories. How does the fact that the Commission has not adopted specific CAF Phase II obligations for PRTC and Viya impact the reliance interests, if any, these carriers could reasonably have had in the status quo continuing through 2020? How should the need for extensive rebuilding factor into the Commission's decision? How should the fact that the Commission is considering the addition of $10.5 million in high-cost funding per year for rebuilding fixed networks in these territories affect its decision? And how should the Commission weigh the efficiency of more competitive approaches that could extend improved service more widely to consumers in Puerto Rico and the U.S. Virgin Islands against any reliance interests in continuing to administer frozen support as before?

12. Given the changed circumstances, the Commission proposes to reconsider the existing frozen high-cost support mechanisms and replace them with a competitive mechanism that would allocate an additional $105 million to fixed networks in the territories over a decade. The Commission proposes to allocate these support amounts so that approximately 80 percent goes to the Uniendo a Puerto Rico Fund and approximately 20 percent to the Connect USVI Fund. As a result, fixed network operators in Puerto Rico would have an opportunity to compete for $444.5 million over the next decade and fixed network operators in the U.S. Virgin Islands would have an opportunity to compete for $186.5 million over the next decade.

13. The Commission seeks comment on this proposal. In the concurrently adopted Order, the Commission used the same 80–20 ratio to balance the difference in population between Puerto Rico and the U.S. Virgin Islands, the significant financial challenges faced by carriers in both areas, the current level of high-cost support available to providers, and other relevant factors. Should the Commission maintain that ratio for the purpose of allocating additional support? Are the total funding amounts appropriate for each territory given the rebuilding required and the improvements need to harden networks against future natural disasters and the expansion needed in rural areas? Is a ten-year term of support, which the Commission has repeatedly used in other high-cost programs to ensure those building out had sufficient time to amortize and recover their costs, appropriate here? How should the Commission address differences in the

geographic or competitive landscape in evaluating its long-term plans? For example, Viya is currently the only fixed provider in the U.S. Virgin Islands. Does that argue for requiring inter-area competition as the Commission does in the Connect America Fund Phase II reverse auction? Or is a quasi-competitive process on the U.S. Virgin Islands nonetheless feasible? Or should the Commission pursue some alternative option?

14. The Commission also invites comment on how to best promote its aim of providing support quickly and efficiently to speed the rebuilding, improvement, and expansion of service. How can the Commission ensure that people living in the territories have access to reasonably comparable, affordable fixed voice services and broadband-capable networks? And as stewards of the USF, the Commission seeks comment on how best to fulfill its commitment to fiscal responsibility to ensure that funds are targeted efficiently.

15. As detailed in the following, the Commission proposes to award high-cost support using a competitive proposal process, similar to a request for proposal process. The Commission also seeks comment on conducting an auction, negotiating directly with ETCs, and establishing build-out obligations while continuing to provide frozen high-cost support at current levels.

16. The Commission proposes to award fixed support through the Uniendo a Puerto Rico Fund and the Connect USVI Fund by evaluating competitive proposals submitted by carriers. This approach could be completed quickly and efficiently, thereby avoiding lengthy delays in getting critical funding to carriers. A competitive proposal process is a more streamlined approach than the typical Commission auction, yet still requires carriers to compete for support. Moreover, this option may better enable the Commission to determine how best to award support for network-hardening purposes than the auction approach.

17. The Commission proposes that accepted proposals will receive support for 10 years, beginning in January 2019 and running through December 2028. The Commission seeks comment on whether to transition support, through a phase-down process, in any geographic area where the incumbent carrier, *i.e.,* PRTC or Viya, did not win support based on its proposal. The Commission provides additional details and seek comment on them in the following.

18. *Eligible Providers.*—The Commission proposes that only a provider that, according to June 2017 FCC Form 477 data, had an existing fixed network and provided broadband service in Puerto Rico or the U.S. Virgin Islands prior to the hurricanes would be eligible to apply to participate. The Commission seeks comment on whether participation should be limited to fixed providers who served at least some residential locations or whether providers that served only business locations should also be permitted to participate. The Commission proposes to limit participation to providers who had provided services before the hurricane because it believes they would be better equipped to rebuild and expand service as quickly as possible. Relatedly, the Commission also believes that existing providers with established track records present a smaller risk of defaulting on their service obligations. However, the Commission seeks comment on whether new entrants should also be eligible. If so, what particular qualifications if any should the Commission impose on them?

19. The Commission further proposes to evaluate the financial and technical capabilities of the applicants through a single-stage application process. Doing so would minimize the amount of time it takes to complete the competitive proposal process and begin awarding support. The Commission seeks comment on whether to use instead the two-phase application process of the competitive bidding rules for universal service in Part 1, Subpart AA of the Commission's rules, as it has done for the CAF Phase II auction.

20. Consistent with the Communications Act of 1934, as amended, and the Commission's rules, a provider must be designated as an ETC before receiving support. To the extent necessary, the Commission proposes to allow providers to obtain ETC designations after winning support rather than before participating in the competitive proposal process, similar to the approach it followed for the CAF Phase II auction. The Commission seeks comment on this approach. What methods would be appropriate for selecting another carrier if the winner fails to timely obtain an ETC designation?

21. *Eligible Areas.*—Given the unique circumstances presented by the widespread destruction of critical infrastructure, the Commission proposes to make eligible all of Puerto Rico. By making the entire territory eligible, the Commission would eliminate the need to establish a challenge process and thus enable a more expeditious completion of the process. Doing so would also encourage applicants to expand service to areas that were previously unserved, in addition to restoring service to areas that had service before the hurricanes. Further, the Commission anticipates that making all of Puerto Rico eligible for support will increase competition, driving down the support amounts proposed in lower-cost areas. The Commission seeks comment on this approach. Similarly, the Commission proposes to make eligible all of the U.S. Virgin Islands and seek comment on that approach.

22. Alternatively, the Commission seeks comment on whether certain areas should be excluded. For example, are there areas where service has already been rebuilt (or will be rebuilt by the end of 2018)? Are there areas where providing high-cost support to one carrier would distort the competitive market and reduce potential competitors' incentives to rebuild service? How can the Commission ensure consistency with its policy against providing funding in areas where there is an unsubsidized competitor? Would the ability of other carriers to bid for such support reduce the funding in such areas to only what's needed to rebuild otherwise unserved areas? Are there areas where support levels would be so low as to be unnecessary to rebuild and improve service, such as census blocks in Puerto Rico identified by the model as having particularly low average monthly costs? How can the Commission best achieve its goal of maximizing the expansion of service to unserved areas in addition to restoring and improving service to areas that had it before the hurricanes?

23. *Minimum Geographic Area.*—The Commission proposes to accept proposals for support to satisfy specific service obligations within each of Puerto Rico's 78 municipios. Using municipios as the basic geographic area for support may allow providers to achieve economies of scale that would not be available if the Commission used smaller areas, such as Puerto Rico's over 900 barrios. On the other hand, there may be some risk that municipios are too large to target funding in a competitively neutral manner—incumbent providers with large existing service territories are likely more amenable to providing service over a wider area. The Commission seeks comment on whether using municipios makes sense or whether it should instead provide support on a more granular basis, such as by barrios, census block groups, or some other geographic unit.

24. The Commission seeks comment on the appropriate minimum geographic area for support in the U.S. Virgin Islands. Should the Commission treat

the entire territory as one geographic area to carry out this initiative? Or should the Commission treat each island in the U.S. Virgin Islands separately for this purpose? Or would using some other census-defined geography such as census tract, census block group, or census block be more appropriate?

25. *Number of Locations in Each Geographic Area.*—The Commission proposes to identify the number of locations in each geographic area by using the Connect America Cost Model (the CAM). The Commission seeks comment on how it can best account for the fact that people may have migrated from Puerto Rico and the U.S. Virgin Islands since the storms. The Commission seeks comment on what other sources of data would more accurately model the number of locations in each area. The Commission also seeks comment on whether to provide support based on only certain locations within each geographic area, such as those that are more costly to serve, and whether to exclude certain other locations from bidding, such as those that are less costly and therefore may not require high-cost support. The Commission proposes, as a condition of receiving support for funded locations, that a winning bidder serve *all* locations within a geographic area, not just those funded (if the Commission decides to fund just a subset of locations). This proposal comports with the Commission's decision to focus on rebuilding all networks and make all of Puerto Rico eligible for bidding, rather than only discrete areas. Alternatively, the Commission seeks comment on limiting the obligation only to funded locations or locations in census blocks identified by the model as being above a certain funding benchmark?

26. Given possible changes in the number of locations post-hurricane and the difficulties in obtaining more recent, accurate data, the Commission also seeks comment on whether to instead evaluate proposals to serve all the locations in a municipio without determining exactly how many locations that represents. In other words, applicants would commit to serve all locations in a municipio rather than to serve a specific number. The Commission also seeks comment on whether differences in municipio characteristics, such as quantity of high cost locations or remoteness, should lead the Commission's to attach different obligations to funding so as to better ensure all parts of the territories are provided with service.

27. Furthermore, if the data the Commission eventually adopts overestimates the number of locations in an area, it seeks comment on what flexibility to offer winning applicants. Should the Commission, for example, reduce support on a pro rata basis if it lowers the number of locations a provider must serve, and if so, what requirements and limitations should the Commission establish for such reductions? Should the Commission consider giving providers more flexibility here than it has in other contexts given the facilities lost and the recent emigration from the territories?

28. *Reserve Prices.*—The Commission proposes to use a three-step process to set reserve prices. First, the Commission would employ the cost model used to establish support for price cap carriers (the CAM) to calculate the average cost per location of all locations in a census block. Second, the Commission would set separate high-cost and extremely high-cost thresholds for Puerto Rico and the U.S. Virgin Islands to ensure the full amount of funding available to each territory over the ten-year period is available for obligation. Third, the Commission would establish a reserve price for each minimum geographic area based on the sum of the support amounts calculated for each eligible census block in that municipio. Under the proposal, WCB would release the reserve price and number of locations for all eligible areas by public notice no later than 30 calendar days before the application deadline to submit competitive proposals.

29. The Commission seeks comment on this proposal, and particularly on the key second step. The Commission notes that the extremely high-cost threshold here would be used to establish a per-location funding cap, similar to how the Commission offered rate-of-return carriers model-based support. How should the Commission establish the appropriate thresholds? The CAM established a high-cost threshold of $52.50 based on assumed take rates and potential average revenues per subscriber. Do those assumptions still hold in the context of Puerto Rico and the U.S. Virgin Islands after the hurricanes? If not, should the Commission lower the high-cost threshold and if so, by how much? By 25 percent? By more? The CAM established a high-cost threshold of $198.60. Is that appropriate here? The Puerto Rico Telecommunications Regulatory Board has stated that more support needs to be directed to the rural parts of the island. Would that suggest setting a higher extremely high-cost threshold? The Commission also seeks comment on how to allocate funds between bringing service to locations that had never been served versus restoring service (potentially at a lower cost) to locations where service had been disrupted by the hurricanes. For example, the Commission has previously assigned zero support to locations below the high-cost threshold on the assumption that a business case nonetheless existed to serve such locations. Does the context of rebuilding networks on these islands suggest revisiting that assumption and assigning some funding—say 10 percent of cost—to cover the costs below the high-cost threshold? The Commission also seeks comment on how the CAM should be adjusted, if at all, to take into account the need for network hardening. For example, should the Commission assume the cost of above-ground plant will increase 10 percent (or more) to account for such hardening before it determines the costs per location?

30. *Selection Process.*—The Commission seeks comment on the appropriate time frame and format for submitting proposals. The Commission proposes to allow confidential proposals. Should the Commission unseal proposals after finishing the evaluations process for transparency reasons? The Commission seeks comment on whether to make public the submitted proposals after the evaluation process has been completed and winning applicants have been determined. The Commission seeks comment on prohibiting multiple carriers from submitting a proposal jointly.

31. The Commission proposes to select winning proposals based primarily on price per-location served while adjusting the bids to consider factors including network resiliency, network deployment timing, and network performance. The Commission seeks comment on these factors and what other factors it should consider when evaluating proposals. Considering price as the primary factor responsibly manages the Fund, but the Commission recognizes the increased costs of deploying a storm-hardened network in Puerto Rico and the USVI. For instance, how should the Commission factor storm hardening proposals into the Commission's evaluation? Should the Commission require or increase the weight of bids that comply with resiliency standards like TIA–222–H, the most up-to-date standard for antenna supporting structures, with best practices promulgated by the FCC's Communications Security, Reliability and Interoperability Council, or with another industry used standard for network resiliency? Should the Commission establish weights to

account for the speed of deployment? What weight would be appropriate to balance costs against encouraging prompt deployment to the territories? Should the Commission establish weights to account for proposals offering ''higher speeds over lower speeds, higher usage allowances over lower usage allowances, and lower latency over higher latency''? If so, what weighting scheme would be appropriate for that purpose? Instead of using specific weights could the Commission define preferences for various characteristics in the proposals? If the Commission does not require proposals to identify a specific number of locations to serve, what factors should it consider in comparing proposals?

32. How should the Commission address package bidding? For example, should the Commission allow package bidding? If so, what limits if any should the Commission put on packages (*e.g.,* should the Commission require all packages to be contiguous or limit the number of minimum geographic areas included in the package)? If selecting two package bids would be the most efficient outcome even if they overlapped in a particular geographic area, should the Commission accept both (perhaps requiring the less efficient bidder to redirect support from the overlapped area to other unserved areas) or reject the less efficient package (perhaps leaving no bidder for some areas)?

33. How should the Commission evaluate bids? Should the Commission direct USAC or WCB to evaluate bids? The Commission proposes directing the reviewer to evaluate the bids in accordance with the selection criteria, methodology and bidding process outlined above. Once that initial evaluation is complete, should the Commission make selections or offer feedback to applicants and allow them to return with best-and-final offers? Or would that introduce undue discretion into the process or create additional administrative burdens or delays? If a dissatisfied applicant wants to challenge its non-selection, would existing appeals processes be sufficient?

34. How should the Commission address areas without bids? One approach would be to invite a second round of competitive proposals, with the difference between bids and reserve prices in the first round being transferred to raise the reserve price of remaining areas (pro rata) in the second round. In other words, if the reserve price for areas won in the first round were $10 million and only $8 million was bid, then $2 million would be available to raise the reserve prices in areas remaining in the second round. The Commission seeks comment on this approach, including whether it would be vulnerable to potential gamesmanship by bidders.

35. In addition, as a backstop, the Commission proposes to require the incumbent carrier to continue to provide service to any unawarded areas using frozen high-cost support—with corresponding service obligations to be determined by the Commission after the competitive proposal process is complete. The Commission notes that for this and other purposes (such as any transitional payments) it would allocate an incumbent carrier's existing frozen support across their service territory in proportion to the reserve prices the Commission initially set for the competitive proposal process. The Commission believes this backstop would place incumbent carriers in no worse a position then they are in today, with frozen support and accompanying service obligations to be determined by the Commission.

36. *Service Obligations.*—In addition to voice service, the Commission proposes to require support recipients to offer broadband service meeting the following metrics: Download/upload speeds of at least 10/1 megabits per second (Mbps), roundtrip latency of no greater than 100 milliseconds (ms), and a minimum usage allowance of the higher of 170 GB per month or one that reflects the average usage of a majority of consumers, using Measuring Broadband America data or a similar data source.

37. The Commission seeks comment on whether these obligations are appropriate. Should the Commission, for instance, require some portion of the areas served to receive 25/3 Mbps service? And, if so, what fraction would be appropriate? Should the Commission impose different requirements for areas based on the amount of support allocated?

38. Further, the Commission proposes requiring each support recipient to offer broadband service in its supported area at rates that are reasonably comparable to rates offered for comparable services in urban areas. Rates will be considered reasonably comparable if they are ''at or below the applicable benchmark to be announced annually by public notice issued by the Wireline Competition Bureau.'' Based on the results of the Urban Rate Survey, the Commission sees no reason to adopt a different benchmark specific to Puerto Rico or the U.S. Virgin Islands. The Commission seeks comment on this approach.

39. *Deployment Milestones.*—As with the CAF Phase II Auction, the Commission proposes that winning bidders must deploy to at least 40 percent of locations after the third year of support, at least 60 percent after the fourth, at least 80 percent after the fifth, and 100 percent after the sixth year of support. The Commission seeks comment on whether this schedule is appropriate. The Commission also seeks comment on how it should track milestones if a particular number of locations, as already discussed, is not defined. Are there other ways to track progress without having to rely on location counts given the possible difficulty of establishing a number of locations?

40. *Oversight and Accountability Measures.*—The Commission has an obligation to ensure that carriers receive support ''only for the provision, maintenance, and upgrading of facilities and service for which the support is intended'' as required by section 254(e) of the Act. The Commission has exercised its oversight obligations in a variety of way since inception of the fund. In the following, the Commission proposes various oversight and accountability measures that, taken together, serve the public interest by enhancing the Commission's ability to monitor the use of USF and ensure its use for intended purposes.

41. *First,* the Commission proposes that support recipients must satisfy all reporting and certification obligations of providers receiving CAF Phase II auction support, including as described in sections 54.313 and 54.316 of the Commission's rules. The Commission seeks comment on this proposal. The Commission seeks comment on whether providers who win support must track their restoration expenditures. Should providers retain documentation on how much support was used for capital expenditures and operating expenditures? What are the associated burdens with retaining expenditure documentation? Would retention of this documentation be duplicative of records needed for deployment milestones?

42. *Second,* the Commission proposes aligning the annual reporting obligations with the obligations of other rate-of-return carriers in the *2016 Rate-of-Return Order,* 81 FR 24282, April 25, 2016, by requiring geocoded location reporting into the HUBB. This reporting obligation would require providers to submit information demonstrating locations the provider is reporting as broadband-enabled where the company is prepared to offer voice and broadband service meeting the requisite performance standards. Do carriers currently retain geolocation data for served locations? If not, what period of

time is needed to enable collection of geolocation data? Should the Commission require this data be reported for only newly deployed locations or all reported locations? Would annual reporting or a longer period more appropriately balance the reporting burden against the accuracy of the data? Additionally, the Commission proposes requiring awarded carriers to submit performance measurements in accordance with the requirements to be defined by the Commission. To the extent that awarded carriers have not participated in that proceeding, the Commission proposes requiring the same testing method options and parameters as price cap carriers.

43. *Third,* the Commission proposes to carefully monitor and reassess the deployment obligations of the awarded support before the end of the fifth year. Understanding the deployment and operational realities of providing service in both Puerto Rico and the U.S. Virgin Islands, the Commission believes this reassessment would be prudent to address any changed circumstances within the territories, whether that be changes in subscribership expectations due to population changes or future disruptive natural disasters. As the current situation demonstrates, the long-term planning involved in any telecommunications deployment decision requires a number of assumptions that may change dramatically over time. Would providing an opportunity for the Commission to reassess deployment obligations be beneficial to providers or cause unneeded uncertainty? Should the reassessment be tied to deployment milestones? For example, the reassessment would not be triggered if a provider is 60 percent deployed after four years, but would occur if a provider failed to meet the deployment obligation. Would it be appropriate to alter the obligations by increasing or decreasing the number of locations or modifying the service obligations?

44. *Fourth,* the Commission proposes to subject awarded carriers to the same compliance standards as any other carrier with defined obligations by defining specific obligations for the support. This may result in a carrier that failed to meet its milestones having support reduced until the carrier can meet its obligations or face recovery actions. The Commission seeks comment on this approach.

45. The Commission also seeks comment on whether successful applicants must obtain a letter of credit by way of security, as must winning bidders in the CAF Phase II auction. If so, how should the letter of credit be structured? Should it be for the full amount awarded, or some lesser amount that will nevertheless protect the USF? Should an alternative to a letter of credit be considered, such as a performance or payment bond?

46. *Fifth,* the Commission proposes to subject all awarded carriers in the territories to ongoing oversight by the Commission and USAC to ensure program integrity and prevent waste, fraud, and abuse. The Commission has a longstanding audit program that is continually updated to respond to the Commission's needs inclusive of changes in program requirements, new guidance from GAO and OMB, and changes in law. Accordingly, the Commission proposes that all awarded carriers would be subject to random compliance audits and other investigations to ensure compliance with program rules and orders. The Commission seeks comment on what sorts of audit procedures the Commission should undertake to confirm that support has been spent on allowed restoration costs. The Commission also seeks comment on whether there are specific circumstances facing carriers in the territories that require modifying the current audit practices.

47. As an alternative to the competitive proposal process, the Commission seeks comment on using an auction for the second stages of the Uniendo a Puerto Rico Fund and the Connect USVI Fund. The Commission notes that it cannot simply apply the same rules of the CAF Phase II Auction here because it seeks to achieve different goals. Among other differences, here the Commission wishes to rebuild networks, including in areas where a business case existed pre-hurricane for providing service, whereas in the CAF Phase II context, the Commission aims to maintain and expand service where there is no such business case.

48. Instead, the Commission seeks comment on using a single-round sealed bid auction to award support. Such an approach generally would award support on a per-location basis, based on the lowest price. Bidders would identify a per-location support price at which they are willing to meet Commission requirements to cover the locations in each eligible area they specify. Bids would then be ranked, lowest to highest, and support would be assigned to those areas with the lowest bid amounts submitted (and within each assigned area, to the lowest bidder), until no further bids can be accommodated under the budget. The terms of such an auction would otherwise largely track the terms for the competitive proposal process described above.

49. The Commission seeks comment on whether the competitive environment in Puerto Rico is sufficiently robust to ensure an auction that distributes funds in a cost-effective way. The Commission seeks comment on whether to use an auction process to distribute funds in Puerto Rico, but not in the U.S. Virgin Islands, given that FCC Form 477 data shows that Viya is currently the only fixed provider there.

50. Are there any specific auction rules or procedures the Commission should consider so that an auction would not be overly complicated for the Commission to administer and would not overly burden potential bidders? Is there an auction design the Commission could use that would achieve its objective of maximizing consumer benefits? Would this approach afford the same flexibility as a competitive proposal process?

51. The Commission seeks comment on whether to structure the second stages based on carrier-submitted proposals to rebuild, improve, and expand service in the territories. Such proposals would not be evaluated on a competitive basis, but would be the result of negotiation between the Commission and carriers. Given similarly unique circumstances, the Commission adopted a framework based on carrier commitments to maintain and expand the availability of service in Alaska.

52. Like the competitive proposal option, through this process the Commission seeks to maximize the number of locations where fixed voice and broadband services would be available in a targeted and cost-effective manner. As with any method of awarding of support, the Commission expects to hold providers accountable to use support for its intended purposes and to meet the deployment commitments it set.

53. To the extent the Commission adopts this approach, it seeks comment on the process by which it would seek proposals, review them, and award support. The Commission anticipates establishing the specific criteria by which it would award support and measure compliance by Public Notice, along with a time frame for submitting proposals. The Commission invites comment on this approach.

54. In the *Universal Service Transformation Order,* 76 FR 73830, November 29, 2011, the Commission allowed price cap carriers serving specific non-contiguous areas of the United States—including Puerto Rico

and the U.S. Virgin Islands—to maintain frozen support levels for those carriers if, in the Bureau's determination, certain conditions were met. Recognizing that these carriers faced different operating conditions and challenges compared to carriers in the contiguous 48 states, the Bureau invoked its discretion. Both PRTC and Viya elected to continue receiving frozen support, with the Commission responsible for adopting specific service obligations tailored to the individual circumstances of each carrier.

55. As the Commission has not yet adopted CAF II obligations for the frozen support that PRTC and Viya continue to receive, it seeks comment on whether to forego reconsidering the Commission's prior decisions and instead simply adopt specific service obligations to reflect the frozen-support amounts PRTC and Viya currently receive. If the Commission pursues this alternative, what obligations would be appropriate and feasible? Should the Commission establish particular expectations regarding expanding service to new areas or implementing more resilient networks?

56. In the aftermath of the hurricanes, the rapid restoration of mobile service was critical in facilitating communications with public safety and civic officials and connecting families to loved ones. Building upon the significant restoration efforts that have taken place to date, the Commission seeks comment on how best to target high-cost support to rebuild, improve, harden, and expand mobile services in Puerto Rico and the U.S. Virgin Islands. The Commission proposes to make $259 million in support available to eligible facilities-based mobile providers over the next three years through the Uniendo a Puerto Rico Fund and the Connect USVI Fund. The Commission's goal is to facilitate timely recovery of mobile services within these territories in a cost-effective manner.

57. The Commission notes that it has previously targeted Puerto Rico and the U.S. Virgin Islands as potential areas eligible for the upcoming MF–II auction. However, the Commission recognized in December that conditions in the territories after the hurricanes made establishing reliable coverage of mobile networks infeasible in the near term. As such, the Commission waived the filing deadline for mobile providers to submit 4G LTE coverage information for a period of 180 days or until the Commission took action addressing the appropriate approach, given the circumstances, for providing ongoing, high-cost support for mobile services in Puerto Rico and the U.S. Virgin Islands, whichever occurred earlier.

58. The Commission now proposes to extend that waiver, exempt these mobile providers from filing this coverage information, and carve Puerto Rico and the U.S. Virgin Islands out from the MF–II auction. Instead, the Commission proposes to supplement existing support over a three-year period by giving providers an additional $21 million to rebuild their networks after the destruction wrought by Hurricanes Irma and Maria and their aftermath. The Commission seeks comment on allocating these support amounts so that approximately 80 percent goes to the Uniendo a Puerto Rico Fund and approximately 20 percent to the Connect USVI Fund. As a result, over the next three years, the Uniendo a Puerto Rico Fund would make available $254.4 million to mobile network operators and the Connect USVI Fund would make available $4.4 million to mobile network operators. These territories currently face serious and continuing challenges in restoring their mobile communications capacity, and the Commission tentatively concludes that this additional funding will allow providers in these territories to repair the damage caused by the hurricanes to their wireless networks as well as make their networks more resilient to future natural disasters.

59. The Commission seeks comment on this proposal. In the concurrently adopted Order, the Commission used the same 80–20 ratio to balance the difference in population between Puerto Rico and the U.S. Virgin Islands, the significant financial challenges faced by carriers in both areas, the current level of high-cost support available to providers, and other relevant factors. Should the Commission maintain that ratio for the purpose of allocating additional support? Are the total funding amounts appropriate for each territory given the rebuilding required and the improvements need to harden networks against future natural disasters and the expansion needed in rural areas? Is a three-year term of support appropriate here? How should the Commission address differences in historic universal service funding in evaluating its long-term plans? For example, mobile carriers in the U.S. Virgin Islands receive almost no funding today. Does that argue for allocating most of the new funding there? Or should the Commission redistribute all funding across both territories setting aside historic allocations?

60. The Commission proposes that only providers that provided facilities-based mobile services in Puerto Rico and the U.S. Virgin Islands prior to the hurricane impacts, according to the June 2017 Form 477 data, would be eligible to elect this new funding. The Commission proposes to allocate the new funding based on the number of subscribers (voice or broadband internet access service) each provider served as of June 30, 2017—similar to how the Commission calculates support in stage one. As an alternative, the Commission seeks comment on allocating all funding available for mobile network operators in the second stages of the Uniendo a Puerto Rico Fund and the Connect USVI Fund based on pre-hurricane subscribership. Such an approach would avoid any inefficiencies in the historic allocation of support among the islands and avoid the need for a decision ahead of time regarding how much in particular should go to Puerto Rico versus the U.S. Virgin Islands. If the Commission pursues this alternative approach, should the Commission set transitional funding amounts for existing recipients of high-cost support? In particular, should the Commission ensure that existing recipients receive at least two-thirds of their current mobile support in 2019 and at least one third in 2020?

61. The Commission proposes that, in exchange for accepting additional support, each mobile provider must commit to, at minimum, a full restoration of its pre-hurricane coverage area, at a level of service that meets or exceeds the minimum standard required of recipients of MF–II support. Such a requirement aligns with the goal of MF–II to ''target universal service funding to support the deployment of the highest level of mobile service available today—4G LTE.'' The Commission tentatively concludes that, given the extent of damage in Puerto Rico and the U.S. Virgin Islands, most providers will already be engaging in substantial rebuilding of towers and infrastructure, and will find it most economical to deploy 4G LTE during such restoration versus alternative technologies. The Commission seeks comment on whether this requirement is appropriate. Should the Commission instead require providers to rebuild their networks at a different standard? For example, should the Commission instead require deployment at the speed benchmark used to identify areas eligible for MF–II? Is there an alternative standard appropriate to ensure that residents of Puerto Rico and the U.S. Virgin Islands have comparable service to other areas of the United States? Should the Commission restrict funding to support

operation, deployment, and enhancement only of 4G LTE?

62. The Commission also seeks comment on whether the Uniendo a Puerto Rico Fund and the Connect USVI Fund should include requirements to expand service. Are there areas, for instance, that lacked coverage before the hurricanes and that the Commission should nonetheless require providers to serve? How should such areas be identified and how should the Commission determine what carriers should be required to serve them? The Commission seeks comment on how quickly rebuilding could be accomplished and what milestones might be appropriate to complete build out. Is three years of funding for rebuilding appropriate? Why or why not?

63. The Commission also seeks comment on the appropriate reporting requirements for support recipients. The Commission proposes to have any mobile providers receiving second-stage support via the Uniendo a Puerto Rico Fund and the Connect USVI Fund report twice per year on their coverage. Specifically, the Commission proposes that providers supply coverage maps using the buildout parameters the Commission will adopt for the MF–II auction. If the Commission adopts a different service requirement for funding recipients than the minimum standard required of recipients of MF–II support, it proposes to make appropriate adjustments to the reporting requirements. The Commission seeks comment on these proposals. The Commission also seeks comment on how this data should best be submitted to the Commission, such as through the regular Form 477 filings or some other process?

64. As noted above, the Commission has an obligation to ensure that carriers receive support ''only for the provision, maintenance, and upgrading of facilities and service for which the support is intended'' as required by section 254(e) of the Act. The Commission seeks comment on appropriate oversight and accountability measures for carriers that receive additional high-cost support as proposed in this Notice. The Commission proposes that recipients of such funds conform to the annual reporting requirements the Commission adopted for MF–II. The Commission also proposes that all support recipients be subject generally to the same audit requirements as recipients of CAF–II support and all other high-cost support. The Commission seeks comment on whether any other oversight or accountability measures are appropriate. Should the Commission require carriers to submit one or more Milestone Reports to demonstrate progress on service restoration? Would it be beneficial for the Commission or USAC to make use of independent testing to determine service speed, quality, and reliability in these areas?

65. The Commission proposes to use an auction to allocate funding following this three-year period, with any funding commitments resulting from such an auction to commence on the day following the end of the three-year period. The Commission seeks comment on whether the competitive environment in Puerto Rico and the U.S. Virgin Islands is sufficiently robust to ensure an auction that distributes funds in a cost-effective way and whether it makes sense from the perspective of administrative efficiency to hold such an auction. Can the Commission use the same general auction rules and same auction design for this auction as it will use for the MF–II auction? Are there any specific auction rules or procedures the Commission should consider so that an auction would not be overly complicated for the Commission to administer and would not overly burden potential bidders?

66. If the Commission were to use an auction to allocate funding, how should it determine which areas would be eligible to win support in the auction? Should the Commission consider an area eligible if it does not meet the speed and technical parameters used to identify areas eligible for MF–II? Should the Commission adopt additional or alternative specifications for eligibility that would be more suitable for Puerto Rico and the U.S. Virgin Islands? For example, should an area be eligible if, despite meeting a certain download speed requirement, it does not meet certain network resiliency requirements, *e.g.* hardening to hurricane impacts? If so, what resiliency requirements would be appropriate? In this document, the Commission proposes that providers supply coverage maps using the technical parameters buildout parameters the Commission will adopt for the MF–II auction. Would that coverage information suffice for determining areas eligible for an auction, or is additional data required, such as a one-time data collection using the MF–II Challenge process technical parameters? If so, when should the Commission collect that data to ensure that funding commitments can begin on schedule?

67. Several parties have proposed that rebuilt networks be ''storm hardened.'' The Commission seeks comment on whether the Uniendo a Puerto Rico Fund and the Connect USVI Fund should require second-stage participants to improve the ability of their facilities and equipment to resist hurricanes and other natural disasters. If so, should the Commission require compliance with resiliency standards like TIA–222–H, the most up-to-date standard for antenna supporting structures or with best practices promulgated by the FCC's Communications Security, Reliability and Interoperability Council? Are there other industry standards that would help improve resistance to flooding, wind damage, and water damage? How should any such requirements be enforced? What are the expected costs of deploying a ''storm hardened'' network, and how should the Commission evaluate the costs and benefits of any such network? Should the Commission consider requiring hardening of certain key network assets, but not the entire network? If so, how should key assets be identified? Would requiring hardening only of assets sufficient to provide voice and basic data service be appropriate? What level of data service would be appropriate? Are costs associated with back-up power endurance, backhaul resiliency, physical infrastructure resiliency, recovery plans, and/or redundant or alternate network implementations appropriate in this context? Should the Commission instead allow carriers to include in their proposals how and to what degree they would harden their networks, and factor that information into the evaluation of proposals?

68. The Commission also proposes to require second-stage participants to provide more detailed information to support tracking of recovery efforts. Although mobile carriers already provide information on coverage (but not signal strength, antenna alignment, and throughput) on a biannual basis through FCC Form 477, that information does not reveal the real-time status of communications systems in the aftermath of a disaster. Carriers currently have the option to provide information about the status of their infrastructure via the Commission's voluntary Disaster Information Reporting System (DIRS), and it proposes to require carriers who accept USF funding through the Uniendo a Puerto Rico Fund and the Connect USVI Fund to participate in DIRS. The Commission seeks comment on this proposal and on the data that DIRS should seek. Would it be appropriate to require mobile carriers to provide coverage maps, signal strength, antenna alignment, and throughput on a periodic basis in DIRS? How often should these reports be provided? Would it be

appropriate to require coverage maps at a more granular boundary value, for example -98 dBm to reflect indoor coverage for both voice and data? Would it be appropriate to require carriers to include information about disruptions to backhaul? Should the DIRS data contain more information about the customers' experience with their mobile service, for example by including more information about the condition of backhaul? If so, at what intervals? What are the costs and benefits of requiring additional reporting? When might it be appropriate to relieve carriers of any enhanced reporting requirements?

69. The Commission anticipates that any second-stage mobile participants in the Uniendo a Puerto Rico Fund and the Connect USVI Fund would continue to adhere to the current post-disaster resiliency framework for some time and seek comment on when that framework should and should not apply. First, are there common metrics used across providers to determine whether and when to open roaming capabilities? Should the Commission no longer expect adherence to the framework when coverage has been rebuilt to pre-hurricane levels? If so, should there be a minimum level of service associated with such coverage? Alternatively, would a set time period for continued adherence, such as one year, be more appropriate and reduce administrative burden? If so, what time period would be appropriate? Finally, should a similar framework be adopted for fixed providers?

70. The Commission also anticipates that any second-stage participants in the Uniendo a Puerto Rico Fund and the Connect USVI Fund would coordinate any construction and access issues with other carriers and state and federal agencies to minimize duplicative facilities, hardening, construction, digging, and other activity. The Commission believes that such coordination could help rebuild service in these areas more quickly and efficiently. The Commission seeks comment on whether voluntary coordination is sufficient or if it should adopt specific requirements. Commenters should identify specific carrier obligations and a framework for coordination. If the Commission adopted requirements, are there any reporting obligations that would be appropriate to ensure cooperation?

71. Finally, the Commission understands that much of Puerto Rico still lacks electrical power. Communications networks require reliable power to operate. The Commission seeks comment on what obligations providers should bear to ensure that their networks can function even when the electrical power grid is down. For instance, the Commission seeks comment on whether carriers could run their networks using energy sources readily available in Puerto Rico and the U.S. Virgin Islands that do not need to be shipped from elsewhere. The Commission seeks comment on the applicable costs of sustainable back-up power. What are the costs of maintaining generators on-site versus using portable generators? What are the costs and additional considerations of obtaining renewable back-up power versus traditional power methods?

72. Finally, the Commission seeks comment on other alternatives.

73. The Commission seeks comment on a petition filed by PRTC on January 19, 2018, asking the Commission to ''create a $200 million emergency Universal Service Fund designated to facilitate restoration of service in insular areas by [ETCs] in Puerto Rico.'' PRTC's request encompasses support for both fixed and mobile providers in Puerto Rico. It suggests the Commission distribute funds ''based on a percentage of the consumer service disruption credits provided by facilities-based ETCs to end user customers'' or ''in proportion to the total number of lines each facilities-based ETC restores during the next twelve months.'' The Commission seeks specific comment on whether additional short-term funding is necessary for Puerto Rico given the actions it takes in the concurrently adopted Order. If the Commission were to pursue such relief, how could it ensure that any funds are well spent? Do carriers regularly offer ''service disruption credits,'' or do different carriers offer different options to their consumers? And would such an emergency fund create a perverse incentive of rewarding those carriers that had greater service disruptions vis-à-vis those that recovered more quickly from the hurricanes?

74. The Commission also seeks comment on the petition filed by Viya proposing a one-time infusion of $45 million in support to help it rebuild its fixed network in the U.S. Virgin Islands, the petition filed by Viya on October 5, 2017, that sought ''a supplemental, one-time infusion of up to $50 million for carriers to rebuild wireless networks using hurricane-hardened facilities'' in the U.S. Virgin Islands, and the petition filed by Open Mobile seeking additional high-cost support and an advance on its support payments. The Commission seeks specific comment on whether additional short-term funding is necessary for the U.S. Virgin Islands given the actions it takes in the concurrently adopted Order. If the Commission were to pursue such relief, how could it ensure that any funds are well spent?

III. Procedural Matters

A. Initial Paperwork Reduction Act

75. This document contains proposed information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

76. *Initial Regulatory Flexibility Certification.* The Regulatory Flexibility Act of 1980 as amended (RFA) requires that a regulatory flexibility analysis be prepared for rulemaking proceedings, unless the agency certifies that ''the rule will not have a significant economic impact on a substantial number of small entities.'' The RFA generally defines ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

77. This Notice proposes annual support to rebuild, improve, and expand fixed and mobile services in Puerto Rico and the U.S. Virgin Islands. The Notice proposes making support available to any fixed or mobile provider who obtains an ETC designation, using a competitive and subscriber-based process, respectively. Ten fixed and mobile carriers in Puerto Rico and the U.S. Virgin Islands currently receive high-cost support. Even assuming other carriers will obtain an ETC designation to receive part of the additional support proposed by the Notice, the Commission does not anticipate the proposed rule to affect more than 15 providers out of the 737 providers currently receiving high-cost support. Accordingly, the Commission anticipates that this Notice

will not affect a substantial number of carriers, and so it does not anticipate that it will affect a substantial number of small entities. Therefore, the Commission certifies that this Notice will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).

78. *Comments.* All comments to this Notice should be filed in WC Docket No. 18–143, The Uniendo a Puerto Rico Fund and the Connect USVI Fund.

IV. Ordering Clauses

79. Accordingly, *it is ordered*, pursuant to the authority contained in sections 4(i), 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 214, 254, 303(r), and 403, and sections 1.1, 1.3, and 1.412 of the Commission's rules, 47 CFR 1.1, 1.3, and 1.412, Notice of Proposed Rulemaking *is adopted*. The Notice is effective thirty (30) days after publication of the text or summary thereof in the **Federal Register**.

80. *It is further ordered* that pursuant to applicable procedures set forth in sections 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415, 1.419, interested parties may file comments on the Notice on or before July 5, 2018, and reply comments on or before July 18, 2018.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2018–12625 Filed 6–12–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 18–153, RM–11801; DA 18–496]

Television Broadcasting Services; Block Island and Newport, Rhode Island

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Ocean State Television, LLC (Petitioner or OST), licensee of television station WPXQ–TV, channel 17, Block Island, Rhode Island (WPXQ). WPXQ operates on channel 17 on a shared basis with commercial television station WLWC, New Bedford, Massachusetts, also licensed to OST. OST requests an amendment of the DTV Table of Allotments to delete channel 17 at Block Island, Rhode Island, and substitute channel 17 at Newport, Rhode Island. Petitioner also requests modification of WPXQ's license to specify Newport as its community of license pursuant to agency rules. The Petitioner asserts that substantial public interests weigh heavily in favor of reallocating WPXQ to Newport. Newport has a population of 24,027 while Block Island's population consists of approximately 1,000. Petitioner asserts that the proposed reallotment will cause no public harm because Block Island will not only continue to be served by five full-power commercial and one full-power non-commercial television stations, but will also continue to receive the exact same over-the-air service from Petitioner that they are receiving currently. The proposal would result in a preferential allotment by providing Newport with its first local full-power television services in satisfaction of the Commission's second allotment priority, which is also consistent with Commission precedent and consistent with the public interest.

DATES: Comments must be filed on or before July 13, 2018, and reply comments on or before July 30, 2018.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 445 12th Street SW, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Ocean State Television, LLC, c/o Cooley LLP, John R. Feore, Jr., Esq., Jason Rademacher, Esq., 1299 Pennsylvania Avenue NW, Suite 700, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Darren Fernandez, *Darren.Fernandez@fcc.gov,* phone 202–418–2769, Video Division, Media Bureau.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 18–153, adopted May 14, 2018, and released May 15, 2018. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW, Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts (other than *ex parte* presentations exempt under 47 CFR 1.1204(a)) are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1208 for rules governing restricted proceedings.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

Proposed rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Rhode Island is amended by adding channel 17 at Newport and removing channel 17 at Block Island.

[FR Doc. 2018–12657 Filed 6–12–18; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 83, No. 114

Wednesday, June 13, 2018

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

Food and Nutrition Service

Agency Information Collection Activities; Proposals, Submissions, and Approvals: Child Nutrition Program Operations Study–II (CN–OPS–II)

AGENCY: Food and Nutrition Service (FNS), United States Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of the currently approved collection for the Child Nutrition Program Operations Study–II (CN–OPS II) [OMB Control Number 0584–0607]. The purpose of the revision is to update the survey instruments for school year (SY) 2018–19 to include topics of current interest and collect timely data to inform Child Nutrition Programs (CNP) operations.

DATES: Written comments on this notice must be received on or before August 13, 2018.

ADDRESSES: Comments may be sent to: Holly Figueroa, Social Science Research Analyst, Special Nutrition Evaluation Branch, Office of Policy Support, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Holly Figueroa at 703–305–2576 or via email to *holly.figueroa@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans, contact Holly Figueroa, Social Science Research Analyst, Special Nutrition Evaluation Branch, Office of Policy Support, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302; *Fax:* 703–305–2576; *Email: holly.figueroa@fns.usda.gov.*

SUPPLEMENTARY INFORMATION: 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 that were 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 those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Child Nutrition Program Operations Study–II (CN–OPS–II).

Form Number: N/A.

OMB Number: 0584–0607.

Expiration Date of Approval: 07/31/2020.

Type of Information Collection Request: Revision of a currently approved collection.

Abstract: The objective of the Child Nutrition Program Operations Study–II (CN–OPS–II) is to collect timely data on policies, administrative, and operational issues on the Child Nutrition Programs. The ultimate goal is to analyze these data and to provide input for new legislation on Child Nutrition Programs as well as to provide pertinent technical assistance and training to program implementation staff.

The CN–OPS–II will help the Food and Nutrition Service (FNS) better understand and address current policy issues related to Child Nutrition Programs (CNP) operations. The policy and operational issues include, but are not limited to, the preparation of the program budget, development and implementation of program policy and regulations, and identification of areas for technical assistance and training. Specifically, this study will help FNS obtain:

- General descriptive data on the Child Nutrition (CN) program characteristics to help FNS respond to questions about the nutrition programs in schools;
- Data related to program administration for designing and revising program regulations, managing resources, and reporting requirements; and
- Data related to program operations to help FNS develop and provide training and technical assistance for School Food Authorities (SFAs) and State Agencies responsible for administering the CN programs.

The activities to be undertaken subject to this notice include:

- Conducting a web survey of approximately 1,750 SFA Directors.
- Conducting a web survey of all 55 State Agency CN Directors.

Affected Public: State, Local and Tribal Governments (SFA Directors for public schools and State CN Directors).

Estimated Number of Respondents: The total estimated number of respondents is 3,379 (1,814 respondents and 1,565 non-respondents). Three State CN Directors and six SFA Directors are expected to participate in the pre-test. The estimated number of respondents for each of the web surveys is as follows:

(1) *State CN Director Web Survey:* The sample for this collection includes all 55 State CN Directors (50 U.S. States, 4 U.S. Territories, and the District of Columbia), all of whom are expected to respond.

(2) *SFA Director Web Survey:* The sample for this collection includes 2,188 SFA Directors selected, using a stratified probability proportional-to-size (PPS) design, from the universe of SFAs operating in public school districts in the U.S. and outlying Territories that are required to submit the FNS–742 Verification Collection Report Summary form. Of the full sample, 1,750 SFA Directors are expected to respond for a response rate of 80 percent.

Estimated Frequency of Response per Respondent: SFA Director and State CN Director respondents will be asked to complete their respective web surveys one time. Each State CN Director may

receive up to four follow-up/reminder emails and up to two reminder phone calls until the target of 55 respondents is reached. Each SFA Director may receive up to four follow-up/reminder emails and up to three reminder phone calls until the target number of 1,750 respondents is reached. FNS estimates that respondents will average 3.02 responses (5,479 responses/1,814 respondents) across the entire collection, with non-respondents averaging 4.38 responses (6,860 responses/1,565 non-respondents). Across all participants in the collection (respondents and non-respondents) the average number of responses is 3.65.

Estimated Total Annual Responses: The estimated total number of annual responses is 12,339. This includes 5,479 for all respondents and 6,860 for non-respondents.

Estimated Time per Response: The estimated time per response ranges from 2 minutes (0.03 hours) to 3 hours depending on the instrument. The average estimated time for all participants (respondents and non-respondents) in this collection is 20 minutes (0.33 hours) per response.

Estimated Total Annual Burden on Respondents: The annual reporting burden is estimated at 4,101.87 hours. See Table 1 for estimated total annual burden per respondent type.

Dated: May 31, 2018.

Brandon Lipps,

Administrator, Food and Nutrition Service.

BILLING CODE 3410–30–P

Table 1. Burden Table CN-OPS II Year 4 (SY 2018-19)

			Responsive					Non-Responsive					All
Type of respondents	**Type of survey instruments**	**Sample Size**	**Number of respondents**	**Frequency of response**	**Total Annual responses**	**Hours per response**	**Annual burden (hours)**	**Number of Non-respondents**	**Frequency of response**	**Total Annual responses**	**Hours per response**	**Annual burden (hours)**	**Total Annual hour burden**
CN Directors	Hard copy pre-test	3	3	1	3	3	9	0	0	0	0.50	0	9.00
CN Directors	Web-based Survey	55	55	1	55	2	110	0	0	0	0.08	0	110.00
CN Directors	Invitation Letter	55	22	1	22	0.05	1.1	33	1	33	0.03	1.1	2.20
CN Directors	Follow-up email*	33	13	1	13	0.05	0.65	20	1	20	0.03	0.66667	1.32
CN Directors	Reminder Email - Week 2*	20	8	1	8	0.05	0.4	12	1	12	0.03	0.4	0.80
CN Directors	Reminder Email - Week 4*	12	5	1	5	0.05	0.25	7	1	7	0.03	0.23333	0.48
CN Directors	Reminder Email - Week 6*	7	3	1	3	0.05	0.15	4	1	4	0.03	0.13333	0.28
CN Directors	Telephone Reminder - Week 7*	4	2	1	2	0.083	0.167	2	1	2	0.03	0.06667	0.23
CN Directors	Telephone Reminder - Week 8*	2	2	1	2	0.083	0.167	0	0	0	0.03	0	0.17
CN Directors	Thank You Letter	55	55	1	55	0.05	2.75	0	0	0	0.03	0	2.75
CN Directors	Email Notification & FAQ	55	55	1	55	0.5	27.5	0	0	0	0.03	0	27.50
SFA Directors	Hard copy pre-test	6	6	1	6	3	18	0	0	0	0.50	0	18.00
SFA Directors	Web-based Survey	2,188	1,750	1	1,750	2	3,500	438	1	438	0.083	36.50	3,536.50
SFA Directors	Invitation Letter	2,188	656	1	656	0.05	32.80	1,532	1	1,532	0.03	51	83.87
SFA Directors	Follow-up email**	1,532	383	1	383	0.05	19.15	1,149	1	1,149	0.03	38	57.45
SFA Directors	Reminder Email - Week 2**	1,149	287	1	287	0.05	14.35	862	1	862	0.03	29	43.08
SFA Directors	Reminder Email - Week 5**	862	129	1	129	0.05	6.45	733	1	733	0.03	24	30.88
SFA Directors	Reminder Email - Week 7**	733	110	1	110	0.05	5.50	623	1	623	0.03	21	26.27
SFA Directors	Telephone Reminder - Week 8**	623	93	1	93	0.083	7.75	530	1	530	0.03	18	25.42
SFA Directors	Telephone Reminder - Week 9**	530	53	1	53	0.083	4.42	477	1	477	0.03	16	20.32
SFA Directors	Telephone Reminder - Week 10**	477	39	1	39	0.083	3.25	438	1	438	0.03	15	17.85
SFA Directors	Thank You Letter	1,750	1,750	1	1,750	0.05	87.50	0	0	0	0.03	0	87.50
TOTAL		**2,252**	**1,814**	**3.02**	**5,479**	**0.703**	**3,851.30**	**1,565**	**4.38**	**6,860**	**0.037**	**250.57**	**4,101.87**

***Based on 40 percent response rate for email and telephone reminders until target of 55 respondents are reached.**
**** Based on declining response rates on subsequent contacts until target of 1,750 respondents is reached. Initial response rate is 30%.**

[FR Doc. 2018–12650 Filed 6–12–18; 8:45 am]
BILLING CODE 3410–30–C

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that the meeting of the Arizona Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Mountain Time) Friday, June 15, 2018. The purpose of this meeting is for the Committee to vote on the final draft of their advisory memorandum issued to the U.S. Commission on Civil Rights focused on voting rights.

DATES: These meetings will be held on Friday, June 15, 2018 at 12:00 p.m. MT.

Public Call Information: Dial: 877–719–9801 *Conference ID:* 4127448.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 877–719–9801, conference ID number: 4127448. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at *https://facadatabase.gov/committee/meetings.aspx?cid=235.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Approval of minutes from previous meeting
III. Discuss Advisory Memorandum
IV. Vote on Advisory Memorandum
V. Public Comment
VI. Next Steps
VII. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of this Committee voting on its advisory memorandum that will supplement the U.S. Commission on Civil Rights' 2018 statutory enforcement report.

Dated: June 8, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–12691 Filed 6–12–18; 8:45 am]
BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–809]

Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that certain companies covered by this administrative review made sales of circular welded non-alloy steel pipe (CWP) from the Republic of Korea (Korea) at less than normal value during the period of review (POR) November 1, 2015, through October 31, 2016.

DATES: Applicable June 13, 2018.

FOR FURTHER INFORMATION CONTACT: Andre Gziryan or Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–2201 or (202) 482–0410, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 6, 2017, Commerce published the *Preliminary Results* of the administrative review.[1] We invited interested parties to comment on the *Preliminary Results* and received case and rebuttal briefs from interested parties.[2]

Commerce exercised its discretion to toll all deadlines affected by the closure of the Federal Government from January 20 through 22, 2018.[3] On March 16, 2018, Commerce postponed the final results of this review until June 7, 2018.[4]

Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise subject to the order is circular welded non-alloy steel pipe and tube. Imports of the product are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090. While the HTSUS subheadings are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is

[1] *See Circular Welded Non-Alloy Steel Pipe from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2015–2016,* 82 FR 57583 (December 6, 2017) (*Preliminary Results*).

[2] *See* the case briefs from Wheatland Tube Company, Husteel Co., Ltd., Hyundai Steel Company, and SeAH Steel Corporation, dated January 12, 2018, and the rebuttal briefs from Wheatland Tube Company, Husteel Co., Ltd., Hyundai Steel Company, and SeAH Steel Corporation, dated January 19, 2018.

[3] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated January 23, 2018. All deadlines in this segment of the proceeding have been extended by three days.

[4] *See* Memorandum, ''Circular Welded Non-Alloy Steel Pipe from the Republic of Korea: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated March 16, 2018.

contained in the Issues and Decision Memorandum.[5]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this review are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues raised is attached 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 *https://access.trade.gov* and to all parties in the Central Records Unit, Room B–8024 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.*

Changes Since the Preliminary Results

Based on our analysis of comments received, we revised the preliminary margin calculations for the two mandatory respondents, Husteel Co., Ltd. (Husteel) and Hyundai Steel Company (Hyundai Steel). These revisions resulted in changes to the margins for Husteel, Hyundai Steel, and the three respondents not selected for individual examination for the final results of this review.

Final Results of the Administrative Review

We determine that the following weighted-average dumping margins exist for the respondents for the period November 1, 2015, through October 31, 2016.

Producer/exporter	Weighted-average dumping margin (percent)
AJU Besteel	19.28
Husteel Co., Ltd	7.71
Hyundai Steel Company[6]	30.85
NEXTEEL	19.28
SeAH Steel Corporation	19.28

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the final results in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce 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.

For Husteel and Hyundai Steel, we calculated importer-specific assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for each importer's examined sales and the total entered value of the sales, in accordance with 19 CFR 351.212(b)(1).[7] For entries of subject merchandise during the period of review produced by Husteel or Hyundai Steel for which it did not know its merchandise was destined for the United States, 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 the companies which were not selected for individual examination, AJU Besteel, NEXTEEL, and SeAH Steel Corporation, we will instruct CBP to apply the rates listed above to all entries of subject merchandise produced and/or exported by these firms. We intend to issue liquidation instructions to CBP 15 days after publication of the final results of these reviews.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice for all shipments of CWP from Korea 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 the companies listed above will be equal to the weighted-average dumping margins established in these final results of administrative review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the producer has been covered in a prior complete segment of this proceeding, the cash deposit rate will be the rate established for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 4.80 percent,[8] the all-others rate determined in the less-than-fair-value investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

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 Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

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 violation subject to sanction.

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

[5] *See* the Memorandum, ''Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review of Circular Welded Non-Alloy Steel Pipe from the Republic of Korea; 2015–2016,'' dated concurrently with and hereby adopted by this notice (Issues and Decision Memorandum).

[6] In the initiation notice, we initiated reviews of both Hyundai HYSCO and Hyundai Steel Company, but stated that Hyundai Steel Company is the successor-in-interest to Hyundai HYSCO. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 4294, 4296 (January 13, 2017).

[7] In these final results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

[8] *See Notice of Antidumping Duty Orders: Certain Circular Welded Non-Alloy Steel Pipe from Brazil, the Republic of Korea (Korea), Mexico, and Venezuela, and Amendment to Final Determination of Sales at Less Than Fair Value: Certain Circular Welded Non-Alloy Steel Pipe from Korea,* 57 FR 49453 (November 2, 1992).

Dated: June 7, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

Summary
Background
Scope of the Order
Rates for Respondents Not Selected for Individual Examination
Discussion of the Issues
Comment 1: Particular Market Situation
Comment 2: Additional Particular Market Situation Adjustments
Comment 3: Allegations of Improper Political Influence
Comment 4: Differential Pricing
Comment 5: Universe of Sales (Husteel Co., Ltd. (Husteel))
Comment 6: Certain Grades Sold (Husteel)
Comment 7: Universe of Sales (Hyundai Steel Company (Hyundai Steel))
Comment 8: Advertising Expenses (Hyundai Steel)
Comment 9: Assessment Rates (Hyundai Steel)

[FR Doc. 2018–12692 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; National Institute of Standards and Technology (NIST), Generic Clearance for Usability Data Collections

AGENCY: National Institute of Standards and Technology (NIST).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, 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.

DATES: Written comments must be submitted on or before August 13, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 1401 Constitution Avenue NW, Washington, DC 20230 (or via the internet at *PRAcomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Maureen O'Reilly, Management Analyst, NIST, 100 Bureau Drive, MS 1710, Gaithersburg, MD 20899–1710, telephone 301–975–3189, or via email to *maureen.oreilly@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

In accordance with the Executive Order 12862, the National Institute of Standards and Technology (NIST), a non-regulatory agency of the Department of Commerce, proposes to conduct a number of data collection efforts—both quantitative and qualitative. The data collections will be designed to determine requirements and evaluate the usability and utility of NIST research for measurement and standardization work. These data collections efforts may include, but may not be limited to electronic methodologies, empirical studies, video and audio collections, interviews, and questionnaires. For example, data collection efforts may include the cryptography software survey and the password generation study. NIST will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. NIST will not conduct individual data collections under this generic clearance that are mandatory, required, or regulated. The data collected will be used to guide NIST research. NIST will take steps to ensure anonymity of respondents in each activity covered under this request.

II. Method of Collection

NIST will collect this information by electronic means when possible, as well as by mail, fax, telephone and person-to-person interviews. If an information collection is conducted in person, NIST will provide the respondent with a paper copy of the collection instrument that displays the ''notwithstanding statement'', OMB Control # and current Expiration date.

III. Data

OMB Control Number: 0693–0043.

Form Number: None.

Type of Review: Revision and extension of a currently approved information collection.

Affected Public: Individuals or households, State, local or tribal government, Federal government.

Estimated Number of Respondents: 15,000.

Estimated Time per Response: Varied, dependent upon the data collection method used. The estimated response time to complete a questionnaire is 15 minutes or 2 hours to participate in an empirical study.

Estimated Total Annual Burden Hours: 15,000.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

NIST invites comments 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 (including hours and cost) of the proposed collection of information; (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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–12694 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; Manufacturing Extension Partnership Management Information Reporting

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, 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.

DATES: Written comments must be submitted on or before August 13, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 1401 Constitution Avenue NW,

Washington, DC 20230 (or via the internet at *PRAcomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Melissa Davis, National Institute of Standards and Technology, Manufacturing Extension Partnership, 100 Bureau Drive, Gaithersburg, MD 20899, MS4800, 301–975–5039, *melissa.davis@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Manufacturing Extension Partnership (MEP) is a national network of locally based manufacturing extension centers that assists small- and medium-sized manufacturers to improve their productivity, improve profitability, and enhance their economic competitiveness. The information collected will provide the MEP with information regarding MEP Center performance regarding the delivery of technology, and business solutions to U.S.-based manufacturers. The collected information will assist in determining the performance of the MEP Centers at both local and national levels, provide information critical to monitoring and reporting on MEP programmatic performance, and assist management in policy decisions. Responses to the collection of information are mandatory per the regulations governing the operation of the MEP Program (15 CFR parts 290, 291, 292, and H.R. 1274—section 2). The information collected will include center inputs and activities including services delivered, clients served, center staff, quarterly expenses and revenues, partners, strategic plan, operation plans, and client success stories. No confidentiality for information submitted is promised or provided. In order to reflect new initiatives and new data needs, NIST MEP has identified a need to revise its existing reporting processes by modifying existing reporting elements that will enable NIST MEP to better monitor and assess the extent to which the Centers are meeting program goals and milestones.

II. Method of Collection

The information will be collected from the MEP Centers through the MEP Enterprise Information System (MEIS), *https://meis.nist.gov.*

III. Data

OMB Control Number: 0693–0032.

Form Number(s): None.

Type of Review: Regular submission (revision of a currently approved information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 51.

Estimated Time per Response: 125 hours in year of Annual Review. 175 hours in year of Panel Review.

Estimated Total Annual Burden Hours: 6,375 hours in year of Annual Review. 8,925 hours in year of Panel Review.

Estimated Total Annual Cost to Public: $0.

IV. Request for 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 (including hours and cost) of the proposed collection of information; (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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–12693 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advisory Committee on Earthquake Hazards Reduction Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Earthquake Hazards Reduction (ACEHR or Committee), will meet on Wednesday, November 7, 2018, from 8:30 a.m. to 5:00 p.m. Mountain Time and Thursday, November 8, 2018, from 8:30 a.m. to 2:30 p.m. Mountain Time. The primary purpose of this meeting is to review the National Earthquake Hazards Reduction Program (NEHRP) agency updates on their latest activities and receive the NEHRP agency responses to the Committee's 2017 biennial and 2018 interim Reports on the Effectiveness of the NEHRP. The agenda may change to accommodate Committee business. The final agenda and any meeting materials will be posted on the NEHRP website at *http://nehrp.gov/.*

DATES: The ACEHR will meet on Wednesday, November 7, 2018, from 8:30 a.m. to 5:00 p.m. Mountain Time. The meeting will continue on Thursday, November 8, 2018, from 8:30 a.m. to 2:30 p.m. Mountain Time.

ADDRESSES: The meeting will be held in the Katharine Blodgett Gebbie Laboratory Conference Room 1A106, Building 81, at the National Institute of Standards and Technology (NIST), 325 Broadway Street, Boulder, Colorado 80305. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Tina Faecke, Management and Program Analyst, National Earthquake Hazards Reduction Program, Engineering Laboratory, NIST, 100 Bureau Drive, Mail Stop 8604, Gaithersburg, Maryland 20899–8604. Ms. Faecke's email address is *tina.faecke@nist.gov* and her phone number is (301) 975–5911.

SUPPLEMENTARY INFORMATION: The Committee was established in accordance with the requirements of Section 103 of the NEHRP Reauthorization Act of 2004 (Pub. L. 108–360). The Committee is composed of 15 members appointed by the Director of NIST, who were selected for their established records of distinguished service in their professional community, their knowledge of issues affecting NEHRP, and to reflect the wide diversity of technical disciplines, competencies, and communities involved in earthquake hazards reduction. In addition, the Chairperson of the U.S. Geological Survey Scientific Earthquake Studies Advisory Committee serves as an ex-officio member of the Committee. The Committee assesses:

- Trends and developments in the science and engineering of earthquake hazards reduction;
- The effectiveness of NEHRP in performing its statutory activities;
- Any need to revise NEHRP; and
- The management, coordination, implementation, and activities of NEHRP.

Background information on NEHRP and the Advisory Committee is available at *http://nehrp.gov/.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C.

App., notice is hereby given that the ACEHR will hold an open meeting on Wednesday, November 7, 2018, from 8:30 a.m. to 5:00 p.m. Mountain Time and Thursday, November 8, 2018, from 8:30 a.m. to 2:30 p.m. Mountain Time. The meeting will be held in the Katharine Blodgett Gebbie Laboratory Conference Room 1A106, Building 81, at NIST, 325 Broadway Street, Boulder, Colorado 80305. The meeting will be open to the public. The primary purpose of this meeting is to review the NEHRP agency updates on their latest activities and receive the NEHRP agency responses to the Committee's 2017 biennial and 2018 interim Reports on the Effectiveness of the NEHRP. The final agenda and any meeting materials will be posted on the NEHRP website at *http://nehrp.gov/.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request a place on the agenda. On November 8, 2018, approximately fifteen minutes will be reserved near the beginning of the meeting for public comments, and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about three minutes each. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Ms. Tina Faecke, *tina.faecke@nist.gov,* by 5:00 p.m. Eastern time, Wednesday, October 31, 2018.

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 to ACEHR, National Institute of Standards and Technology, 100 Bureau Drive, MS 8604, Gaithersburg, Maryland 20899–8604, via fax at (301) 975–4032, or electronically by email to *tina.faecke@nist.gov.*

All visitors to the NIST site are required to pre-register to be admitted. Anyone wishing to attend this meeting must register by 5:00 p.m. Eastern Time, Wednesday, October 24, 2018, in order to attend. Please submit your full name, email address, and phone number to Tina Faecke. Non-U.S. citizens must submit additional information; please contact Ms. Faecke. Ms. Faecke's email address is *tina.faecke@nist.gov* and her phone number is (301) 975–5911. For participants attending in person, please note that federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109–13), or by a state that has an extension for REAL ID compliance. NIST currently accepts other forms of federal-issued identification in lieu of a state-issued driver's license. For detailed information please contact Ms. Faecke at (301) 975–5711 or visit: *http://www.nist.gov/public_affairs/visitor/.*

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2018–12644 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Mammals and Endangered Species

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permits and permit amendments.

SUMMARY: Notice is hereby given that permits or permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone: (301) 427–8401; fax: (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan (Permit No. 22062), Amy Hapeman (Permit Nos. 21295 and 21366), Erin Markin (Permit No. 21467), and Sara Young (Permit No. 21158–02); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the research, go to *www.federalregister.gov* and search on the permit number provided in the table below.

Permit No.	RIN	Applicant	Previous **Federal Register** notice	Permit or amendment issuance date
21295	0648–XF910	Olga von Ziegear, Winged Whale Research, P.O. Box 15191, Fitz Creek, AK 99603.	82 FR 61752, December 29, 2017.	May 8, 2018.
21366	0648–XG057	Margaret Lamont, Ph.D., U.S. Geological Survey, 7320 NW 71st St., Gainesville, FL 32653.	83 FR 9297, March 5, 2018	May 9, 2018.
21467	0648–XG037	Karen Holloway-Adkins, East Coast Biologists, Inc., P.O. Box 33715, Indialantic, FL 32903.	83 FR 9297, March 5, 2018	May 10, 2018.
22062	0648–XG130	Patricia Fair, Ph.D., Medical University of South Carolina, Hollings Marine Laboratory, 331 Fort Johnson Road, Charleston, SC 29412.	83 FR 13736; March 30, 2018	May 1, 2018.
21158–02	0648–XF592	Robert Garrott, Ph.D., Montana State University, 310 Lewis Hall, Bozeman, MT 59717.	83 FR 16343; April 16, 2018	May 24, 2018.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not

operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: June 8, 2018.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–12705 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG283

North Pacific Fishery Management Council (NPFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) will host an Assessment Methods Workshop in June.

DATES: The meeting will be held on Wednesday, June 27, 2018, from 8 a.m. to 5 p.m. and on Thursday, June 28, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held in the Traynor Room, Building 4 at the Alaska Fisheries Science Center, 7700 Sand Point Way NE, Seattle, WA 98115. Teleconference number: 1–877–953–3919 (PP: 5944500).

Council address: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Diana Stram, Council staff; telephone: (907) 271–2801.

SUPPLEMENTARY INFORMATION:

Agenda

Wednesday, June 27 and Thursday, June 28, 2018

The workshop will review ensemble stock assessment modeling and evaluate how it fits in the NPFMC system. To also discuss considerations for potentially reducing an ABC from the maximum to account for observations and uncertainties not included in the assessment model or Tier system; and produce recommendations and a report to be considered by the September Joint Groundfish Plan Team. The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org/.*

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: June 8, 2018.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–12688 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG289

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Fishery Data for Stock Assessment Working Group to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Monday, June 25, 2018 at 9:30 a.m.

ADDRESSES: The meeting will be held at the School for Marine Science and Technology (UMASS Dartmouth), 836 South Rodney French Boulevard, New Bedford, MA 02744; telephone: (508) 999–8193.

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; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Fishery Data for Stock Assessment Working Group will present and discuss work to address the group's four main deliverables; begin discussions on working group recommendations and address other business as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. 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 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. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 8, 2018.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–12690 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG290

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 60 Data Scoping webinar.

SUMMARY: The SEDAR 60 assessment of the South Atlantic stock of Red Porgy will consist of a series of webinars and an in-person workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: A SEDAR 60 Data Scoping webinar will be held on Friday, June 29, 2018, from 9 a.m. until 12 p.m.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julia Byrd at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405. *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. The product of the SEDAR webinar series will be a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Data Scoping webinar are as follows:

Participants will identify who will be providing updated and/or new datasets.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 8, 2018.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–12687 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG287

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) adhoc Sablefish Management and Trawl Allocation Attainment Committee (SaMTAAC) will hold a meeting.

DATES: The meeting will be held Friday, June 29, 2018, starting at 8 a.m. and will end when business for the day has been completed.

ADDRESSES: The meeting will be held at the Waterton Hotel, 4242 Roosevelt Way NE, Seattle, WA 98105; telephone: (206) 826–4242.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Dr. Jim Seger, Pacific Council; telephone: (503) 820–2416.

SUPPLEMENTARY INFORMATION: This will be the first SaMTAAC meeting and its primary purpose is to orient the SaMTAAC and its advisors around to its charge, review information and alternatives already developed, and identify additional information that may be helpful to the committee for its first full meeting. The committee's charge is as follows: Identifying obstacles to achieving the goals and objectives of the catch share plan related to under attainment of non-sablefish trawl allocations and unharvested sablefish quota pounds (QP) south of 36° N latitude. As appropriate to overcome identified obstacles, the committee will discuss and develop options, including but not limited to, actions that may modify rules for gear switching by trawl permit holders and QP leasing to vessels using fixed gear, as well as options that may encourage increased utilization of sablefish QPs south of 36° N latitude.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at *kris.kleinschmidt@noaa.gov* or (503) 820–2411 at least 10 days prior to the meeting date.

Dated: June 8, 2018.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–12689 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG067

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Chevron Richmond Refinery Long Wharf Maintenance and Efficiency Project in San Francisco Bay, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Chevron to incidentally take, by Level A and/or Level B harassment, seven species of marine mammals during the Long Wharf Maintenance and Efficiency Project (WMEP) in San Francisco Bay, California.

DATES: This Authorization is applicable from June 1, 2018 through May 31, 2019.

FOR FURTHER INFORMATION CONTACT: Rob Pauline, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On February 1, 2018, NMFS received a request from Chevron for an IHA to take marine mammals incidental to pile driving and pile removal associated with the WMEP in San Francisco Bay, California. Chevron's request is for take of seven species by Level A and Level B harassment. Neither Chevron nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS has issued an IHA to Chevron authorizing the take of seven species by Level A and Level B harassment. Pile driving and removal will take 28 days and will be timed to occur within the work windows developed for Endangered Species Act (ESA)—listed fish species (June 1 through November 30). The IHA is effective from June 1, 2018 through May 31, 2019. This IHA would cover one year of a larger project for which Chevron intends to request additional take authorizations for subsequent facets of the project.

Description of Planned Activity

Chevron's Richmond Refinery Long Wharf (Long Wharf) located in San Francisco Bay, is the largest marine oil terminal in California. The Long Wharf has existed in its current location since the early 1900s (Figure 1–1 in Application). The existing configuration of these systems have limitations to accepting more modern, fuel efficient vessels with shorter parallel mid-body hulls and in some cases do not meet current Marine Oil Terminal Engineering and Maintenance Standards (MOTEMS). The purpose of the planned WMEP is to comply with current MOTEMS requirements and to improve safety and efficiency at the Long Wharf. The planned project will involve modifications at four berths (Berths 1, 2, 3, and 4). Modifications to the Long Wharf include replacing gangways and cranes, adding new mooring hooks and standoff fenders, adding new dolphins and catwalks, and modifying the fire water system at Berths 1, 2, 3 and/or 4, as well as the seismic retrofit to the Berth 4 loading platform. The type and numbers of piles to be installed, as well as those that will be removed during the 2018–2022 period are summarized in Table 1.

Table 1. Planned Pile Installation and Removal for Entire Project 2018-2022.

Item		Description	No. Piles	Pile Installation / Removal Method
New Installation	1	Berth 1 Mooring Hook Dolphin	13	Impact
	2	Berth 1 Outer Breasting Dolphin	17	Impact
	3	Berth 1 Inner Breasting Point	8	Impact
	4	Berth 1 Gangway	4	Impact
	5	Berth 1 Walkways	0	-
	6	Berth 2 South Outside Fender	10	Impact
	7	Berth 2 South Inside Fender	10	Impact
	8	Berth 2 North Inside Fender	9	Impact
	9	Berth 2 North Outside Fender	10	Impact
	10	Berth 2 Main Hose Crane	4	Impact
	11	Berth 2 Aux Crane	4	Impact
	12	Berth 2 Vapor Recovery Hose Crane	0	-
	13	Berth 2 Gangway	4	Impact
	14	Berth 3 Gangway	4	Impact
	15	Berth 4 South Breasting Dolphin	22	Impact
	16	Berth 4 North Breasting Dolphin	22	Impact
	17	Berth 4 Walkways	0	-
		Total 24-inch Square Concrete Piles	**141**	
	18	Berth 4 Loading Platform Retrofit (60-inch-diameter Steel Piles)	8	Impact
	19	Berth 4 Barrier Piles (4 Clusters of 13 Composite Piles)	52	Vibrate
		Total Additional Fill	**201**	
Permanent Removal	20	Berth 1 Pile Removal	-2	Vibrate
	21	Berth 2 Pile Removal (106 Wooden - Actual Count)	-106	Vibrate
	22	Berth 2 Whaler Removal (excluding wooden Piles)	-	-
	23	Berth 2 Brace Piles (22-inch Square Concrete Jacketed Timber Piles)	-3	Cut
	24	Berth 4 Concrete Pile Removal	-2	Cut
	25	Berth 1 Existing Walkway	-	-
		Total Removal	**-113**	
		Net Change	**88**	**-**
Temporary Fill	26	Berth 1 Pile Removal	36	Vibrate
	27	Berth 2 Pile Removal (106 Wooden - Actual Count)	-	-
	28	Berth 2 Whaler Removal (excluding wooden Piles)	12	Vibrate

The combined modifications to Berths 1 to 4 would require the installation of 141 new concrete piles to support new and replacement equipment and their associated structures. The Berth 4 loading platform would add eight, 60-inch diameter steel piles as part of the seismic retrofit. The project would also add four clusters of 13 composite piles each (52 total) as markers and protection of the new batter (driven at an angle) piles on the east side of the Berth 4 retrofit. The project would remove 106 existing timber piles, three existing 22-inch and two existing 24-inch concrete piles. A total of 12 temporary piles would also be installed and removed during the seismic retrofit of Berth 4.

Note that the proposed IHA will only cover pile driving and removal that will occur during the 2018 work season, as provided in Table 2.

TABLE 2—PILE DRIVING SUMMARY FOR 2018 WORK SEASON

Pile type	Pile driver type	Number of piles	Number of driving days
36-inch steel template pile	Vibratory	8	2
Concrete pile removal	Vibratory	5	1
24-inch concrete	Impact	8	8
14-inch H pile installation (for temporary fenders)	Vibratory/Impact*	36	12
Timber pile removal	Vibratory	53	5

*A vibratory driver will be preferentially used for installation of the temporary H piles. In the event that the pile hits a buried obstruction and can no longer be advanced with a vibratory driver, and impact hammer may be used.

These actions could produce underwater sound at levels that could result in the injury or behavioral harassment of marine mammal species. A detailed description of Chevron's planned project is provided in the **Federal Register** notice for the proposed IHA (83 FR 18802; April 30, 2018). Since that time, no changes have been made to the planned project activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS's proposal to issue an IHA to Chevron was published in the **Federal Register** on April 30, 2018 (83 FR 18802). That notice described, in detail, Chevron's activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, proposed amount and manner of take, and proposed mitigation, monitoring and reporting measures. During the 30-day public comment period, NMFS received one comment letter from the Marine Mammal Commission (Commission); the Commission's recommendations and our responses are provided here, and the comments have been posted online at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.*

Comment: The Commission commented that the method NMFS used to estimate the numbers of takes during the proposed activities, which summed fractions of takes for each species across project days, does not account for and negates the intent of NMFS' 24-hour reset policy. The Commission also recommends that NMFS develop and share guidance on this issue.

Response: NMFS will share the guidance with the Commission following the completion of internal review and looks forward to discussing the issue with them in the future.

Comment: The Commission requested clarification of certain issues associated with NMFS's notice that one-year renewals could be issued in certain limited circumstances and expressed concern that the process would bypass the public notice and comment requirements. The Commission also suggested that NMFS should discuss the possibility of renewals through a more general route, such as a rulemaking, instead of notice in a specific authorization. The Commission further recommended that if NMFS did not pursue a more general route, that the agency provide the Commission and the public with a legal analysis supporting our conclusion that this process is consistent with the requirements of section 101(a)(5)(D) of the MMPA.

Response: The process of issuing a renewal IHA does not bypass the public notice and comment requirements of the MMPA. The notice of the proposed IHA expressly notifies the public that under certain, limited conditions an applicant could seek a renewal IHA for an additional year. The notice describes the conditions under which such a renewal request could be considered and expressly seeks public comment in the event such a renewal is sought. Importantly, such renewals would be limited to where the activities are identical or nearly identical to those analyzed in the proposed IHA, monitoring does not indicate impacts that were not previously analyzed and authorized, and the mitigation and monitoring requirements remain the same, all of which allow the public to comment on the appropriateness and effects of a renewal at the same time the public provides comments on the initial IHA. NMFS has, however, modified the language for future proposed IHAs to clarify that all IHAs, including renewal IHAs, are valid for no more than one year and that the agency would consider only one renewal for a project at this time. In addition, notice of issuance or denial of a renewal IHA would be published in the **Federal Register**, as are all IHAs. Last, NMFS will publish on our website a description of the renewal process before any renewal is issued utilizing the new process.

Comment: The Commission recommended that NMFS review more thoroughly both the applications prior to deeming them complete and its notices prior to submitting them for publication in the **Federal Register** and that NMFS better evaluate the proposed exclusion/shut-down zones that are to be implemented for each proposed incidental take authorization.

Response: NMFS thanks the Commission for its recommendation.

Comment: The Commission expressed concern about what they assert is the lack of adequate time to provide public comments as well as the abbreviated timeframes during which NMFS is able to address public comments. The Commission recommended that NMFS ensure that it publishes and finalizes proposed incidental harassment authorizations sufficiently before the planned start date of the proposed activities to ensure full consideration is given to all comments received.

Response: NMFS provided the required 30-day notice for public comment, and has adequately considered all public comments received in making the necessary findings.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SAR; *www.nmfs.noaa.gov/pr/sars/*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website. We provided a description of the specified activity in our **Federal Register** notice announcing the proposed authorization (83 FR 18802; April 30, 2018). Please refer to that document; we provide only a summary table here (Table 3).

TABLE 3—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF THE PROJECT AREA

Common name	Scientific name	Stock	ESA/MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae						
Gray whale	*Eschrichtius robustus*	Eastern North Pacific	-/-; (N)	20,990 (0.05, 20,125, 2011)	624	132

TABLE 3—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF THE PROJECT AREA—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]
Family Balaenidae						
Family Delphinidae						
Bottlenose dolphin	*Tursiops truncatus*	California Coastal	-/-;(N)	453 (0.06, 346, 2011)	2.7	≥2.0
Family Phocoenidae (porpoises)						
Harbor porpoise	*Phocoena phocoena*	San Francisco-Russian River Stock.	-/-;(N)	9,886 (0.51, 6,625, 2011)	66	0
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions)						
California sea lion	*Zalophus californianus*	Eastern U.S. stock	-/-;(N)	296,750 (-, 153,337, 2011)	9,200	389
Northern fur seal	*Callorhinus ursinus*	California stock	-/-;(N)	14,050 (-, 7,524, 2013)	451	1.8
Family Phocidae (earless seals)						
Pacific harbor seal	*Phoca vitulina*	California stock	-/-;(N)	30,968 (-,27,348, 2012)	1,641	43
Northern elephant seal	*Mirounga angustirostris*	California Breeding stock	-/-;(N)	179,000 (-, 81,368, 2010)	4,882	8.8

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *www.nmfs.noaa.gov/pr/sars/.* CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable. For certain stocks of pinnipeds, abundance estimates are based upon observations of animals (often pups) ashore multiplied by some correction factor derived from knowledge of the species' (or similar species') life history to arrive at a best abundance estimate; therefore, there is no associated CV. In these cases, the minimum abundance may represent actual counts of all animals ashore.

[3] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

Note that while humpback whales and Guadalupe fur seals have been observed in the Bay, their typical temporal and/or spatial occurrence is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here.

Humpback whales are rare, though well-publicized, visitors to the interior of San Francisco Bay. A humpback whale journeyed through the Bay and up the Sacramento River in 1985 and re-entered the Bay in the fall of 1990, stranding on mudflats near Candlestick Park (Fimrite 2005). In May 2007, a humpback whale mother and calf spent just over two weeks in San Francisco Bay and the Sacramento River before finding their way back out to sea. Although it is possible that a humpback whale will enter the Bay and find its way into the project area during construction activities, their occurrence is unlikely. Guadalupe fur seals occasionally range into the waters of Northern California and the Pacific Northwest. The Farallon Islands (off central California) and Channel Islands (off southern California) are used as haulouts during these movements (Simon 2016). Juvenile Guadalupe fur seals occasionally strand in the vicinity of San Francisco, especially during El Niño events. Most strandings along the California coast are animals younger than two years old, with evidence of malnutrition (NMFS 2017c). In the rare event that a Guadalupe fur seal is detected within the Level A or Level B harassment zones, work will cease until the animal has left the area.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

We provided a description of the anticipated effects of the specified activity on marine mammals in our **Federal Register** notice announcing the proposed authorization (83 FR 18802; April 30, 2018). Please refer to that document for our detailed analysis; we provide only summary information here.

The introduction of anthropogenic noise into the aquatic environment from pile driving and removal is the primary means by which marine mammals may be harassed from Chevron's specified activity. The effects of pile driving noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.,* impulsive vs. non-impulsive), the species, age and sex class (*e.g.,* adult male vs. mom with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Southall *et al.,* 2007, Wartzok *et al.,* 2004). Animals exposed to natural or anthropogenic sound may experience physical and behavioral effects, ranging in magnitude from none to severe (Southall *et al.,* 2007). In general, exposure to pile driving noise has the potential to result in auditory threshold shifts (permanent threshold shift (PTS) and temporary threshold shift (TTS)) and behavioral reactions (*e.g.,* avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). No new permanent impacts to habitats used by marine mammals would result from the project. Some short-term impacts to prey availability (*e.g.,* fish) and minor impacts to the immediate substrate may occur as a result of increased turbidity from pile installation and removal but the effects are expected to be temporary and minimal.

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which will inform both NMFS' consideration of small numbers and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which

(i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the acoustic source (*i.e.,* pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency species and a single phocid species due to larger predicted auditory injury zones. Auditory injury is unlikely to occur for low-frequency, mid-frequency species, or pinniped groups, with the exception of harbor seals. The mitigation and monitoring measures are expected to minimize the severity of such taking to the extent practicable.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Described in the most basic way, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. Below, we describe these components in more detail and present the authorized take estimate.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 decibel (dB) re 1 micro pascal (μPa) root mean square (rms) for continuous (*e.g.* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. For in-air sounds, NMFS predicts that pinnipeds exposed above received levels of 100 dB re 20 μPa (rms) and harbor seals exposed above 90 dB re 20 μPa (rms) will be behaviorally harassed.

Chevron's planned activity includes the use of continuous (vibratory driving) and impulsive (impact driving) sources, and therefore the 120 and160 dB re 1 μPa (rms) are applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Technical Guidance, 2016) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The applicant's planned activity includes the use of impulsive (impact driving) and non-impulsive (vibratory driving) sources.

These thresholds are provided in Table 4. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2016 Technical Guidance, which may be accessed at: *http://www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.*

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Table 4. Thresholds identifying the onset of Permanent Threshold Shift.

	PTS Onset Acoustic Thresholds* (Received Level)	
Hearing Group	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1* $L_{pk,flat}$: 219 dB $L_{E,LF,24h}$: 183 dB	*Cell 2* $L_{E,LF,24h}$: 199 dB
Mid-Frequency (MF) Cetaceans	*Cell 3* $L_{pk,flat}$: 230 dB $L_{E,MF,24h}$: 185 dB	*Cell 4* $L_{E,MF,24h}$: 198 dB
High-Frequency (HF) Cetaceans	*Cell 5* $L_{pk,flat}$: 202 dB $L_{E,HF,24h}$: 155 dB	*Cell 6* $L_{E,HF,24h}$: 173 dB
Phocid Pinnipeds (PW) (Underwater)	*Cell 7* $L_{pk,flat}$: 218 dB $L_{E,PW,24h}$: 185 dB	*Cell 8* $L_{E,PW,24h}$: 201 dB
Otariid Pinnipeds (OW) (Underwater)	*Cell 9* $L_{pk,flat}$: 232 dB $L_{E,OW,24h}$: 203 dB	*Cell 10* $L_{E,OW,24h}$: 219 dB

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μPa, and cumulative sound exposure level (L_E) has a reference value of 1μPa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (i.e., varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

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Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds.

Pile driving will generate underwater noise that potentially could result in disturbance to marine mammals swimming by the project area. Transmission loss (TL) underwater is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source until the source becomes indistinguishable from ambient sound. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. A standard sound propagation model, the Practical Spreading Loss model, was used to estimate the range from pile driving activity to various expected SPLs at potential project structures. This model follows a geometric propagation loss based on the distance from the driven pile, resulting in a 4.5 dB reduction in level for each doubling of distance from the source. In this model, the SPL at some distance away from the source (*e.g.,* driven pile) is governed by a measured source level, minus the TL of the energy as it dissipates with distance. The TL equation is:

$$TL = 15\log10(R_1/R_2)$$

Where:

TL is the transmission loss in dB,
R_1 is the distance of the modeled SPL from the driven pile, and
R_2 is the distance from the driven pile of the initial measurement.

The degree to which underwater noise propagates away from a noise source is dependent on a variety of factors, most notably by the water bathymetry and presence or absence of reflective or absorptive conditions including the sea surface and sediment type. The TL model described above was used to calculate the expected noise propagation from both impact and vibratory pile driving, using representative source levels to estimate the zone of influence (ZOI) or area exceeding specified noise criteria.

Source Levels

Sound source levels from the Chevron site were not available. Therefore, literature values published for projects similar to the Chevron project were used to estimate source levels that could potentially be produced. Results are shown in Table 5.

Modifications at the four berths require the placement of new 24-inch diameter square concrete piles. Approximately one to two of these piles would be installed in one workday, using impact driving methods. Based on measured blow counts for 24-inch concrete piles driven at the Long Wharf Berth 4 in 2011, installation for each pile could require up to approximately 300 blows and 1.5 second per blow average over a duration of approximately 20 minutes per pile, with 40 minutes of pile driving time per day if two piles are installed. To estimate the noise effects of the 24-inch square concrete piles, the general values provided by Caltrans (2015a) are shown in Table 5.

To estimate the noise effects of impact driving of 14-inch steel H piles, the values provided by Caltrans were also utilized. These source values are 208 dB peak, 187 rms, and 177 dB SEL (single strike). Based on these levels, impact driving of the 14-inch steel H piles is expected to produce underwater sound exceeded the Level B 160 dB RMS threshold over a distance of 631 meters.

During construction, temporary fendering would be installed at Berth 2 which will be supported by 36 steel 14-inch steel H piles. It is estimated that each pile could be driven in five (5) minutes. Two (2) to four (4) piles would be installed in any single workday for a total of approximately 12 days of installation. For the purposes of calculating the distance to Level A thresholds, four piles per day is assumed. The piles would be removed after the permanent fenders are in place. A vibratory hammer would be used to vibrate the piles to facilitate pulling them from the mud. The best match for estimated source levels is the Port of Anchorage pile driving test project. During vibratory pile driving associated with the Anchorage project, peak noise levels ranged from 165 to 175 dB, and the RMS ranged between 152 and 168 dB, both measured at approximately 15 meters (50 ft) (Caltrans 2015a).

The source levels for vibratory installation of 36-inch temporary steel piles were from the Explosive Handling Wharf–2 (EHW–2) project located at the Naval Base Kitsap in Bangor, Washington as stated in Caltrans (2015a). During vibratory pile driving measured peak noise levels were approximately 180 dB, and the RMS was approximately 169 dB at a 10 meter (33ft) distance. These temporary piles would require a drive time per pile of approximately 10 minutes. Up to four (4) of these piles could be installed in any single workday for a total of 40 minutes.

The most applicable source values for wooden pile removal were derived from measurements taken at the Port Townsend dolphin pile removal in Washington. During vibratory pile extraction associated with this project, which occurred under similar circumstances, measured peak noise levels were approximately 164 dB, and the RMS was approximately 150 dB (WSDOT 2011). Applicable sound values for the removal of concrete piles could not be located, but they are expected to be similar to the levels produced by wooden piles described above, as they are similarly sized, non-metallic, and will be removed using the same methods.

During construction, 106 16-inch timber piles, and seven 18 to 24-inch square concrete piles would be removed. Up to twelve of these piles could be extracted in one workday. Extraction time needed for each pile may vary greatly, but could require approximately 400 seconds (approximately 7 minutes).

TABLE 5—THE SOUND LEVELS (dB PEAK, dB RMS, AND dB sSEL) EXPECTED TO BE GENERATED BY EACH HAMMER AND PILE TYPE

Type of pile	Hammer type	Estimated pressure level (dB peak)	Estimated pressure level (dB RMS)	Estimated single strike sound exposure level (dB SEL)
24-inch sq. concrete	Impact	188	176	166
14-inch Temporary steel H-pile	Impact	208	[1] 187	177
14-inch Temporary steel H-pile	Vibratory	180	[2] 168	.....
36-inch Steel Pipe	Vibratory	180	169	.....
Wood and concrete pile extraction	Vibratory	164	[3] 150	.....

[1] SL was based on an assumed 10–dB difference between the SELs-s and SPLrms SLs. The $SPL_{rms}SL$ was not reported in Caltrans.
[2] Measured at 14 m.
[3] Measured at 16 m.

When NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, NMFS developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which will result in some degree of overestimate of Level A take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources NMFS User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below.

Table 6 shows the inputs that were used in the User Spreadsheet to determine cumulative PTS Thresholds. Table 7 shows the Level A Isopleths as determined utilizing inputs from Table 6. Level B isopleths for impact and vibratory driving and extraction are shown in Table 8.

TABLE 6—INPUTS FOR USER SPREADSHEET

Spreadsheet tab used	E.1: Impact pile driving (stationary source: impulsive, intermittent)	E.1: Impact pile driving (stationary source: impulsive, intermittent)	A: Stationary source: non-impulsive, continuous	A: Stationary source: non-impulsive, continuous	A: Stationary source: non-impulsive, continuous
Pile Type and Hammer Type	24-inch sq. concrete piles.	14-inch Steel H-pile	14-inch Steel H-pile	36-in steel	Wood concrete pile extraction.
Source Level	166 (Single strike/shot SEL).	177 (Single strike/shot SEL).	168 RMS	169 RMS	150 RMS.
Weighting Factor Adjustment (kHz)	2	2	2.5	2.5	2.5.
Number of strikes in 1 h OR number of strikes per pile.	300	200	NA	NA	NA.
Activity Duration (h) within 24-h period OR number of piles per day.	2 piles	4 piles	0.333	0.6667	1.333.
Propagation (xLogR)	15	15	15	15	15.
Distance of source level measurement (meters).	10	10	14	10	16.

TABLE 7—RADIAL DISTANCES TO LEVEL A ISOPLETH DURING IMPACT AND VIBRATORY DRIVING

Project element requiring pile installation	Distance in meters (feet)				
	Low-frequency cetaceans	Mid-frequency cetaceans	High-frequency cetaceans	Phocid pinnipeds	Otariid pinnipeds
Impact Driving					
24-inch square concrete (1–2 per day)	52 (171)	2 (6)	62 (204)	28 (92)	2 (7)
14-inch steel H pile (4 per day	343 (1,124)	12 (40)	408 (1,339)	183 (602)	13 (44)
Vibratory Driving/Extraction					
14-inch steel H pile (4 per day)	13 (46)	1 (3)	20 (66)	8 (26)	1 (3)
36-inch steel pipe pile (4 per day)	18 (58)	2 (6)	26 (86)	11 (35)	1 (2)
Wood and concrete pile extraction (12 per day)	2 (5)	<1 (3)	4 (13)	2 (6)	<1 (3)

TABLE 8—RADIAL DISTANCES TO LEVEL B ISOPLETHS DURING IMPACT AND VIBRATORY DRIVING

Pile type	Distance to threshold in meters (feet)
Impact Driving (160 dB threshold)	
24-inch square concrete	117 (382)
14-inch steel H pile	631 (2,070)
Vibratory Driving/Extraction (120 dB threshold)	
14-inch steel H pile	22,188 (72,795)
36-inch steel pipe pile	18,478 (60,609)
Wood and concrete pile extraction	1,600 (5,249)

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

San Francisco Bay has five known harbor seal haulout sites that include Alcatraz Island, Castro Rocks, Yerba Buena Island, Newark Slough, and Mowry Slough. Yerba Buena Island, Alcatraz and Castro Rocks are within or near the areas within ensonified Level B zones. Castro Rocks is the largest harbor seal haulout site in the northern part of San Francisco Bay and is the second largest pupping site in the Bay (Green *et al.* 2002). The pupping season is from March to June in San Francisco Bay. During the molting season (typically June-July and coincides with the period when piles will be driven) as many as approximately 130 harbor seals on average have been observed using Castro Rocks as a haulout. Harbor seals are more likely to be hauled out in the late afternoon and evening, and are more likely to be in the water during the morning and early afternoon (Green *et al.* 2002). However, during the molting season, harbor seals spend more time hauled out and tend to enter the water later in the evening. During molting, harbor seals can stay onshore resting for an average of 12 hours per day during the molt compared to around 7 hours per day outside of the pupping/molting seasons (NPS 2014). Tidal stage is a major controlling factor of haulout usage at Castro Rocks with more seals present during low tides than high tide periods since it is completely underwater at high tide twice per day (Green *et al.* 2002). Additionally, the number of seals hauled out at Castro Rocks also varies with the time of day, with proportionally more animals hauled out during the nighttime hours (Green *et al.* 2002). Therefore, the number of harbor

seals in the water around Castro Rocks will vary throughout the work period. However, it is likely that all seals hauled out at the site will be exposed to project related underwater noise at some point each day. The number of harbor seals located at Castro Rocks is based on the highest mean plus the standard error of harbor seals observed at Castro Rocks during recent annual surveys conducted by the National Park Service (NPS) (Codde, S. and S. Allen. 2013, 2015, and 2017), resulting in a value of 176 seals. The same NPS survey determined that harbor seal population in the Central Bay at Alcatraz and Yerba Buena Island is approximately 167 seals (Codde, S. and S. Allen. 2013, 2015, and 2017).

California sea lions haul out primarily on floating docks at Pier 39 in the Fisherman's Wharf area of the San Francisco Marina, approximately 12.5 kilometer (km) (7.8 miles (mi)) southwest of the project area. Based on counts done in 1997 and 1998, the number of California sea lions that haul out at Pier 39 fluctuates with the highest occurrences in August and the lowest in June. In addition to the Pier 39 haulout, California sea lions haul out on buoys and similar structures throughout the Bay. They are seen swimming off mainly the San Francisco and Marin shorelines within the Bay but may occasionally enter the project area to forage. Over the monitoring period for the Richmond-San Rafael Bridge RSRB, monitors sighted at least 90 California sea lions in the North Bay and at least 57 in the Central Bay (Caltrans 2012). During monitoring for the San Francisco-Oakland Bay Bridge (SFOBB) Project in the central Bay, 69 California sea lions were observed in the vicinity of the bridge over a 17-year period from 2000–2017 (Caltrans 2018), and from these observations, an estimated density of 0.161 animals per square kilometer (km^2) is derived (Caltrans 2018).

A small but growing population of harbor porpoises utilizes San Francisco Bay. Harbor porpoises are typically spotted in the vicinity of Angel Island and the Golden Gate (6 and 12 km southwest respectively) with lesser numbers sighted in the vicinity of Alcatraz and around Treasure Island (Keener 2011). Porpoises but may utilize other areas in the Central Bay in low numbers, including the planned project area. However, harbor porpoise are naturally inclined to remain near the shoreline areas and downstream of large landmasses as they are constantly foraging. For this reason, the project area would present a less than likely area to observe harbor porpoise as they would either need to traverse the perimeter of the Bay to arrive there, or would have to swim through the open Bay. Both scenarios are possible, but would represent uncommon behavior. Based on monitoring conducted for the SFOBB project, between 2000–2017 an in-water density of 0.031 animals per km^2 estimated by Caltrans for this species. However, porpoise occurrence increased significantly in 2017 resulting in a 2017 only density of 0.167 animals per km^2 (Caltrans 2018).

Small numbers of northern elephant seals haul out or strand on coastline within the Central Bay. Monitoring of marine mammals in the vicinity of the SFOBB has been ongoing for 15 years; from those data, Caltrans has produced an estimated at-sea density for northern elephant seal of 0.06 animal per km^2 (Caltrans, 2015b). Most sightings of northern elephant seal in San Francisco Bay occur in spring or early summer, and are less likely to occur during the periods of in-water work for this project. As a result, densities during pile driving for the planned action would be much lower.

The incidence of northern fur seal in San Francisco Bay depends largely on oceanic conditions, with animals more likely to strand during El Niño events. The likelihood of El Niño conditions occurring in 2018 is currently low, with La Niña or neutral conditions expected to develop (NOAA, 2018).

The range of the bottlenose dolphin has expanded northward along the Pacific Coast since the 1982–1983 El Niño (Carretta *et al.* 2013, Wells and Baldridge 1990). They now occur as far north as the San Francisco Bay region and have been observed along the coast in Half Moon Bay, San Mateo, Ocean Beach in San Francisco, and Rodeo Beach in Marin County. Observations indicate that bottlenose dolphin occasionally enter San Francisco Bay, sometimes foraging for fish in Fort Point Cove, just east of the Golden Gate Bridge (Golden Gate Cetacean Research 2014). Transient individuals of this species occasionally enter San Francisco Bay, but observations indicate that they usually remain in proximity to the Golden Gate near the mouth of the Bay. Beginning in 2015, two individuals have been observed frequently in the vicinity of Oyster Point, located south of San Francisco (GGCR, 2018; Perlman, 2017). Bottlenose dolphins are being observed in San Francisco bay more frequently in recent years. Groups with an average size of five animals have been observed entering the Bay in the vicinity of Yerba Buena Island at a rate of once per week. They usually are observed over two week spans and then depart for an extended period of time (NMFS, 2017).

Gray whales occasionally enter the Bay during their northward migration period, and are most often sighted in the Bay between February and May. Most venture only about 2 to 3 km (about 1–2 mi) past the Golden Gate, but gray whales have occasionally been sighted as far north as San Pablo Bay. Pile driving is not expected to occur during this time, and gray whales are not likely to be present at other times of year.

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

The following assumptions are made when estimating potential incidences of take:

- All marine mammal individuals potentially available are assumed to be present within the relevant area, and thus incidentally taken;
- An individual can only be taken once during a 24-h period;
- Exposures to sound levels at or above the relevant thresholds equate to take, as defined by the MMPA.

Limited density data is available for marine mammal species in San Francisco Bay. Estimates here are determined using data taken during marine mammal monitoring associated with RSRB retrofit project, the San Francisco-Oakland Bay Bridge replacement project, and other marine mammal observations for San Francisco Bay. For Pacific harbor seal, data was also derived from recent annual surveys of haulouts in the Bay conducted by the National Park Service (Codde, S. and S. Allen. 2013, 2015, and 2017).

Pacific Harbor Seal

As noted above, take estimates are based on the highest mean plus the standard error of harbor seals observed by NPS at Castro Rocks which equals 176 animals (Codde, S. and S. Allen. 2013, 2015, and 2017). Castro Rocks is inundated with water twice/day during the high tides. So during every work day (7 a.m. to 7 p.m.) the entire haulout will be in the water twice per day. Of these 176 seals, the proportion that may enter the areas over which the Level B harassment thresholds may be exceeded are estimated as follows:

- *Impact driving of 24-inch concrete piles at all Berths:* It is assumed that 10 percent of the animals that enter the water from Castro Rocks will enter the small Level B zones associated with this pile type as shown in Figure 6–1 in the application. Thus, it is estimated that up to 17.6 individuals per day could be exposed (176/10 = 17.6) by entering the Level B harassment zone to the south of Castro Rocks;

• *Impact driving of 14-inch steel H piles:* Impact driving would only occur in the event that a pile encounters an obstruction such as an old timber pile beneath the mud line, which is unlikely to occur. These piles will be preferentially driven with a vibratory driver. Therefore, Level B take for this activity is based on installation using vibratory driver. Level A take is based on installation using impact driving. For the purposes of calculating Level A take, as a proportion of Level B take, it is assumed that approximately 25 percent of the 176 harbor seals using Castro Rocks could approach and be subject to Level B harassment due to the limited amount of time impact driving is expected to occur as well as the size and location of the Level B isopleth (Figure 6–2 in application). Therefore, it is assumed that up to 44 individuals per day could be exposed when this activity is being conducted;

• *Vibratory driving and removal of the 36-inch steel pipe piles at Berth 4:* Isopleths for this vibratory driving encompass Castro Rocks, therefore it is assumed that all of the estimated 176 animals in the water, could be exposed when these piles are being driven at Berth 4;

• *Vibratory driving/extraction of the 14-inch H piles at Berth 2:* Isopleths for this vibratory driving encompass Castro Rocks, therefore is assumed that all of the 176 animals in the water could be exposed when this activity is being conducted at Berth 2; and

• *Vibratory removal of timber and concrete piles at Berths 1, 2 and 4:* Isopleths for this vibratory removal encompass Castro Rocks, therefore it is assumed that all of the estimated 176 animals in the water could be exposed during these activities.

In order to account for other individuals that may be foraging in the more distant part of the Level B harassment zone, additional take of harbor seal has been estimated based on other harbor seal populations in the Central Bay. Using the same data set (Codde, S. and S. Allen. 2013, 2015, and 2017) that was used for Castro Rocks, a population for the Central Bay of 167 harbor seals was established based on other Central Bay haulouts at Alcatraz and Yerba Buena Island. The area of the Central Bay (bound by the Golden Gate, Richmond Bridge, SFOBB, and adjoining coastline) is approximately 134 km^2, resulting in a harbor seal density of 1.25 animals per km^2. The population that hauls out at Castro Rocks is not included in this density estimate because of the proximity of the haulout site to the project and potential take of those harbor seals has been estimated separately using the methods described above. The estimated take based on the Central Bay density is added to the take estimated for the Castro Rocks population, as provided in Table 9 below. Also provided in Table 9 is the estimated Level A take for impact driving of the steel 14-inch H piles, which has been estimated by taking Level B take and multiplying it by the ratio of the Level A zone area to the Level B zone area. Level A take is not requested for vibratory driving.

TABLE 9—DAILY LEVEL A AND LEVEL B HARASSMENT ESTIMATE FOR PACIFIC HARBOR SEAL

Pile type	Level B zone (km^2)	Level A zone, minus exclusion zone (km^2)	Estimated Level B take per day			Estimated Level A take per day—total
			Central bay [1] (1.25 per km^2)	Project vicinity	Harbor seal—total	
Vibratory Driving						
14-inch steel H pile	190.55	NA	238.39	176	414.39	NA
36-inch steel pile	176.44	NA	220.55	176	396.55	NA
Timber/Concrete Pile Removal	7.14	NA	8.92	176	184.92	NA
Impact Driving						
14-inch steel H pile	1.36	0.10	*1.7	*44	45.7	3.36
24-inch concrete pile	0.04	0	0.05	17.6	17.65	0

*Only displayed to provide the calculation of Level A take. Level B take authorized for vibratory driving would cover any Level B take from occasional impact driving.

For impact pile driving of the 14-inch steel H piles, the PTS Zone is large enough to warrant a smaller exclusion zone and the authorization of some Level A harassment for harbor seal so that pile driving can be completed on schedule. A 35 meter shutdown zone (smaller than the Level A Zone) for this species would be established, but individuals that place themselves in the Level A zone but outside of the shut-down zone may experience Level A harassment, if they reside in that area for a long enough duration.

California Sea Lion

The estimated California seal lion density of 0.16 animals per km^2 previously described was used to calculate potential Level B exposures as shown in Table 10.

TABLE 10—DAILY LEVEL B HARASSMENT EXPOSURE ESTIMATE FOR CALIFORNIA SEA LION

Pile type	Level B zone (km^2)	Level B take estimate (based on Central Bay density of 0.16 animals per km^2)
Vibratory Driving		
14-inch steel H pile	190.55	30.48
36-inch steel pile	176.44	28.23

TABLE 10—DAILY LEVEL B HARASSMENT EXPOSURE ESTIMATE FOR CALIFORNIA SEA LION—Continued

Pile type	Level B zone (km²)	Level B take estimate (based on Central Bay density of 0.16 animals per km²)
Timber/Concrete Pile Removal	7.14	1.14
Impact Driving		
14-inch steel H pile 24-inch concrete pile 0.04 0.01.	*NA	*NA

*Level B take authorized for vibratory driving would cover any Level B take from occasional impact driving.

Harbor Porpoise

Based on monitoring conducted for the SFOBB project described previously, an in-water density of 0.17 animals per km² was estimated by Caltrans for this species (NMFS 2017b). Using this in-water density and the areas of potential harassment, take is estimated for harbor porpoise as provided in Table 11. Also provided in Table 11 is the estimated Level A take for impact driving, which has been estimated by taking Level B take and multiplying it by the ratio of the Level A zone area to the Level B zone area. A single harbor porpoise could be exposed to Level A harassment during impact driving or 14-inch steel H-piles as shown in Table 11. NMFS, however, conservatively proposes to authorize Level A take of four animals which is the average group size.

TABLE 11—DAILY LEVEL A AND LEVEL B HARASSMENT ESTIMATE FOR PACIFIC HARBOR PORPOISE

Pile type	Level B zone (km²)	Level A zone, minus exclusion zone (km²)	Level B estimate Central Bay in-water—0.17 per km²	Estimated Level A take per day
Vibratory Driving				
14-inch steel H pile	190.55	.....	32.39	NA
36-inch steel pile	176.44	.....	29.99	NA
Timber/Concrete Pile Removal	7.14	.....	1.21	NA
Impact Driving				
14-inch steel H pile	1.36	*0.32	*0.23	0.05
24-inch concrete pile	0.04	0	0.01	0

*Only displayed to provide the calculation of Level A take. Level B take authorized for vibratory driving would cover any Level B take from occasional impact driving.

For impact pile driving of the 14-inch H piles, the Level A Zone is large enough to warrant the authorization of some Level A. A 250 meter shutdown zone for this species would be established, but individuals that place themselves in the Level A zone but outside of the shut-down zone may experience Level A harassment, if they reside in that area for a long enough duration.

Northern Elephant Seal

Monitoring of marine mammals in the vicinity of the SFOBB produced an estimated density for northern elephant seal of 0.06 animal per km² (Caltrans, 2015b). Most sightings of northern elephant seal in San Francisco Bay occur in spring or early summer, and are less likely to occur during the periods of in-water work for this project. As a result, densities during pile driving for the planned action would be much lower. It is possible that a lone northern elephant seal may enter the Level B harassment area once per day during pile driving, for a total of 28 takes. Level A harassment of this species is not expected to occur and is not authorized by NMFS.

Northern Fur Seal

As noted previously, the incidence of northern fur seal in San Francisco Bay depends largely on oceanic conditions, with animals more likely to strand during El Niño events. The likelihood of El Niño conditions occurring in 2018 is currently low, with La Niña or neutral conditions expected to develop (NOAA, 2018). Given the low probability that fur seals would enter into the Bay and project area in 2018, Chevron has conservatively requested and NMFS has authorized10 fur seals takes by Level B harassment. Level A harassment of this species is not anticipated or authorized by NMFS.

Bottlenose Dolphin

When this species is present in San Francisco Bay, it is more typically found close to the Golden Gate. Recently, beginning in 2015, two individuals have been observed frequently in the vicinity of Oyster Point (GGCR, 2016; GGCR 2017; Perlman, 2017). The average reported group size for bottlenose dolphins is five. Reports show that a group normally comes into San Francisco Bay near Yerba Buena Island once per week for approximately 2-week

stints and then leaves the Bay (NMFS, 2017b). Chevron assumed groups of five individuals may enter San Francisco Bay and the ensonified area three times during separate two-week spans. Therefore, groups of 5 animals would potentially be exposed at a rate of once per week over six weeks, resulting in up to 30 Level B exposures. As such, NMFS authorizes the take by Level B harassment of 30 bottlenose dolphins. Although a small Level A zone for mid-frequency cetaceans is estimated during impact driving, marine mammal monitoring of the shutdown would ensure that take by Level A harassment does not occur.

Gray Whale

Gray whales are the only whale species that travels far into San Francisco bay with any regularity. They occasionally enter the Bay during their northward migration period, and are most often sighted in the Bay between February and May. Most venture only about 2 to 3 km (about 1–2 mi) past the Golden Gate, but gray whales have occasionally been sighted as far north as San Pablo Bay. Pile driving is not anticipated to occur during the February through May timeframe and gray whales are not likely to be present at other times of year. In the very unlikely event that a gray whale or pair of gray whales makes its way close to the project area while pile driving activities are under way, Chevron has requested take by Level B harassment of up to two (2) gray whales per year. NMFS agrees and has authorized the take of 2 gray whales by Level B harassment. No Level A take is authorized.

Tables 12 and 13 summarize the estimate of Level B and Level A harassment, respectively, for each species by pile driving activity for the 2018 construction season. For harbor seals, sea lions, harbor porpoise and elephant seals, the Level B harassment estimates are based on the number of individuals assumed to be exposed per day, the number of days of pile driving expected based on an average installation rate. The Level A harassment estimates are derived from the Level B harassment estimates by taking the Level B harassment total and multiplying it by the fractional ratio of the area of the Level A zone to the Level B zone.

TABLE 12—TOTAL ESTIMATED TAKE BY LEVEL B HARASSMENT BY SPECIES AND PILE TYPE

Pile type	Pile driver type	Number of piles	Number of driving days	Species						
				Harbor seal	CA sea lion	Harbor porpoise	Gray whale *	N. elephant seal	N. fur seal *	Bottlenose dolphin *
36-inch steel template pile **.	Vibratory	8	2	793.1	56.46	59.98	NA	2	NA	NA
Concrete pile removal	Vibratory	5	1	184.92	1.14	1.21	NA	1	NA	NA
24-inch concrete	Impact	8	8	141.2	0.08	0.08	NA	8	NA	NA
14-inch H pile installation	Impact/Vibratory	36	12	4,972.68	365.76	388.68	NA	12	NA	NA
Timber pile removal	Vibratory	53	5	924.6	5.7	6.05	NA	5	NA	NA
Total Take by Species (2018).				7,017	429	456	2	28	10	30

* Take is not calculated by activity type for these species, only a total is given.
** Only the installation of the template piles will occur in 2018. Take associated with their removal will be requested in a subsequent IHA.
*** These piles will be preferentially driven with a vibratory driver, which would have a larger Level B zone than installation with an impact driver. Thus, Level B take for this species is based on installation using vibratory driver, and not an impact driver.

TABLE 13—AUTHORIZED TAKE BY LEVEL A HARASSMENT

Pile type	Pile driver type	Number of driving days	Harbor seal	Harbor porpoise
36-inch steel template pile	Vibratory	2	0	0
Concrete pile removal	Vibratory	1	0	0
24-inch concrete	Impact	8	0	0
14-inch H pile installation	Impact/Vibratory	12	40	* 4
Timber pile removal	Vibratory	5	0	0
Total Take			40	4

* Harbor porpoise takes were increased to 4 to account for average group size.

Table 14 provides a summary of authorized Level A and Level B takes as well as the percentage of a stock authorized for take.

TABLE 14—AUTHORIZED TAKE AND PERCENTAGE OF STOCK OR POPULATION

Species	Stock	Authorized Level A takes	Authorized Level B takes	Percent population
Harbor seal	California	40	6,977	22.6%
California sea lion	Eastern U.S.		429	<0.01
Harbor porpoise	San Francisco—Russian River	4	451	4.5
Northern elephant seal	California Breeding		28	<0.01
Gray whale	Eastern North Pacific		2	<0.01
Northern fur seal	California		10	<0.01
Bottlenose Dolphin	California Coastal		30	6.6

Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations.

Mitigation for Marine Mammals and Their Habitat

The following measures would apply to Chevron's mitigation requirements:

• *Seasonal Restriction*—To minimize impacts to listed fish species, pile-driving activities would occur between June 1 and November 30;

• *Daylight Construction Period*—Work would occur only during daylight hours (7:00 a.m. to 7:00 p.m.) when visual marine mammal monitoring can be conducted;

• *Establishment of Shutdown Zone*—For all pile driving and removal activities, Chevron will establish a shutdown zone. The purpose of a shutdown zone is generally to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). A shutdown zone will be established which will include all or a portion of the area where underwater SPLs are expected to reach or exceed the cumulative SEL thresholds for Level A harassment as provided in Table 7. The shutdown isopleths for pinnipeds (harbor seals, California sea lion, Northern elephant seal, northern fur seal) and mid-frequency cetaceans (bottlenose dolphins) will be set at 15 meters during vibratory driving. A 30 meter shutdown zone during vibratory driving will be established for low-frequency cetaceans (gray whale) and high-frequency cetaceans (harbor porpoise). During impact driving the shutdown zones will be set at 250 meters for high-frequency cetaceans (harbor porpoise), 350 meters for low-frequency cetaceans (gray whales), and 35 meters for pinnipeds (harbor seal, California sea lion, Northern elephant seal, northern fur seal) and mid-frequency cetaceans (bottlenose dolphin);

• *10-Meter Shutdown Zone*—During the in-water operation of heavy machinery (*e.g.,* barge movements), a 10-m shutdown zone for all marine mammals will be implemented. If a marine mammal comes within 10 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions;

• *Establishment of Monitoring Zones for Level A and Level B*—Chevron will establish and monitor Level A harassment zones during impact driving for harbor seal extending to 183 meters and harbor seals and extending to 408 m for harbor porpoises. These are areas beyond the shutdown zone in which animals could be exposed to sound levels that could result in PTS. Chevron will also establish and monitor Level B harassment zones which are areas where SPLs are equal to or exceed the 160 dB rms threshold for impact driving and the 120 dB rms threshold during vibratory driving and extraction. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project area outside the shutdown zone and thus prepare for a potential cease of activity should the animal enter the shutdown zone. The Level B zones are depicted in Table 11. As shown, the largest Level B zone is equal to 190.55 km^2, making it impossible for Protected Species Observers (PSOs) to view the entire harassment area. Due to this, Level B exposures will be recorded and extrapolated based upon the number of observed take and the percentage of the Level B zone that was not visible;

• S*oft Start*—The use of a soft-start procedure are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. Chevron shall use soft start techniques when impact pile driving. Soft start requires contractors to provide an initial set of strikes at reduced energy, followed by a thirty-second waiting period, then two subsequent reduced energy strike sets;

• *Pile Caps/Cushions*—Chevron will employ the use of pile caps or cushions as sound attenuation devices to reduce impacts from sound exposure during impact pile driving;

• *Pre-Activity Monitoring*—Pre-activity monitoring shall take place from 30 minutes prior to initiation of pile driving activity and post-activity monitoring shall continue through 30 minutes post-completion of pile driving activity. Pile driving may commence at the end of the 30-minute pre-activity monitoring period, provided observers have determined that the shutdown zone is clear of marine mammals, which includes delaying start of pile driving activities if a marine mammal is sighted in the zone, as described below;

• If a marine mammal approaches or enters the shutdown zone during activities or pre-activity monitoring, all pile driving activities at that location shall be halted or delayed, respectively. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not resume or commence until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone and 15 minutes have passed without re-detection of the animal. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes; and

• *Non-authorized Take Prohibited*—If a species for which authorization has not been granted or a species for which authorization has been granted but the authorized takes are met, is observed approaching or within the monitoring zone, pile driving and removal activities must shut down immediately using delay and shut-down procedures. Activities must not resume until the animal has been confirmed to have left

the area or an observation time period of 15 minutes has elapsed.

Based on our evaluation of the applicant's planned measures, as well as other measures considered by NMFS, NMFS has determined that the required mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Visual Monitoring

The following visual monitoring measures are required as part of the issued IHA.

- One day of biological monitoring would occur within one week before the project's start date to establish baseline observations;
- Monitoring distances, in accordance with the identified shutdown, Level A, and Level B zones, will be determined by using a range finder, scope, hand-held global positioning system (GPS) device or landmarks with known distances from the monitoring positions;
- Monitoring locations will be established at locations offering best views of the monitoring zone;
- Monitoring will be continuous unless the contractor takes a break longer than 2 hours from active pile driving, in which case, monitoring will be required 30 minutes prior to restarting pile installation;
- For in-water pile driving, under conditions of fog or poor visibility that might obscure the presence of a marine mammal within the shutdown zone, the pile in progress will be completed and then pile driving suspended until visibility conditions improve;
- At least two PSOs will be actively scanning the monitoring zone during all pile driving activities;
- Monitoring of pile driving shall be conducted by qualified PSOs (see below), who shall have no other assigned tasks during monitoring periods. Chevron shall adhere to the following conditions when selecting observers:

(1) Independent PSOs shall be used (*i.e.,* not construction personnel);

(2) At least one PSO must have prior experience working as a marine mammal observer during construction activities;

(3) Other PSOs may substitute education (degree in biological science or related field) or training for experience; and

(4) Chevron shall submit PSO CVs for approval by NMFS;

- Chevron will ensure that observers have the following additional qualifications:

(1) Ability to conduct field observations and collect data according to assigned protocols;

(2) Experience or training in the field identification of marine mammals, including the identification of behaviors;

(3) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

(4) Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and

(5) Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving and removal activities. It will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets. Specifically, the report must include:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Deviation from initial proposal in pile numbers, pile types, average driving times, etc.
- Weather parameters (*e.g.,* percent cover, visibility);
- Water conditions (*e.g.,* sea state, tide state);
- For each marine mammal sighting the following must be recorded:

(1) Species, numbers, and, if possible, sex and age class of marine mammals;

(2) Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;

(3) Location and distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point; and

(4) Estimated amount of time that the animals remained in the Level B zone.

- Description of implementation of mitigation measures within each monitoring period (*e.g.,* shutdown or delay);
- Other human activity in the area.
- A summary of the following must be included in the report.

(1) Total number of individuals of each species detected within the Level A and Level B Zones, and estimated take extrapolated across entire Level B zone; and

(2) Daily average number of individuals of each species

(differentiated by month as appropriate) detected within the Level B Zone, and estimated take extrapolated across entire Level B zone.

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA (if issued), such as an injury, serious injury or mortality, Chevron would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator. The report would include the following information:

- Description of the incident;
- Environmental conditions (*e.g.,* Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Chevron to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Chevron would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that Chevron discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition as described in the next paragraph), Chevron would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Chevron to determine whether modifications in the activities are appropriate.

In the event that Chevron discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Chevron would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator within 24 hours of the discovery. Chevron would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Hydroacoustic Monitoring

Sound Source Verification (SSV) testing of would be conducted under this IHA. The purpose of the planned acoustic monitoring plan is to collect underwater sound-level information at both near and distant locations during vibratory pile extraction and installation and impact pile installation. The plan provides a protocol for hydroacoustic measurements during pile driving operations. Acoustic monitoring would be conducted on a minimum of two of each pile type. Since little data exist for source levels associated with installation of 24-inch square concrete piles (including data on single strike sound exposure level metrics) Chevron would conduct in-situ measurements during installation of eight piles. The SSV testing would be conducted by an acoustical firm with prior experience conducting SSV testing. Final results would be sent to NMFS. Findings may be used to establish Level A and Level B isopleths during impact and vibratory driving. Any alterations to the shutdown or harassment zones based on testing data must be approved by NMFS. The Hydroacoustic Monitoring Plan is contained on the following NMFS website*: https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.*

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

Pile driving and extraction associated with Chevron's WMEP project as outlined previously have the potential to injure, disturb or displace marine mammals. Specifically, the specified activities may result in Level B harassment (behavioral disturbance) for seven marine mammal species authorized for take from underwater sound generated during pile driving operations. Level A harassment in the form of PTS may also occur to limited numbers of two species. No serious injuries or mortalities are anticipated to occur as a result of Chevron's pile driving activities.

A limited number of animals (40 harbor seals and 4 harbor porpoises) could experience Level A harassment in the form of PTS if they stay within the Level A harassment zone during impact driving of 24-inch steel H-piles. Installation of these piles would occur over eight days and impact driving will not be the primary method of installation. The piles will mainly be installed using only vibratory driving. Impact driving will be used only if the vibrated pile encounters an obstruction such as an old sunken pile. It is unlikely that this would occur for all four piles projected to be installed each driving day. An assumption of four piles per day was used to calculate Level A zone sizes. If four piles did require impact installation on a single day it is unlikely that the same individual marine mammal would be within the relatively small Level A zone during the installation of every pile. In most instances impact driving will not be required at all. Furthermore, the degree of injury is expected to be mild and is not likely to affect the reproduction or

survival of the individual animals. It is expected that, if hearing impairments occurs, most likely the affected animal would lose a few dB in its hearing sensitivity, which in most cases is not likely to affect its survival and recruitment.

The Level B takes that are anticipated and authorized are expected to be limited to short-term behavioral harassment. Marine mammals present near the action area and taken by Level B harassment would most likely show overt brief disturbance (*e.g.,* startle reaction) and avoidance of the area from elevated noise level during pile driving. Repeated exposures of individuals to levels of sound that may cause Level B harassment are unlikely to significantly disrupt foraging behavior. Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in fitness for the affected individuals, and thus would not result in any adverse impact to the stock as a whole.

The project is not expected to have significant adverse effects on affected marine mammal habitat. The activities may cause fish to leave the area temporarily. This could impact marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities and the relatively small area of affected habitat, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

The likelihood that marine mammals will be detected by trained observers is high under the environmental conditions described for the project. The employment of the soft-start mitigation measure would also allow marine mammals in or near the shutdown and Level A zone zones to move away from the impact driving sound source. Therefore, the mitigation and monitoring measures are expected to reduce the potential for injury and reduce the amount and intensity of behavioral harassment. Furthermore, the pile driving activities analyzed here are similar to, or less impactful than, numerous construction activities conducted in similar locations which have taken place with no reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality is anticipated or authorized;
- Anticipated incidences of Level A harassment would be in the form of a small degree of PTS to a limited number of animals;
- Anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior;
- The relatively short and intermittent duration of in-water construction activities;
- The small percentage of the stock that may be affected by project activities (<22.8 percent for all stocks); and
- Efficacy of mitigation measures is expected to minimize the likelihood and severity of the level of harassment.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the required monitoring and mitigation measures, NMFS finds that the total marine mammal take from the planned activity will have a negligible impact on all affected marine mammal stocks or species.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 14 depicts the number of animals that could be exposed to Level A and Level B harassment from work associated with Chevron's project. The analysis provided indicates that authorized takes account for no more than 22.6 percent of the populations of the stocks that could be affected. These are small numbers of marine mammals relative to the sizes of the affected stocks.

Based on the analysis contained herein of the planned (including the required mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Authorization

NMFS has issued an IHA to Chevron to take seven species of marine mammal incidental to pile driving and removal activities at Chevron's Long Wharf from June 1, 2018 through May 31, 2019 provided the previously mentioned

mitigation, monitoring, and reporting requirements are incorporated.

Dated: June 7, 2018.

Elaine T. Saiz,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–12629 Filed 6–12–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Availability of Software and Documentation for Licensing

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Availability of Mi-Std-1553B decoder software and documentation for licensing.

SUMMARY: Pursuant to the provisions of Section 801 of Public Law 113–66 (2014 National Defense Authorization Act) as extended by Section 818 of Public Law 114–328; the Department of the Air Force announces the availability of Mil-Std-1553B decoder software and related documentation for decoding the interaction of bus controllers (BC) and remote terminals (RT) using field programmable gate array (FPGA) implementation technology.

ADDRESSES: Licensing interests should be sent to: Air Force Research Laboratory, Sensors Directorate, AFRL/RYO, 2241 Avionics, Wright-Patterson AFB, OH 45433; Facsimile: (937) 656–4676.

FOR FURTHER INFORMATION CONTACT: Air Force Research Laboratory, Sensors Directorate, AFRL/RYO, 2241 Avionics, Wright-Patterson AFB, OH 45433; Facsimile: (937) 656–4676.

SUPPLEMENTARY INFORMATION: The Mil-Std-1553B decoder is written in the VHDL programming language and is vendor agnostic. This software is useful for implementation in technologies that need to passively collect, monitor or process existing Mil-Std-1553B bus interactions in real-time.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2018–12716 Filed 6–12–18; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

2018 Public Interface Control Working Group and Forum for the Navstar Gps Public Documents

AGENCY: Global Positioning System Directorate (GPSD), Department of the Air Force.

ACTION: Meeting notice.

SUMMARY: This notice informs the public that the Global Positioning Systems (GPS) Directorate will host the 2018 Public Interface Control Working Group and Open Public Forum on September 12, 2018 for the following NAVSTAR GPS public documents: IS–GPS–200 (Navigation User Interfaces), IS–GPS–705 (User Segment L5 Interfaces), IS–GPS–800 (User Segment L1C Interface), ICD–GPS–240 (NAVSTAR GPS Control Segment to User Support Community Interfaces), and ICD–GPS–870 (NAVSTAR GPS Control Segment to User Support Community Interfaces). Additional logistical details can be found below.

DATES: 0830–1600 PST, 12 September 2018.

ADDRESSES: TASC/Engility, 100 N Sepulveda Blvd., El Segundo, CA 90245, The Great Room; Dial In: 310–653–2663 Meeting ID: 8337375 Password: 123456.

FOR FURTHER INFORMATION CONTACT: 1Lt Michael Telcide (310–653–4191) or Mr. Daniel Godwin (310–653–3163); *SMCGPER@us.af.mil.*

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to update the public on GPS public document revisions and collect issues/comments for analysis and possible integration into future GPS public document revisions. All outstanding comments on the GPS public documents will be considered along with the comments received at this year's open forum in the next revision cycle. The 2018 Interface Control Working Group and Open Forum are open to the general public. For those who would like to attend and participate, we request that you register no later than August 30, 2018. Please send the registration information to *SMCGPER@us.af.mil,* providing your name, organization, telephone number, email address, and country of citizenship.

Comments will be collected, catalogued, and discussed as potential inclusions to the version following the current release. If accepted, these changes will be processed through the formal directorate change process for IS–GPS–200, IS–GPS–705, IS–GPS–800, ICD–GPS–240, and ICD–GPS–870. All comments must be submitted in a Comments Resolution Matrix. This form along with current versions of the documents and the official meeting notice are posted at: *http://www.gps.gov/technical/icwg/meetings/2018/.*

Please submit comments to the SMC/GPS Requirements (SMC/GPER) mailbox at *SMCGPER@us.af.mil* by August 24, 2018. Special topics may also be considered for the Public Open Forum. If you wish to present a special topic, please submit any materials to SMC/GPER no later than August 1, 2018. For more information, please contact 1Lt Michael Telcide at 310–653–4191 or Mr. Daniel Godwin at 310–653–3640.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2018–12715 Filed 6–12–18; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Full-Service Community Schools Program

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2018 for the Full-Service Community Schools (FSCS) program, Catalog of Federal Domestic Assistance (CFDA) number 84.215J.

DATES:

Applications Available: June 13, 2018.

Deadline for Notice of Intent to Apply: June 28, 2018.

Date of Pre-Application Webinar: June 20, 2018. For information about the pre-application webinar, visit the FSCS website at: *https://innovation.ed.gov/what-we-do/parental-options/full-service-community-schools-program-fscs/applicant-info-and-eligibility/.*

Deadline for Transmittal of Applications: July 13, 2018.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

FOR FURTHER INFORMATION CONTACT: Michelle Johnson Armstrong, U.S.

Department of Education, 400 Maryland Avenue SW, Room 4W214, Washington, DC 20202. Telephone: (202) 205–1729. Email: *FSCS@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.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The FSCS program is newly authorized by sections 4621–4623 and 4625 of the Elementary and Secondary Education Act, as amended by the Every Student Succeeds Act (ESEA). This program provides support for the planning, implementation, and operation of full-service community schools that improve the coordination, integration, accessibility, and effectiveness of services for children and families, particularly for children attending high-poverty schools, including high-poverty rural schools.

Background: Community school strategies hold considerable promise for creating good schools for all students, but especially those living in poverty. This is of particular relevance in the face of growing achievement and opportunity gaps at a moment in which the Nation faces a decentralization of decision making about the use of Federal dollars.[1]

The growing interest in community schools, also known as full-service community schools, coupled with this competition, present an opportunity for nationwide school improvement. While earlier versions of the ESEA authorized community schools as a strategy and allowable activity, the reauthorized ESEA offers continued flexibilities at the State and district levels to implement strategies supported by community schools, such as coordination of school and community resources (ESEA sections 1114(b)(5) and 1115(b)(2)) and afterschool programming and support for a community school coordinator (ESEA section 4108(a)(5)(H)). If a State or district lacks the resources to implement community schools at scale, it can productively begin in neighborhoods where community schools are most needed and, therefore, students are most likely to benefit. The Department, through the FSCS program, provides catalytic support for the planning, implementation, operation, and coordination of effective services for children and families, particularly those in high-poverty urban and rural areas at the local level. According to a 2017 report, ''a well-implemented community school leads to improvement in student and school outcomes and contributes to meeting the educational needs of low-achieving students in high-poverty schools. Strong research reinforces the efficacy of integrated student supports, expanded learning time and opportunities, and family and community engagement as intervention strategies.'' [2]

Over the last decade, the field has observed a wide range of practices coordinated and implemented in full-service community schools. Assuming stable leadership and a strong instructional program, full-service community schools have been associated with improved attendance and student achievement,[3] increased family and community engagement,[4] and improved student behavior and youth development.[5] In addition, research suggests that system-wide support is critical to developing, implementing, and sustaining effective full-service community schools; full-service community schools have greater potential for impact when strong infrastructures are in place to support sustaining the overall effort and expanding the number of FSCS sites throughout a local educational agency (LEA) (as defined in this notice).

Priorities: This notice contains one absolute priority and four competitive preference priorities. In accordance with 34 CFR 75.105(b)(2)(iv), the absolute priority is from section 4625(b)(1)(A) of the ESEA. The competitive preference priorities are from sections 4625(b)(1)(B), 4625(b)(2), 4625(b)(3), and 8101(21)(A)(i) of the ESEA and 34 CFR 75.226(c).

Absolute Priority: For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Eligible entities that will serve a minimum of two or more full-service community schools eligible for a schoolwide program (as defined in this notice) under section 1114(b) of the ESEA as part of a community- or district-wide strategy.

Competitive Preference Priorities: For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award an additional two points to an application that meets Competitive Preference Priority 1 and we award an additional point to an application that meets any of Competitive Preference Priority 2, Competitive Preference Priority 3, or Competitive Preference Priority 4, for a maximum of five additional points under the competitive preference priorities. Applicants may apply under any, all, or none of the competitive preference priorities. Applicants must identify the priorities they are seeking points for in order to receive those points.

These priorities are:

Competitive Preference Priority 1—Rural Districts-Small and Rural or Rural and Low-Income. (0 or 2 points)

The Secretary gives priority to applicants that include a LEA that is currently eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under title V, part B (sections 5211 and 5221) of the ESEA. Applicants may determine whether a particular LEA is eligible for these programs by referring to information on the following Department websites: For the SRSA program, *https://www2.ed.gov/programs/reapsrsa/eligible16/index.html* and for the RLIS program, *https://www2.ed.gov/programs/reaprlisp/eligibility.html.*

Note: An LEA includes a public charter school that operates as an LEA.

Competitive Preference Priority 2—Broadly Representative Consortiums. (0 or 1 point)

The Secretary gives priority to an applicant that demonstrates that it is a consortium comprised of a broad representation of stakeholders.

Competitive Preference Priority 3—History of Effectiveness. (0 or 1 point)

The Secretary gives priority to an applicant that demonstrates that it is a

[1] Maier, A., Daniel, J., Oakes, J., & Lam, L. (2017). *Community Schools as an Equitable School Improvement Strategy: A Review of the Evidence.*

[2] Maier, A., Daniel, J., Oakes, J., & Lam, L. (2017). *Community Schools as an Equitable School Improvement Strategy: A Review of the Evidence. Learning Policy Institute,* December 2017.

[3] Krenichyn, K., Clark, H., & Benitez, L. (2008). *Children's Aid Society 21st Century Community Learning Centers After-School Programs at Six Middle Schools: Final Report of a Three-Year Evaluation, 2004–2007.* New York: ActKnowledge.

[4] Quinn, J., & Dryfoos, J. (2009). *Freeing teachers to teach: Students in full-service community schools are ready to learn. American Educator,* Summer 2009: 16–21.

[5] Whalen, S. (2007). *Three Years Into Chicago's Community Schools Initiative (CSI): Progress, Challenges, and Lessons Learned.* Chicago: University of Illinois at Chicago. Retrieved April 9, 2010. *www.aypf.org/documents/CSI_ThreeYearStudy.pdf.*

consortium with a history of effectiveness.

Competitive Preference Priority 4—Evidence-Based Activities, Strategies, or Interventions. (0 or 1 point)

The Secretary gives priority to an application that is supported by promising evidence (as defined in this notice).

Definitions: The definitions for ''Community-based organization,'' ''Eligible entity,'' ''Full-service community school,'' ''Local educational agency,'' ''Pipeline services,'' and ''State educational agency'' are from sections 4622 and 8101 of the ESEA. The definitions for ''Baseline,'' ''Experimental study,'' ''Nonprofit,'' ''Performance measure,'' ''Performance target,'' ''Project,'' ''Project component,'' ''Promising evidence,'' ''Relevant outcome,'' ''Quasi-experimental design study,'' and ''What Works Clearinghouse Handbook'' are from 34 CFR 77.1. The definition of ''School eligible for a schoolwide program'' is from 34 CFR 200.25(b).

Baseline means the starting point from which performance is measured and targets are set.

Community-based organization means a public or private nonprofit (as defined in this notice) organization of demonstrated effectiveness that—

(a) Is representative of a community or significant segments of a community; and

(b) Provides educational or related services to individuals in the community.

Eligible entity means a consortium of one or more LEAs; or the Bureau of Indian Education; and one or more community-based organizations, nonprofit organizations, or other public or private entities.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbook (as defined in this notice):

(a) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(b) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(c) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Full-service community school means a public elementary school or secondary school that—

(a) Participates in a community-based effort to coordinate and integrate educational, developmental, family, health, and other comprehensive services through community-based organizations and public and private partnerships; and

(b) Provides access to such services in school to students, families, and the community, such as access during the school year (including before- and after-school hours and weekends), as well as during the summer.

Local educational agency (LEA) means:

(a) In General. A public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or of or for a combination of school districts or counties that is recognized in a State as an administrative agency for its public elementary schools or secondary schools.

(b) Administrative Control and Direction. The term includes any other public institution or agency having administrative control and direction of a public elementary school or secondary school.

(c) Bureau of Indian Education Schools. The term includes an elementary school or secondary school funded by the Bureau of Indian Education but only to the extent that including the school makes the school eligible for programs for which specific eligibility is not provided to the school in another provision of law and the school does not have a student population that is smaller than the student population of the local educational agency receiving assistance under the ESEA with the smallest student population, except that the school shall not be subject to the jurisdiction of any State educational agency (as defined in this notice) other than the Bureau of Indian Education.

(d) Educational Service Agencies. The term includes educational service agencies and consortia of those agencies.

(e) State Educational Agency. The term includes the State educational agency in a State in which the State educational agency is the sole educational agency for all public schools.

Nonprofit, as applied to an agency, organization, or institution, means that it is owned and operated by one or more corporations or associations whose net earnings do not benefit, and cannot lawfully benefit, any private shareholder or entity.

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance.

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project.

Pipeline services means a continuum of coordinated supports, services, and opportunities for children from birth through entry into and success in postsecondary education, and career attainment. Such services shall include, at a minimum, strategies to address through services or programs (including integrated student supports) the following:

(a) High-quality early childhood education programs.

(b) High-quality school and out-of-school-time programs and strategies.

(c) Support for a child's transition to elementary school, from elementary school to middle school, from middle school to high school, and from high school into and through postsecondary education and into the workforce, and including any comprehensive readiness assessment determined necessary.

(d) Family and community engagement and supports, which may include engaging or supporting families at school or at home.

(e) Activities that support postsecondary and workforce readiness, which may include job training, internship opportunities, and career counseling.

(f) Community-based support for students who have attended the schools in the area served by the pipeline, or students who are members of the community, facilitating their continued

connection to the community and success in postsecondary education and the workforce.

(g) Social, health, nutrition, and mental health services and supports.

(h) Juvenile crime prevention and rehabilitation programs.

Project means the activity described in an application.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(a) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(b) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(c) A single study assessed by the Department, as appropriate, that—

(i) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(ii) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

School eligible for a schoolwide program means any school eligible under 34 CFR 200.25(b) to operate a school-wide program.

State educational agency (SEA) means the agency primarily responsible for the State supervision of public elementary schools and secondary schools.

What Works Clearinghouse Handbook (WWC Handbook) means the standards and procedures set forth in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (incorporated by reference, see 34 CFR 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbook documentation.

Application Requirements: The following requirements are from section 4625(a) of the ESEA. In order to receive funding, an applicant must include the following in its application:

(a) A description of the eligible entity.

(b) A memorandum of understanding among all partner entities in the eligible entity that will assist the eligible entity to coordinate and provide pipeline services and that describes the roles the partner entities will assume.

(c) A description of the capacity of the eligible entity to coordinate and provide pipeline services at two or more full-service community schools.

(d) A comprehensive plan that includes descriptions of the following:

(i) The student, family, and school community to be served, including demographic information.

(ii) A needs assessment that identifies the academic, physical, nonacademic, health, mental health, and other needs of students, families, and community residents.

(iii) Annual measurable performance objectives and outcomes, including an increase in the number and percentage of families and students targeted for services each year of the program, in order to ensure that children are—

(A) Prepared for kindergarten;

(B) Achieving academically; and

(C) Safe, healthy, and supported by engaged parents.

(iv) Pipeline services, including existing and additional pipeline services, to be coordinated and provided by the eligible entity and its partner entities, including an explanation of—

(A) Why such services have been selected;

(B) How such services will improve student academic achievement; and

(C) How such services will address the annual measurable performance objectives and outcomes described above.

(v) Plans to ensure that each full-service community school site has a full-time coordinator of pipeline services at such school, including a description of the applicable funding sources, plans for professional development for the personnel managing, coordinating, or delivering pipeline services, and plans for joint utilization and management of school facilities.

(vi) Plans for annual evaluation based upon attainment of the performance objectives and outcomes described above.

(vii) Plans for sustaining the programs and services described in the application after the grant period.

(e) An assurance that the eligible entity and its partner entities will focus services on schools eligible for a schoolwide program under section 1114(b) of the ESEA.

Applications that do not address the application requirements are not eligible for funding and will not be reviewed.

Program Authority: 20 U.S.C. 7275.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $7,500,000.

Estimated Range of Awards: $275,000–$500,000 for each 12-month budget period; $1,375,000–$2,500,000 for the entire project period.

Estimated Average Size of Awards: $450,000 for each 12-month period.

Maximum Award: We will not make an award exceeding $2,500,000 for the entire project period.

Minimum Award: The Secretary may not award a grant under this subpart for activities described in this section to an eligible entity in an amount that is less than $75,000 for each year of the grant.

Estimated Number of Awards: 14–17.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* A consortium of—

(a) (i) One or more LEAs; or

(ii) The Bureau of Indian Education; and

(b) one or more community-based organizations, nonprofit organizations, or other public or private entities.

A consortium must comply with the provisions governing group applications in 34 CFR 75.127 through 75.129.

2. a. *Cost Sharing or Matching:* To be eligible for an award, a portion of the services provided by the applicant must be supported through non-Federal contributions, either in cash or in-kind donations. The applicant must propose the amount of cash or in-kind resources to be contributed for each year of the grant. The Bureau of Indian Education may meet the matching requirement using funds from other Federal sources.

b. *Supplement not Supplant:* This program is subject to supplement-not-supplant funding requirements. Grantees must use FSCS grant funds to supplement, and not supplant, any other Federal, State, and local funds that would otherwise have been available to carry out activities authorized under section 4625 of the ESEA.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Planning:* Interagency collaborative efforts are highly complex undertakings that require extensive planning and communication among partners and key stakeholders. Partnerships should be based on identified needs and organized around a set of mutually defined results and outcomes. Applicants under this program may not use more than 10 percent of the total amount of grant funds for planning purposes during the first year of the grant. Funding received by grantees during the remainder of the project period must be devoted to program implementation.

5. *Use of Funds:* Grantees must use FSCS grant funds to: (1) Coordinate not less than three existing pipeline services, as of the date their grants are awarded, and provide not less than two additional pipeline services, at two or more public elementary schools or secondary schools; (2) to the extent practicable, integrate multiple pipeline services into a comprehensive and coordinated continuum to achieve the annual measurable performance objectives and outcomes under section 4625(a)(4)(C) of the ESEA to meet the holistic needs of children; and (3) if applicable, coordinate and integrate services provided by community-based organizations and government agencies with services provided by specialized instructional support personnel.

6. *Evaluation:* Grantees must conduct an annual evaluation of their project's progress in meeting the purpose of the FSCS program set out in section 4621(2) of the ESEA and use those evaluations to refine and improve activities carried out under the grant and the annual measurable achievement objectives and outcomes set out in section 4625(a)(4)(C). Grantees must make the results of their annual evaluation publicly available, including by providing public notice of the availability of such results.

Note: Nothing in section 4625 of the ESEA shall be construed to alter or otherwise affect the rights, remedies, and procedures afforded school or LEA employees under Federal, State, or local laws (including applicable regulations or court orders) under the terms of collective bargaining agreements, memoranda of understanding, or other agreements between such employees and their employers.

IV. Application and Submission Information

1. *Application Submission Instructions:* For information on how to submit an application please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the FSCS program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8 (a), we waive intergovernmental review in order to make awards by the end of FY 2018.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 150 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to develop a more efficient process for reviewing grant applications if it has a better understanding of the number of entities that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify the Department of the applicant's intent to submit an application for funding by sending a short email message indicating the applicant's intent to submit an application for funding. The email need not include information regarding the content of the proposed application, only the applicant's intent to submit it. This email notification

should be sent to *FSCS@ed.gov* with ''INTENT TO APPLY'' in the subject line by June 28, 2018. Applicants that do not notify us of their intent to apply may still apply for funding.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following the title of the specific selection criterion. Each criterion also includes the factors that reviewers will consider in determining the extent to which an applicant meets the criterion.

Points awarded under these selection criteria are in addition to any points an applicant earns under the competitive preference priorities in this notice. The maximum score that an application may receive under the competitive preference priorities and the selection criteria is 105 points.

The selection criteria are as follows:

(a) *Quality of the Project Design* (up to 15 points).

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers—

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

(b) *Quality of the Project Services* (up to 25 points).

The Secretary considers the quality of the services to be provided by the proposed project. In determining the quality of project services, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. In addition, the Secretary considers the following—

(1) The likely impact of the services to be provided by the proposed project on the intended recipients of those services.

(2) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

(c) *Adequacy of Resources* (up to 15 points).

The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers the following factors—

(1) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project;

(2) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits.

(d) *Quality of the Management Plan* (up to 20 points).

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors—

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(2) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(e) *Quality of the Project Evaluation* (up to 25 points).

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors—

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* We have established one performance measure for the FSCS program: The percentage and number of individuals targeted for services and who receive services during each year of the project period.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations 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 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.

Dated: June 8, 2018.

James C. Blew,

Acting Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2018–12701 Filed 6–12–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education is issuing a notice inviting applications for new awards for fiscal year (FY) 2018 for Personnel Development to Improve Services and Results for Children with Disabilities—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel, Catalog of Federal Domestic Assistance (CFDA) number 84.325D.

DATES:

Applications Available: June 13, 2018.

Deadline for Transmittal of Applications: July 30, 2018.

Deadline for Intergovernmental Review: September 26, 2018.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

FOR FURTHER INFORMATION CONTACT: Celia Rosenquist, U.S. Department of Education, 400 Maryland Avenue SW, Room 5146, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7373.

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.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for personnel preparation in special education, early

intervention, related services, and regular education to work with children, including infants and toddlers, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

Priorities: This competition includes two absolute priorities and one competitive preference priority. In accordance with 34 CFR 75.105(b)(2)(v), Absolute Priority 1 is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1462 and 1481). Absolute Priority 2 and the competitive preference priority are from the Secretary's Final Supplemental Priorities and Definitions for Discretionary Grant Programs, published in the **Federal Register** on March 2, 2018 (83 FR 9096) (Supplemental Priorities).

Absolute Priorities: For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet these priorities.

These priorities are:

Absolute Priority 1—Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel

Background

The mission of the Office of Special Education and Rehabilitative Services (OSERS) is to improve early childhood, educational, and employment outcomes and raise expectations for all people with disabilities, their families, their communities, and the Nation.

The purpose of this Preparation of Special Education, Early Intervention, and Related Services Leadership Personnel competition is to support existing doctoral degree programs that prepare special education, early intervention, and related services personnel who are well-qualified for, and can act effectively in, leadership positions as researchers and preparers of special education, early intervention, and related services personnel in institutions of higher education (IHEs), or as leaders in national organizations, State educational agencies (SEAs), lead agencies (LAs), local educational agencies (LEAs), early intervention services programs (EIS programs), or schools. Absolute Priority 1 is consistent with the Supplemental Priorities, specifically, Supplemental Priority 5—Meeting the Unique Needs of Students and Children With Disabilities and/or Those with Unique Gifts and Talents; and Supplemental Priority 8—Promoting Effective Instruction in Classrooms and Schools.

There is a well-documented need for leadership personnel to fill faculty and leadership positions in special education, early intervention, and related services (Castillo, Curtis, & Tan, 2014; deBettencourt, Hoover, Rude, & Taylor, 2016; Montrosse & Young, 2012; Robb, Smith, & Montrosse, 2012; Smith, Montrosse, Robb, Tyler, & Young, 2011; Smith, Robb, West, & Tyler, 2010; Woods & Snyder, 2009). These leaders conduct research to increase the knowledge of effective interventions and services for children, including infants and toddlers, and youth with disabilities. These leaders also teach practices supported by evidence to future special education, early intervention, related services, and regular education professionals who will work in a variety of educational settings and provide services directly to these children (Robb et al., 2012; Smith et al., 2010; West & Hardman, 2012). Shortages in these leadership positions limit the field's capacity to generate new knowledge of effective interventions and to prepare future professionals to improve outcomes for children with disabilities (Smith et al., 2011). In addition, leadership shortages limit the field's capacity to ensure that children, including infants and toddlers, and youth with disabilities have the opportunity to meet challenging objectives and receive an educational program that is both meaningful and appropriately ambitious, which is essential for preparing them for future success.

Shortages of leadership personnel at State and local agencies to fill special education and early intervention administrator positions have also been noted (Billingsley, Crockett, & Kamman, 2014). These administrators supervise and evaluate the implementation of instructional programs supported by evidence to make sure that State or local agencies are meeting the needs of children with disabilities. Administrators also ensure that schools and programs meet Federal, State, and local requirements for special education, early intervention, and related services (Lashley & Boscardin, 2003).

Federal support can increase the supply of personnel who have the necessary knowledge and skills to assume leadership positions in special education, early intervention, and related services as researchers and preparers of special education, early intervention, related services, and regular education personnel in IHEs, or as leaders in national organizations, SEAs, LAs, LEAs, EIS programs, or schools. Critical competencies for special education, early intervention, and related services personnel vary depending on the type of leadership personnel and the requirements of the preparation program but can include, for example, skills needed for postsecondary instruction, administration, policy development, professional practice, leadership, or research. However, all leadership personnel need to have current knowledge of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities. This knowledge should be applicable to children served in a variety of educational settings (*e.g.,* public schools, including charter schools, or private schools) or early childhood and early intervention settings (*e.g.,* home, community-based, Early Head Start and Head Start, child care, or public and private preschools), and the interventions and services must include those that promote literacy development, literacy skills, or other skills critical for college and today's careers.

Priority

The purpose of this priority is to support existing doctoral degree programs that prepare special education, early intervention, and related services personnel at the doctoral degree level who are well qualified for, and can act effectively in, leadership positions as researchers and preparers of special education, early intervention, related services, and regular education personnel in IHEs, or as leaders in national organizations, SEAs, LAs, LEAs, or EIS programs. This priority supports two types of programs:

Type A programs are designed to prepare special education, early intervention, and related services personnel as researchers and preparers of personnel in IHEs. Type A programs culminate in a doctoral degree.

Note: Preparation programs that lead to clinical doctoral degrees in related services (*e.g.,* a Doctor of Audiology degree or Doctor of Physical Therapy degree) are not included in this priority. These types of preparation programs are eligible to apply for funding under the Personnel Preparation in Special Education, Early Intervention, and Related Services priority (CFDA 84.325K) that the

Office of Special Education Programs (OSEP) intends to fund in FY 2018.

Type B programs are designed to prepare special education or early intervention administrators to work as leaders in national organizations, SEAs, LAs, LEAs, or EIS programs. Type B programs prepare personnel for positions such as SEA special education administrators, LEA or regional special education directors, school-based special education directors, preschool coordinators, and early intervention coordinators. Type B programs culminate in a doctoral degree.

Note: OSEP intends to fund in FY 2018 at least seven high-quality applications proposing Type B programs and may fund applications out of rank order. These applications must be of high quality and should score higher than 84 on a 100-point scale, exclusive of competitive preference points, in the technical review.

Note: The preparation of school principals is not included in this priority.

Note: Applicants must identify the specific program type, A or B, for which they are applying for funding as part of the abstract. Applicants may not submit the same proposal for more than one program type.

To be considered for funding under this absolute priority, program applicants must meet the application requirements contained in the priority. All projects funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority.

The requirements of this priority are as follows:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how—

(1) The project addresses the need for leadership personnel to provide, prepare others to provide, or supervise the provision of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities.[1] These interventions should be applicable to children served in a variety of educational settings (*e.g.,* public schools, including charter schools, or private schools) or early childhood and early intervention settings (*e.g.,* home, community-based, Early Head Start and Head Start, child care, or public and private preschools), and the interventions and services must include those that promote literacy development, literacy skills, or other skills critical for college and today's careers. To address this requirement, the applicant must present—

(i) Appropriate and applicable data (*e.g.,* national, State) demonstrating the need for the leadership personnel the applicant proposes to prepare; and

(ii) Data demonstrating the success of the doctoral program to date in producing leaders in special education, early intervention, or related services such as: The professional accomplishments of program graduates (*e.g.,* public service, honors, or peer-reviewed publications (for Type A programs)) that demonstrate their leadership in special education, early intervention, or related services; the success of program graduates as educators of teachers, service providers, or administrators, including any results from evaluating the impact of those teachers, service providers, or administrators, on the outcomes of children with disabilities; the average amount of time it takes for program graduates to complete the program; The number of program graduates; and the percentage of program graduates finding employment directly related to their preparation.

Note: Data on the success of a doctoral program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (*i.e.,* the total number of scholars or program graduates) must be provided.

(2) Scholar competencies to be acquired in the program relate to knowledge and skills needed by the leadership personnel the applicant proposes to prepare, including knowledge of technologies designed to provide instruction. To address this requirement, the applicant must—

(i) Identify the competencies needed by leadership personnel in postsecondary instruction, administration, policy development, professional practice, leadership, or research in order to provide, prepare others to provide, or supervise the provision of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities; and

(ii) Provide the conceptual framework of the leadership preparation program, including any empirical support, that will promote the acquisition of the identified competencies needed by leadership personnel, including knowledge of technologies designed to provide instruction, and, where applicable, how these competencies relate to the project's specialized preparation area.

(b) Demonstrate, in the narrative section of the application under ''Quality of the Project Services,'' how—

(1) The applicant will recruit and support high-quality scholars. The narrative must describe—

(i) The selection criteria the applicant will use to identify high-quality applicants for admission in the program;

(ii) The recruitment strategies the applicant will use to attract high-quality applicants and any specific recruitment strategies targeting high-quality applicants from groups that are underrepresented in the teaching profession, including individuals with disabilities; and

(iii) The approach the applicant will use to help all scholars, including individuals with disabilities, complete the program; and

(2) The project is designed to promote the acquisition of the competencies needed by leadership personnel to provide, prepare others to provide, or supervise the provision of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities. These interventions should be applicable to children served in a variety of educational settings (*e.g.,* public schools, including charter schools, or private schools) or early childhood and early intervention settings (*e.g.,* home, community-based, Early Head Start and Head Start, child care, or public and private preschools), and the interventions and services must include those that promote literacy development, literacy skills, or other skills critical for college and today's careers. To address this requirement, the applicant must—

(i) Describe how the components of the project, such as coursework, internship experiences, research requirements, and other opportunities provided to scholars to analyze data, critique research and methodologies, and practice newly acquired knowledge and skills, will enable the scholars to acquire the competencies needed by leadership personnel for postsecondary instruction, administration, policy development, professional practice, leadership, or research in special education, early intervention, or related services;

(ii) Describe how the components of the project are integrated in order to support the acquisition and enhancement of the identified

[1] For purposes of this priority, ''high-need children with disabilities'' refers to children or students (ages birth through 21, depending on the State) who are eligible for services under IDEA, and who may be at risk of educational failure or otherwise in need of special assistance or support because they: (1) Are living in poverty, (2) are English learners, (3) are academically far below grade level, (4) have left school before receiving a regular high school diploma, (5) are at risk of not graduating with a regular high school diploma on time, (6) are homeless, (7) are in foster care, or (8) have been incarcerated.

competencies needed by leadership personnel in special education, early intervention, or related services, including knowledge of technologies designed to provide instruction;

(iii) Describe how the components of the project prepare scholars to provide, prepare others to provide, or supervise the provision of effective interventions and services that improve outcomes for children with disabilities, including high-need children with disabilities, in a variety of educational or early childhood and early intervention settings;

(iv) Demonstrate, through a letter of support from a partnering agency, school, or program, that it will provide scholars with a high-quality internship experience in a high-need LEA; [2] a high-poverty school; [3] a school identified for comprehensive support and improvement; [4] a school implementing a targeted support and improvement plan [5] for children with disabilities; an early childhood and early intervention program located within the geographical boundaries of a high-need LEA; or an early childhood and early intervention program located within the geographical boundaries of an LEA serving the highest percentage of schools identified for comprehensive support and improvement or implementing targeted support and improvement plans in the State;

(v) Describe how the project will use resources, as appropriate, available through technical assistance centers, which may include centers funded by the Department;

(vi) Describe the approach that faculty members will use to mentor scholars with the goal of helping them acquire competencies needed by leadership personnel and advancing their careers in special education, early intervention, or related services; and

(vii) Describe how the components of the project, mentoring, and other project opportunities will promote the acquisition of scholars' critical leadership skills, including communication, networking, and collaboration.

(c) Demonstrate, in the narrative section of the application under ''Quality of the Project Evaluation,'' how the applicant will—

(1) Evaluate how well the goals or objectives of the proposed leadership project have been met. The applicant must describe the outcomes to be measured for both the project and the scholars, particularly the acquisition of scholars' competencies and their impact on the services provided by future teachers, service providers, or administrators; and the evaluation methodologies to be employed, including proposed instruments, data collection methods, and possible analyses;

(2) Collect, analyze, and use data on current scholars and scholars who graduate from the program to improve the proposed program on an ongoing basis; and

(3) Report the evaluation results to OSEP in the applicant's annual and final performance reports.

(d) Demonstrate, in the narrative under ''Required Project Assurances'' or appendices as directed, that the following program requirements are met. The applicant must—

(1) Include in appendix B to the application—

(i) Course syllabi for all coursework in the major and any required coursework for a minor;

(ii) Course syllabi for all research methods, evaluation methods, or data analysis courses required by the degree program and elective research methods, evaluation methods, or data analysis courses that have been completed by more than one scholar enrolled in the program in the last five years; and

(iii) For new coursework, proposed syllabi;

(2) Ensure that the proposed number of scholars to be recruited into the program can graduate from the program by the end of the grant's project period. The described scholar recruitment strategies, including recruitment of individuals with disabilities, the program components and their sequence, and proposed budget must be consistent with this project requirement;

(3) Ensure scholars will not be selected based on race or national origin/ethnicity. Per the Supreme Court's decision in *Adarand Constructors, Inc.* v. *Pena,* 515 U.S. 200 (1995), the Department does not allow the selection of individuals on the basis of race or national origin/ethnicity. For this reason, grantees must ensure that any discussion of the recruitment of scholars based on race or national origin/ethnicity distinguishes between increasing the pool of applicants and actually selecting scholars;

(4) Ensure that the project will meet all requirements for grantees in disbursing scholarships as outlined in 34 CFR 304.23. Failure by a grantee to properly meet these requirements would be a violation of the grant award that could result in sanctions, including the grantee being liable for returning any misused funds to the Department. Specifically, before disbursement of scholarship assistance to an individual, a grantee must—

(i) Ensure that the scholar—

(A) Is a citizen or national of the United States;

(B) Is a permanent resident of—

(*1*) Puerto Rico, the United States Virgin Islands, Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands; or

(*2*) The Republic of the Marshall Islands, the Federated States of Micronesia, or the Republic of Palau during the period in which these entities are eligible to receive an award under the Personnel Development to Improve Services and Results for Children with Disabilities program; or

(C) Provides evidence from the U.S. Department of Homeland Security that the individual is—

(*1*) A lawful permanent resident of the United States; or

(*2*) In the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident;

(ii) Limit the cost of attendance portion of the scholarship assistance (as discussed in 34 CFR 304.21(a)) to the amount by which the individual's cost of attendance at the institution exceeds the amount of grant assistance the scholar is to receive for the same academic year under title IV of the HEA; and

[2] For the purposes of this priority, the term ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line.

[3] For the purposes of this priority, ''high-poverty school'' means a school in which at least 50 percent of students are from low-income families as determined using one of the measures of poverty specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school is determined on the basis of the most currently available data.

[4] For the purposes of this priority, the term ''school identified for comprehensive support and improvement'' means a statewide identified category of school that includes (a) not less than the lowest-performing five percent of all schools receiving funds under this part in the State; (b) all public high schools in the State failing to graduate one-third or more of their students; (c) public schools in the State described under section 1111(d)(3)(A)(i)(II) of the ESEA; and (d) at the discretion of the State, additional statewide categories of schools as defined in section 1111(c)(4)(D)(i) of the ESEA.

[5] For the purposes of this priority, the term ''schools implementing targeted support and improvement plans'' means a school that has developed and is implementing a school-level targeted support and improvement plan to improve student outcomes based on the indicators in the statewide accountability system as defined in section 1111(d)(2) of the ESEA.

(iii) Obtain a Certification of Eligibility for Federal Assistance from each scholar, as prescribed in 34 CFR 75.60, 75.61, and 75.62.

(5) Ensure that the project will meet the requirements in 34 CFR 304.23, particularly those related to informing all scholarship recipients of their service obligation commitment. Failure by a grantee to properly meet these requirements is a violation of the grant award that may result in sanctions, including the grantee being liable for returning any misused funds to the Department. Specifically, the grantee must prepare, and ensure that each scholarship recipient signs, the following two documents:

(i) A Pre-Scholarship Agreement prior to the scholar receiving a scholarship for an eligible program (Office of Management and Budget (OMB) Control Number 1820–0686); and

(ii) An Exit Certification immediately upon the scholar leaving, completing, or otherwise exiting that program (OMB Control Number 1820–0686);

(6) Ensure that prior approval from the OSEP project officer will be obtained before admitting additional scholars beyond the number of scholars proposed in the application and before transferring a scholar to another preparation program funded by OSEP;

(7) Ensure that the project will meet the statutory requirements in section 662(e) through (h) of IDEA;

(8) Ensure that at least 65 percent of the total requested budget over the five years will be used for scholar support;

(9) Ensure that the IHE will not require scholars enrolled in the program to work (*e.g.,* as graduate assistants) as a condition of receiving support (*e.g.,* tuition, stipends) from the proposed project, unless the work is specifically related to the acquisition of scholars' competencies and the requirements for completion of their personnel preparation program. This prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA;

(10) Ensure that the budget includes attendance of the project director at a three-day project directors' meeting in Washington, DC, during each year of the project. The budget may also provide for the attendance of scholars at the same three-day project directors' meetings in Washington, DC;

(11) Ensure that the project director, key personnel, and scholars will actively participate in the cross-project collaboration, advanced trainings, and cross-site learning opportunities (*e.g.,* webinars, briefings) supported by OSEP. This network is intended to promote opportunities for participants to share resources and generate new knowledge by addressing topics of common interest to participants across projects including Department priorities and needs in the field;

(12) Ensure that if the project maintains a website, that it will be of high quality, with an easy-to-navigate design, that meets government or industry-recognized standards for accessibility;

(13) Ensure that scholar accomplishments (*e.g.,* publications, awards) will be reported in annual and final performance reports; and

(14) Ensure that annual data will be submitted on each scholar who receives grant support (OMB Control Number 1820–0686). The primary purposes of the data collection are to track the service obligation fulfillment of scholars who receive funds from OSEP grants and to collect data for program performance measure reporting under the Government Performance and Results Act of 1993 (GPRA). Applicants are encouraged to visit the Personnel Development Program Data Collection System (DCS) website at *https://pdp.ed.gov/osep* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant, although grantees may submit data as needed, year round. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590). Data collection includes the submission of a signed, completed Pre-Scholarship Agreement and Exit Certification for each scholar funded under an OSEP grant (see paragraph (4) of this section, subparagraphs (i) and (ii)).

Absolute Priority 2—Promoting Innovation and Efficiency, Streamlining Education With an Increased Focus on Improving Student Outcomes, and Providing Increased Value to Students and Taxpayers

Background

The Department seeks to encourage grantees to leverage sources of support that may exist for their activities, beyond what is provided by the Department. Therefore, we have included an absolute priority for matching support through non-Federal contributions, either in cash or in-kind donations. Although the cash or in-kind resources to be contributed must be at least 10 percent of the total grant award, we encourage a higher percentage through the competitive preference priority included within this absolute priority.

Applicants must address this absolute priority, and the competitive preference priority, if applicable, in the budget information (ED Form 524, Section B) and budget narrative. The applicant must propose the amount of cash or in-kind resources to be contributed for each year of the grant.

Priority

Projects that are designed to demonstrate matching support [6] for the proposed project at 10 percent of the total amount of the grant.

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that address the following priority. Under 34 CFR 75.105(c)(2)(i) we award an additional one point to an application that meets paragraph (i) of the competitive preference priority and an additional two points to an application that meets paragraph (ii) of the competitive preference priority.

This priority is:

Projects that are designed to demonstrate matching support for the proposed projects:

(i) 50 percent of the total amount of the grant (1 point); or

(ii) 100 percent of the total amount of the grant (2 points).

References

Billingsley, B. S., Crockett, J., & Kamman, M. L. (2014).
Recruiting and retaining teachers and administrators in special education. In P. T. Sindelar, E. D. McCray, M. T. Brownell, & B. Lignugaris/Kraft (Eds.), *Handbook of research on special education teacher preparation* (pp. 94–112). New York, NY: Routledge.

Castillo, J. M., Curtis, M. J., & Tan, S. Y. (2014). Personnel needs in school psychology: A 10-year follow-up study on predicted personnel shortages. *Psychology in the Schools, 51,* 832–849.

deBettencourt, L. U., Hoover, J. J., Rude, H. A., & Taylor, S. S. (2016). Preparing special education higher education faculty: The influence of contemporary education issues and policy

[6] For the purposes of this priority, matching support can be either cash or in-kind donations. According to 2 CFR 200.306, a cash expenditure or outlay of cash with respect to the matching budget by the grantee is considered a cash contribution. Certain cash contributions that the organization normally considers an indirect cost should not be counted as a direct cost for the purposes of meeting matching support. According to 2 CFR 200.434, third-party in-kind contributions are services or property (*e.g.,* land, buildings, equipment, materials, supplies), that are contributed by a non-Federal third-party at no charge to the grantee.

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Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $4,250,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2019 from the list of unfunded applications from this competition.

Estimated Range of Awards: $225,000–$250,000 per year.

Estimated Average Size of Awards: $237,500 per year.

Maximum Award: We will not make an award exceeding $250,000 for a single budget period of 12 months.

Estimated Number of Awards: 17.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs, private nonprofit organizations.

2. *Cost Sharing or Matching:* Cost sharing or matching is required for this competition. See Absolute Priority 2.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application. The grantee may award subgrants to entities it has identified in an approved application.

4. *Other General Requirements:* (a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* For information on how to submit an application please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance of the Project (10 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project will prepare personnel for fields

in which shortages have been demonstrated;

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project; and

(iii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(b) *Quality of Project Services (45 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services;

(ii) The extent to which the proposed activities constitute a coherent, sustained program of training in the field; and

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice.

(c) *Quality of Project Evaluation (25 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project;

(ii) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(iii) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible; and

(iv) The extent to which the methods of evaluation will provide timely guidance for quality assurance.

(d) *Quality of Management Plan and Resources (20 points).*

(1) The Secretary considers the quality of the management plan and the adequacy of resources for the proposed project.

(2) In determining the quality of the management plan and the adequacy of resources, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of key project personnel;

(ii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks;

(iii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project;

(iv) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization; and

(v) The extent to which the budget is adequate to support the proposed project.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* Under GPRA, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on the quality of the Personnel Development to Improve Services and Results for Children with Disabilities program. These measures include: (1) The percentage of preparation programs that incorporate scientifically or evidence-based practices into their curricula; (2) the percentage of scholars completing preparation programs who are knowledgeable and skilled in evidence-based practices for children with disabilities; (3) the percentage of scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of scholars completing preparation programs who are working in the area(s) in which they were prepared upon program completion; and (5) the Federal cost per scholar who completed the preparation program.

In addition, the Department will gather information on the following outcome measures: (1) The percentage of scholars who completed the preparation program and are employed in high-need districts; (2) the percentage of scholars who completed the preparation program and are employed in the field of special education for at least two years; and (3) the percentage of scholars who completed the preparation program and who are rated effective by their employers.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW, Room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations 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 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.

Dated: June 8, 2018.

Johnny W. Collett,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2018–12717 Filed 6–12–18; 8:45 am]

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DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children With Disabilities Who Have High-Intensity Needs

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting

applications for new awards for fiscal year (FY) 2018 for Personnel Development to Improve Services and Results for Children with Disabilities—Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs, Catalog of Federal Domestic Assistance (CFDA) number 84.325K.

DATES:

Applications Available: June 13, 2018.

Deadline for Transmittal of Applications: July 30, 2018.

Deadline for Intergovernmental Review: September 26, 2018.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

FOR FURTHER INFORMATION CONTACT: Maryann McDermott, U.S. Department of Education, 400 Maryland Avenue SW, Room 5144, Potomac Center Plaza, Washington, DC 20202–5108. Telephone: (202) 245–7439.

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.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for personnel preparation in special education, early intervention, related services, and regular education to work with children, including infants and toddlers, and youth with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1462 and 1481).

Absolute Priority: For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs.

Background

The mission of the Office of Special Education and Rehabilitative Services (OSERS) is to improve early childhood, educational, and employment outcomes and raise expectations for all people with disabilities, their families, their communities, and the Nation.

The purpose of this priority is to increase the number and improve the quality of personnel who are fully credentialed to serve children, including infants and toddlers, and youth with disabilities who have high-intensity needs,[1] especially in areas of chronic personnel shortage. The priority will fund high-quality interdisciplinary[2] projects that prepare special education, early intervention, and related services[3] personnel at the master's degree, educational specialist degree, or clinical doctoral degree levels for professional practice in a variety of educational settings, including natural environments (including the home and community settings in which children without disabilities participate), early learning programs, classrooms, and school settings. This priority is consistent with the Secretary's Supplemental Priority 5—Meeting the Unique Needs of Students and Children With Disabilities and/or Those With Unique Gifts and Talents; and Supplemental Priority 8—Promoting Effective Instruction in Classrooms and Schools, which were published in the **Federal Register** on March 2, 2018 (83 FR 9096).

State demand for fully credentialed special education, early intervention, and related services personnel to serve children, including infants and toddlers, and youth with disabilities exceeds the available supply, particularly in high-need schools[4] (Boe, deBettencourt, Dewey, Rosenberg, Sindelar, & Leko, 2013). These shortages can negatively affect the quality of services provided to children, including infants and toddlers, and youth with disabilities and their families (Boe et al., 2013). These shortages limit the field's capacity in ensuring that children, including infants and toddlers, and youth with disabilities have the opportunity to meet challenging objectives and receive an individualized education program that is both meaningful and appropriately ambitious, which is essential for preparing them for the future.

The need for personnel with the knowledge and skills to serve children, including infants and toddlers, and youth with disabilities who have high-intensity needs is even greater because specialized or advanced preparation is required to collaboratively design and deliver evidence-based instruction and intensive individualized intervention(s) in natural environments, classrooms, and schools that address the needs of these individuals (Boe et al., 2013; Browder, Wood, Thompson, & Ribuffo, 2014; McLeskey & Brownell, 2015). Although children, including infants and toddlers, and youth with disabilities who have high-intensity needs may require the combined

[1] For the purposes of this priority, ''high-intensity needs'' refers to a complex array of disabilities (*e.g.,* multiple disabilities, significant cognitive disabilities, significant physical disabilities, significant sensory disabilities, significant autism, significant emotional disabilities, or significant learning disabilities, including dyslexia) or the needs of children with these disabilities requiring intensive, individualized intervention(s) (*i.e.,* that are specifically designed to address persistent learning or behavior difficulties, implemented with greater frequency and for an extended duration than is commonly available in a typical classroom or early intervention setting, or which require personnel to have knowledge and skills in identifying and implementing multiple evidence-based interventions).

[2] For the purposes of this priority, ''interdisciplinary'' refers to preparing scholars from two or more graduate degree programs in either (a) special education or early intervention and one or more related services through shared coursework, group assignments, and coordinated field experiences; or (b) two or more related services through shared coursework, group assignments, and coordinated field experiences. Different graduate degree programs across more than one institution of higher education may partner to develop an interdisciplinary project.

For the purpose of this priority, ''interdisciplinary'' does not include: (a) Individual scholars who receive two or more graduate degrees; (b) one graduate degree program that prepares scholars with different areas of focus; (c) one graduate degree program that offers interdisciplinary content but does not prepare scholars from two or more degree programs together; and (d) one graduate degree program in special education, early intervention, and related services partnering with a graduate degree program other than special education, early intervention, or related services. Programs in which scholars receive only a certificate or endorsement without a graduate degree are not eligible.

[3] For the purposes of this priority, ''related services'' includes the following: Speech-language pathology and audiology services; interpreting services; psychological services; applied behavior analysis; physical therapy and occupational therapy; recreation, including therapeutic recreation; social work services; counseling services, including rehabilitation counseling; and orientation and mobility services.

[4] For the purposes of this priority, ''high-need school'' refers to a public elementary or secondary school that is a ''high-need local educational agency (LEA),'' ''high-poverty,'' or ''implementing targeted support and improvement plans'' as defined in footnotes 8, 9, and 11, respectively.

expertise of numerous professionals (including special education, early intervention, and related services providers), it is often difficult for personnel from varied professional backgrounds to work together because they lack shared information, understanding, and experience.

Interdisciplinary approaches to personnel preparation provide scholars with experience working and learning in team environments similar to those in which they are likely to work once employed (Smith, 2010). For example, under the IDEA, personnel serving children, including infants and toddlers, and youth with disabilities will work on interdisciplinary teams with parent(s), general and special education teachers, early interventionists, and related service providers with the expertise convened to design, implement, and evaluate intervention plans based on the unique learning and developmental needs of each individual child. To enable personnel to provide efficient, high-quality integrated services, personnel preparation programs need to embed content, practices, and clinical experience into preservice training that will match the interdisciplinary team-based approaches in which graduates are likely to work. This priority aims to fund interdisciplinary projects that will provide such preparation.

Priority

The purpose of this priority is to increase the number and improve the quality of personnel who are fully credentialed to serve children, including infants and toddlers, and youth with disabilities who have high-intensity needs—especially in areas of chronic personnel shortage. The priority will fund high-quality interdisciplinary projects that prepare special education, early intervention, and related services personnel at the master's degree, educational specialist degree, or clinical doctoral degree levels for professional practice in natural environments, early learning programs, classrooms, and school settings serving children, including infants and toddlers, and youth with disabilities.

Specifically, an applicant must propose an interdisciplinary project supporting scholars [5] from two or more graduate degree programs in either (a) special education or early intervention and one or more related services; or (b) two or more related services.

An interdisciplinary project is a project that delivers core content through shared coursework, group assignments, and coordinated clinical experiences as part of two or more master's degree, educational specialist degree, or clinical doctoral degree programs for scholars.

Not all requirements (*e.g.,* courses and clinical experiences) of each participating graduate degree program must be shared across all degree programs participating in the interdisciplinary project, but the interdisciplinary project must: (a) Identify the competencies needed to address the individualized needs of children with disabilities who have high-intensity needs using an interdisciplinary approach to service delivery; (b) outline how the project will build capacity in those areas through shared coursework, group assignments, and coordinated clinical experiences for scholars supported by the proposed project; and (c) identify the aspects of each graduate degree program that are shared across all participating programs and those that remain unique to each.

Projects may include individuals who are in degree programs (*e.g.,* general education, early childhood education, administration) and who are cooperating with, but not funded as scholars by, the applicant's proposed interdisciplinary project. These individuals may participate in interdisciplinary coursework, group assignments, coordinated field experiences, and other opportunities funded by the project (*e.g.,* speaker series, monthly seminars) if doing so does not diminish the benefit for project-funded scholars (*e.g.,* by reducing funds available for scholar support or limiting opportunities for scholars to participate in project activities).

Personnel preparation programs that prepare individuals to be educational interpreters for the deaf at the bachelor's degree level can qualify under this priority, and are exempted from (a) the interdisciplinary requirement; and (b) the requirement for two or more graduate degree programs. All other priority requirements specified for graduate programs will apply to the bachelor's program. While interdisciplinary projects are not required for educational interpreters, they are encouraged.

Focus Areas

Within this absolute priority, the Secretary intends to support interdisciplinary projects under the following two focus areas: (A) Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs; and (B) Preparing Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs.

Applicants must identify the specific focus area (*i.e.,* A or B) under which they are applying as part of the competition title on the application cover sheet (SF form 424, line 4). Applicants may not submit the same proposal under more than one focus area.

Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs. This focus area is for interdisciplinary projects that deliver core content through shared coursework, group assignments, and coordinated clinical experiences for scholars across two or more graduate degree programs in either: (a) Early intervention or early childhood special education and related services for infants, toddlers, and preschool-age children with disabilities who have high-intensity needs; or (b) two or more related services to serve infants, toddlers, and preschool-age children with disabilities who have high-intensity needs.

Early intervention personnel are those who are prepared to provide services to infants and toddlers with disabilities ages birth to three, and early childhood personnel are those who are prepared to provide services to children with disabilities ages three through five (and in States where the age range is other than ages three through five, we defer to the State's certification for early childhood special education). In States where certification in early intervention is combined with certification in early childhood special education, applicants may propose a combined early intervention and early childhood

[5] For the purposes of this priority, ''scholar'' is limited to an individual who (a) is pursuing a master's, educational specialist degree, or clinical doctoral graduate degree in special education, early intervention, or related services (as defined in this notice); (b) receives scholarship assistance as authorized under section 662 of IDEA (34 CFR 304.3(g)); (c) will be eligible for a license, endorsement, or certification from a State or national credentialing authority following completion of the graduate degree program identified in the application; and (d) will be able to be employed in a position that serves children with disabilities for either 51 percent of their time or case load. See *https://pdp.ed.gov/OSEP/Home/Regulation* for more information.

Scholars from each graduate degree program participating in the proposed interdisciplinary project must receive scholar support and be eligible to fulfill service obligation requirements following graduate degree program completion. Scholars from each graduate degree program participating in this project must complete the requirements of their unique graduate degree program and receive different graduate degrees. Individuals pursuing degrees in general education or early childhood education do not qualify as ''scholars'' eligible for scholarship assistance.

special education personnel preparation project under this focus area.

Note: In Focus Area A, the Office of Special Education Programs (OSEP) intends to fund 10 awards. OSEP may fund out of rank order high-quality applications from institutions of higher education (IHEs) that primarily serve traditionally underrepresented groups (Minority-Serving IHEs [6] and Historically Black Colleges and Universities (HBCUs)). These applications must be of high quality and should score higher than 84 on a 100-point scale in the technical review. In order to be considered under this provision, the primary applicant must be a Minority-Serving IHE or HBCU, even in cases of a proposed partnership across entities.

Focus Area B: Preparing Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs. This focus area is for interdisciplinary projects that deliver core content through shared coursework, group assignments, and coordinated clinical experiences to scholars across two or more graduate degree programs in either: (a) Special education and related services for school-age children with disabilities who have high-intensity needs; or (b) two or more related services to serve school-age children with disabilities who have high-intensity needs.

Note: In Focus Area B, OSEP may fund out of rank order high-quality applications from IHEs that primarily serve traditionally underrepresented groups (Minority-Serving IHEs and HBCUs). These applications must be of high quality and should score higher than 84 on a 100-point scale in the technical review. In order to be considered under this provision, the primary applicant must be a Minority-Serving IHE or HBCU, even in cases of a proposed partnership across entities.

Projects funded under Focus Area A or B may use up to 12 months during the first year of the project period and up to $100,000 of Federal funds for program planning without enrolling scholars. Applicants must provide sufficient justification for requesting program planning time and include the intended outcomes of program planning in Year 1, and a description of the proposed strategies and activities to be supported, such as—

(1) Outlining or updating coursework, group assignments, or coordinated clinical experience needed to support interdisciplinary preparation for special education, early intervention, or related services personnel serving children with disabilities who have high-intensity needs;

(2) Building capacity (*e.g.,* hiring of a clinical practice supervisor, providing professional development for clinical field supervisors, and training for faculty);

(3) Purchasing needed resources (*e.g.,* additional teaching supplies or specialized equipment to enhance instruction); or

(4) Negotiating agreements with programs or schools to serve as sites for coordinated clinical experience needed to support delivery of the proposed interdisciplinary project.

Remaining Year 1 Federal funds up to the maximum award available for one budget period of 12 months (*i.e.,* $250,000) may be used for scholar support and other grant activities if included in the Year 1 budget request.

Note: Applicants proposing projects to develop, expand, or add a new area of emphasis to special education, early intervention, or related services programs must provide, in their applications, information on how these new areas will be sustained once Federal funding ends.

To be considered for funding under this absolute priority, all program applicants must meet the application requirements contained in the priority. All projects funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority.

The requirements of this priority are as follows:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how—

(1) The project addresses national, State, regional, or district shortages of personnel who are fully qualified to serve children with disabilities, ages birth through 21, who have high-intensity needs. To address this requirement, the applicant must—

(i) Present data on the quality of each special education, early intervention, or related services personnel preparation degree program participating in the project in areas such as: The average amount of time it takes for scholars to complete the program; the percentage of program graduates who receive a license, endorsement, or certification related to special education, related services, or early intervention services; the percentage of program graduates finding employment related to their preparation after graduation; the success of program graduates in providing special education, early intervention, or related services, which could include data on the learning and developmental outcomes of children with disabilities they serve; the percentage of program graduates who maintain employment for two or more years in the area for which they were prepared; and the percentage of employers who rate the preparation of scholars who complete their degree program as adequate or higher; and

(ii) If available for the degree programs participating in the proposed project, present data on the quality of their interdisciplinary approaches to the preparation of special education, early intervention, or related services personnel.

Note: Data on the quality of a personnel preparation program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (*i.e.,* total number of scholars or program graduates) must be provided.

(2) The project will increase the number of personnel who demonstrate the competencies needed to provide (a) differentiated instruction, and (b) intensive individualized intervention(s) in an interdisciplinary team-based approach to address the individualized needs of children with disabilities who have high-intensity needs, ages birth through 21, that result in improvements in learning or developmental outcomes (*e.g.,* academic, social, emotional, behavioral), or successful transition to postsecondary education and the workforce. To address this requirement, the applicant must—

(i) Identify the competencies [7] that special education, early intervention, or related services personnel need in order to ensure delivery of (a) differentiated instruction, and (b) intense individualized intervention(s) in an interdisciplinary team-based approach that will: Lead to improved learning and developmental outcomes; ensure access to and progress in academic achievement standards or alternate academic achievement standards, as appropriate; lead to successful transition to college and career for children with disabilities, including children with disabilities who have high-intensity needs; and maximize the use of effective technology, including assistive technology, to deliver instruction, interventions, and services;

[6] For the purposes of this priority, ''Minority-Serving IHEs'' refers to IHEs with a minority enrollment of 50 percent or more, which may include Historically Black Colleges and Universities, Tribal Colleges, and Predominantly Hispanic-Serving Colleges and Universities.

[7] For the purposes of this priority, ''competencies'' means what a person knows and can do—the knowledge, skills, and dispositions necessary to effectively function in a role (National Professional Development Center on Inclusion, 2011). These competencies should ensure that personnel are able to use challenging academic standards, child achievement and functional standards, and assessments to improve instructional practices, services, learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral), and college- and career-readiness of children with disabilities.

(ii) Identify the competencies needed by members of interdisciplinary teams that will result in improved outcomes for children with disabilities who have high-intensity needs;

(iii) Identify the competencies that personnel need to support inclusion of children with disabilities who have high-intensity needs in the least restrictive and natural environments to the maximum extent appropriate by intentionally promoting participation in learning and social activities to foster development, learning, academic achievement, friendships with peers, and sense of belonging;

(iv) Identify how scholars will be prepared to develop, implement, and evaluate evidence-based instruction and evidence-based interventions that improve outcomes for children with disabilities who have high-intensity needs in a variety of settings (*e.g.,* natural environments; public schools, including charter schools; private schools, including parochial schools; and other nonpublic education settings, including home education); and

(v) Provide a conceptual framework for the proposed interdisciplinary personnel preparation project, including any empirical support for project activities designed to promote the acquisition of the identified competencies (see paragraph (a)(2)(i) of the requirements for this priority) needed by special education, early intervention, or related services personnel, and how these competencies relate to the proposed project.

(b) Demonstrate, in the narrative section of the application under ''Quality of Project Services,'' how the project—

(1) Will conduct its planning activities, if up to the first 12 months of the project period will be used for planning.

(2) Will recruit and retain high-quality scholars into each of the graduate degree programs participating in the project and ensure equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe—

(i) Criteria the applicant will use to identify high-quality applicants for admission into each of the graduate degree programs participating in the project;

(ii) Recruitment strategies the applicant will use to attract high-quality applicants and any specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, including individuals with disabilities; and

(iii) The approach, including mentoring, monitoring, and accommodations, the applicant will use to support scholars to complete their respective degree programs.

(3) Reflects current evidence-based practices, including practices in the areas of literacy and numeracy development, assessment, behavior, instructional practices, and inclusive strategies, as appropriate, and is designed to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how the project will—

(i) Incorporate current evidence-based practices (including relevant research citations) that improve outcomes for children with disabilities who have high-intensity needs into (a) the required coursework and clinical experiences for each graduate degree program participating in the project; and (b) the shared coursework, group assignments, and coordinated clinical experiences required for the interdisciplinary portions of the project; and

(ii) Use evidence-based professional development practices for adult learners to instruct scholars.

(4) Is of sufficient quality, intensity, and duration to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how—

(i) The components of (a) each graduate degree program participating in the project and (b) the shared coursework, group assignments, and coordinated clinical experiences required for the interdisciplinary portions of the proposed project will support scholars' acquisition and enhancement of the identified competencies;

(ii) The components of (a) each graduate degree program participating in the project and (b) the shared coursework, group assignments, and coordinated clinical experiences required for the interdisciplinary portions of the proposed project will be integrated to allow scholars, in collaboration with other team members, to use their knowledge and skills in designing, implementing, and evaluating practices supported by evidence to address the learning and developmental needs of children with disabilities who have high-intensity needs;

(iii) Scholars will be provided with ongoing guidance and feedback during training; and

(iv) The proposed project will provide ongoing induction opportunities and mentoring support to graduates of each graduate degree program participating in the project.

(5) Will collaborate with appropriate partners, including—

(i) High-need schools, which may include high-need LEAs,[8] high-poverty schools,[9] schools identified for comprehensive support and improvement,[10] and schools implementing a targeted support and improvement plan [11] for children with disabilities; early childhood and early intervention programs located within the geographic boundaries of a high-need LEA; and early childhood and early intervention programs located within the geographical boundaries of an LEA serving the highest percentage of schools identified for comprehensive support and improvement or implementing targeted support and improvement plans in the State. The purpose of these partnerships is to provide clinical practice for scholars aimed at developing the identified competencies as members of interdisciplinary teams; and

(ii) Other personnel preparation programs on campus or at partnering universities for the purpose of sharing resources, supporting program development and delivery, and addressing personnel shortages.

(6) Will use technology, as appropriate, to promote scholar learning and professional practice, enhance the efficiency of the project, collaborate with partners, and facilitate ongoing mentoring and support for scholars.

[8] For the purposes or this priority, ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children are from families with incomes below the poverty line.

[9] For the purposes of this priority, ''high-poverty school'' means a school in which at least 50 percent of students are from low-income families as determined using one of the measures of poverty specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended. For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data.

[10] For the purpose of this priority, the term ''school identified for comprehensive support and improvement'' means a statewide identified category of school that includes (a) not less than the lowest performing five percent of all schools in the State receiving funds under Title I, Part A of the ESEA; (b) all public high schools in the State failing to graduate one third or more of their students; and (c) public schools in the State described under section 1111(d)(3)(A)(i)(II) of the ESEA.

[11] For the purposes of this priority, ''school implementing a targeted support and improvement plan'' means a school that has developed and is implementing a school-level targeted support and improvement plan to improve student outcomes based on the indicators in the statewide accountability system as defined in section 1111(d)(2) of the ESEA.

(7) Will ensure that scholars understand how to use technology to support student learning and students' use of educational and assistive technology; and

(8) Will align with and use resources, as appropriate, available through technical assistance centers, which may include centers funded by the Department.

Note: Use the ''Find a Center'' link at *www.osepideasthatwork.org* for information about OSEP-funded technical assistance centers.

(c) Demonstrate, in the narrative section of the application under ''Quality of Project Evaluation,'' how—

(1) The applicant will use comprehensive and appropriate methodologies to evaluate how well the goals or objectives of the proposed project have been met, including the project processes and outcomes.

(2) The applicant will collect, analyze, and use data related to specific and measurable goals, objectives, and outcomes of the project. To address this requirement, the applicant must describe how—

(i) Scholar competencies and other project processes and outcomes will be measured for formative evaluation purposes, including proposed instruments, data collection methods, and possible analyses; and

(ii) It will collect and analyze data on the quality of services provided by scholars who complete the graduate degree programs involved in this interdisciplinary project and are employed in the field for which they were trained, including data on the learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral, meeting college- and career-ready standards), and on growth toward these outcomes, of the children with disabilities who have high-intensity needs.

Note: Following the completion of the project period, grantees are encouraged to engage in ongoing data collection activities.

(3) The methods of evaluation will produce quantitative and qualitative data for objective performance measures that are related to the outcomes of the proposed project.

(4) The methods of evaluation will provide performance feedback and allow for periodic assessment of progress towards meeting the project outcomes. To address this requirement, the applicant must describe how—

(i) Results of the evaluation will be used as a basis for improving the proposed project to prepare special education, early intervention, or related services personnel to provide (a) focused instruction, and (b) intense individualized intervention(s) in an interdisciplinary team-based approach to improve outcomes of children with disabilities who have high-intensity needs; and

(ii) The grantee will report the evaluation results to OSEP in its annual and final performance reports.

(d) Demonstrate, in the narrative under ''Project Assurances'' or in the applicable appendices, that the following program requirements are met. The applicant must—

(1) Provide scholar support for participants from two or more graduate degree programs partnering in the proposed interdisciplinary personnel preparation project. Consistent with 34 CFR 304.3, each scholar should (a) receive support for no less than one academic year, and (b) be eligible to fulfill service obligation requirements following degree program completion. Funding across degree programs may be applied differently.

(2) Include in Appendix B of the application—

(i) Course syllabi for all coursework in the major of each degree program and all shared courses, group assignments, and coordinated clinical experiences required of interdisciplinary project scholars; and

(ii) For new coursework, proposed syllabi; and

(iii) Table(s) summarizing the program of study for each degree program, and clearly delineating the shared coursework, group assignments, and coordinated field experiences required of project scholars.

(3) Ensure that a comprehensive set of completed syllabi, including syllabi created or revised as part of a project planning year, are submitted to OSEP by the end of Year 1 of the grant.

(4) Ensure scholars will not be selected based on race, ethnicity, or national origin. Per the Supreme Court's decision in *Adarand Constructors, Inc.* v. *Pena,* 515 U.S. 200 (1995), the Department does not allow the selection of individuals on the basis of race, ethnicity, or national origin. For this reason, grantees must ensure that any discussion of the recruitment of scholars based on race, ethnicity, or national origin distinguishes between increasing the pool of applicants and actually selecting scholars.

(5) Ensure that the project will meet all requirements for grantees in disbursing scholarships as outlined in 34 CFR 304.23. Failure by a grantee to properly meet these requirements would be a violation of the grant award that could result in sanctions, including the grantee being liable for returning any misused funds to the Department. Specifically, before disbursement of scholarship assistance to an individual, a grantee must—

(i) Ensure that the scholar—

(A) Is a citizen or national of the United States;

(B) Is a permanent resident of—

(*1*) Puerto Rico, the United States Virgin Islands, Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands; or

(*2*) The Republic of the Marshall Islands, the Federated States of Micronesia, or the Republic of Palau during the period in which these entities are eligible to receive an award under the Personnel Development to Improve Services and Results for Children with Disabilities program; or

(C) Provides evidence from the U.S. Department of Homeland Security that the individual is—

(*1*) A lawful permanent resident of the United States; or

(*2*) In the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident;

(ii) Limit the cost of attendance portion of the scholarship assistance (as discussed in 34 CFR 304.21(a)) to the amount by which the individual's cost of attendance at the institution exceeds the amount of grant assistance the scholar is to receive for the same academic year under title IV of the HEA; and

(iii) Obtain a Certification of Eligibility for Federal Assistance from each scholar, as prescribed in 34 CFR 75.60, 75.61, and 75.62.

(6) Ensure that the project will meet all requirements in 34 CFR 304.23, particularly those related to informing all scholarship recipients of their service obligation commitment. Failure by a grantee to properly meet these requirements would be a violation of the grant award that could result in sanctions, including the grantee being liable for returning any misused funds to the Department. Specifically, the grantee must prepare, and ensure that each scholarship recipient signs, the following two documents:

(i) A Pre-Scholarship Agreement prior to the scholar receiving a scholarship for an eligible program (Office of Management and Budget (OMB) Control Number 1820–0686); and

(ii) An Exit Certification immediately upon the scholar leaving, completing, or otherwise exiting that program (OMB Control Number 1820–0686).

(7) Ensure that prior approval from the OSEP project officer will be obtained before admitting additional scholars beyond the number of scholars

proposed in the application and before transferring a scholar to another OSEP-funded grant.

(8) Ensure that the project will meet the statutory requirements in section 662(e) through (h) of IDEA.

(9) Ensure that at least 65 percent of the total requested budget over the five years will be used for scholar support. Applicants proposing to use Year 1 for program development may budget for less than 65 percent of the total requested budget over the five years for scholar support; instead 65 percent of the total award minus funds allocated for program development will be used to calculate the value of required scholar support.

(10) Ensure that the IHE will not require scholars enrolled in the program to work (*e.g.,* as graduate assistants) as a condition of receiving support (*e.g.,* tuition, stipends) from the proposed project, unless the work is specifically related to the acquisition of scholars' competencies and the requirements for completion of their personnel preparation program. This prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA.

(11) Ensure that the budget includes attendance of the project director at a three-day project directors' meeting in Washington, DC, during each year of the project.

(12) Ensure that the project director, key personnel, and scholars will actively participate in the cross-project collaboration, advanced trainings, and cross-site learning opportunities (*e.g.,* webinars, briefings) organized by OSEP. This partnership will be used to build capacity of participants, increase the impact of funding, and promote innovative and interdisciplinary service delivery models across projects.

(13) Ensure that if the project maintains a website, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility.

(14) Ensure that annual data will be submitted on each scholar who receives grant support (OMB Control Number 1820–0686). The primary purposes of the data collection are to track the service obligation fulfillment of scholars who receive funds from OSEP grants and to collect data for program performance measure reporting under the Government Performance and Results Act of 1993 (GPRA). Applicants are encouraged to visit the Personnel Development Program Data Collection System (DCS) website at *https://pdp.ed.gov/osep* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant, although grantees may submit data as needed, year round. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590). Data collection includes the submission of a signed, completed Pre-Scholarship Agreement and Exit Certification for each scholar funded under an OSEP grant (see paragraph (6) of this section, subparagraphs (i) and (ii)).

References

Boe, E.E., deBettencourt, L., Dewey, J.F., Rosenberg, M. S., Sindelar, P. T., & Leko, C.D. (2013). Variability in demand for special education teachers: Indicators, explanations, and impacts. *Exceptionality, 21,* 103–125.

Browder, D.M., Wood, L., Thompson, J., & Ribuffo, C. (2014). *Evidence-based practices for students with severe disabilities* (Document No. IC–3). Retrieved from University of Florida, Collaboration for Effective Educator, Development, Accountability, and Reform Center website: *http://ceedar.education.ufl.edu/tool/innovation-configurations/.*

Individuals with Disabilities Education Act, 20 U.S.C. 1400, *et seq.* (2004).

McLeskey, J., & Brownell, M. (2015*). High-leverage practices and teacher preparation in special education* (Document No. PR–1). Retrieved from University of Florida, Collaboration for Effective Educator, Development, Accountability, and Reform Center website: *http://ceedar.education.ufl.edu/wp-content/uploads/2016/05/High-Leverage-Practices-and-Teacher-Preparation-in-Special-Education.pdf.*

National Professional Development Center on Inclusion. (August, 2011). *Competencies for early childhood educators in the context of inclusion: Issues and guidance for States.* Chapel Hill, NC: The University of North Carolina, FPG Child Development Institute.

Smith, J. (2010). An interdisciplinary approach to preparing early intervention professionals: A university and community collaborative initiative. *Teacher Education and Special Education,* 33(2), 131–142.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $83,541,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2018, of which we intend to use an estimated $10,000,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2019 from the list of unfunded applications from this competition.

Estimated Range of Awards: See chart.

Estimated Average Size of Awards: See chart.

Maximum Award: See chart.

Estimated Number of Awards: See chart.

Project Period: See chart.

PERSONNEL DEVELOPMENT TO IMPROVE SERVICES AND RESULTS FOR CHILDREN WITH DISABILITIES (84.325k) APPLICATION NOTICE FOR FISCAL YEAR 2018

CFDA No. and name	Applications available	Deadline for transmittal of applications	Deadline for intergovernmental review	Estimated range of awards	Estimated average size of awards	Maximum award for each budget period of 12 months	Estimated number of awards	Project period	Contact person
84.325K Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs.	June 13, 2018.	July 30, 2018.	September 26, 2018.	.....	.....	.....	.....	.....	Focus Area A or Minority Serving Institutions: Dawn Ellis, 202–245–6417, *dawn.ellis@ed.gov,* Potomac Center Plaza, Room 5137.
Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs.	.....	.....	.....	$200,000–250,000	$250,000	$250,000 *	10	Up to 60 mos.	Focus Area B: Maryann McDermott, 202–245–7439, *maryann.mcdermott@ed.gov,* Potomac Center Plaza, Room 5144, or
Focus Area B: Preparing Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs.	.....	.....	.....	200,000–250,000	250,000	250,000 *	30	Up to 60 mos.	Sarah Allen, 202–245–7875, *sarah.allen@ed.gov,* Potomac Center Plaza, Room 5144.

* We will not make an award exceeding $250,000 for a single budget period of 12 months.

Note: The Department is not bound by any estimates in this notice.

III. Eligibility Information

1. *Eligible Applicants:* IHEs and private nonprofit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application. The grantee may award subgrants to entities it has identified in an approved application.

4. *Other General Requirements:* (a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* For information on how to submit an application please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at *www.gpo.gov/fdsys/pkg/FR-2018-02-12/pdf/2018-02558.pdf.*

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance of the Project (10 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project will prepare personnel for fields in which shortages have been demonstrated; and

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

(b) *Quality of Project Services (45 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In determining the quality of the project services, the Secretary considers the following factors:

(i) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice;

(ii) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services;

(iii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services; and

(iv) The extent to which the proposed activities constitute a coherent, sustained program of training in the field.

(c) *Quality of Project Evaluation (25 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project;

(ii) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measureable;

(iii) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible; and

(iv) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(d) *Quality of Project Personnel, Management Plan, and Resources (20 points).*

(1) The Secretary considers the quality of the project personnel, management plan, and the adequacy of resources for the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of key project personnel;

(ii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks;

(iii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project;

(iv) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization; and

(v) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for

Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* Under GPRA, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on the quality of the Personnel Development to Improve Services and Results for Children with Disabilities program. These measures include: (1) The percentage of preparation programs that incorporate scientifically or evidence-based practices into their curricula; (2) the percentage of scholars completing preparation programs who are knowledgeable and skilled in evidence-based practices that improve outcomes for children with disabilities; (3) the percentage of scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of scholars completing preparation programs who are working in the area(s) in which they were prepared upon program completion; and (5) the Federal cost per scholar who completed the preparation program.

In addition, the Department will gather information on the following outcome measures: (1) The percentage of scholars who completed the preparation program and are employed in high-need districts; (2) the percentage of scholars who completed the preparation program and are employed in the field of special education for at least two years; and (3) the percentage of scholars who completed the preparation program and who are rated effective by their employers.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW, Room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations 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 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.

Dated: June 8, 2018.

Johnny W. Collett,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2018–12718 Filed 6–12–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2018–FSA–0053]

Privacy Act of 1974; System of Records

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice of a Modified System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of Education (Department) publishes this notice of a modified system of records for the ''Customer Engagement Management System (CEMS)'' (18–11–11) to expand the CEMS system to cover records that the Department previously maintained in the Department's system of records entitled ''Common Services for Borrowers (CSB)'' (18–11–16) to carry out the responsibilities of the Department to receive, review, evaluate, process, and render decisions on the eligibility of individuals for relief under the borrower defense regulations and, where requests for borrower defense to repayment are successful, to determine the relief that is appropriate to borrowers under the circumstances as well as to initiate appropriate proceedings to require schools whose acts or omissions resulted in the successful defenses against repayment to pay the Department the amounts of the loans to which the defenses apply. This modification also renames the system of records, which was formerly entitled the ''Office of the Student Loan Ombudsman Records.'' The Department previously created the system of records entitled the ''Office of the Student Loan Ombudsman Records'' for a number of purposes related to the duties and responsibilities of the Ombudsman, including verifying the identities of individuals; recording complaints and comments; tracking individual cases through final resolution; reporting trends; analyzing the data to recommend improvements in the Student Financial Assistance Programs; and assisting in the resolution of disputes.

DATES: Submit your comments on this modified system of records notice on or before July 13, 2018.

This modified system of records will become applicable upon publication in the **Federal Register** on June 13, 2018, unless the modified system of records notice needs to be changed as a result of public comment.

Modified routine uses (1), (3), (5), (7), and (10) and new routine uses (8) and (11) listed under ''ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES'' will become applicable on July 13, 2018, unless the modified system of records notice needs to be changed as a result of public comment. The Department will publish any significant changes resulting from public comment.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''help'' tab.
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about this modified system of records, address them to: Ombudsman/Director, Ombudsman Group, Customer Experience, FSA, U.S. Department of Education, 830 First Street NE, 4th Floor/MC–5144, Union Center Plaza (UCP), Washington, DC 20202–5144.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Joyce DeMoss, Ombudsman/Director, Ombudsman Group, Customer Experience, FSA, U.S. Department of Education, 830 First Street NE, 4th Floor/MC–5144, Union Center Plaza (UCP), Washington, DC 20202–5144. Telephone: (202) 377–3992.

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Department is renaming the system of records from the ''Office of the Student Loan Ombudsman Records'' to the ''Customer Engagement Management System (CEMS).'' The system of records described in this notice maintains records on individuals who are, were, or may be participants in any of the Student Financial Assistance Programs authorized under title IV of the Higher Education Act of 1965, as amended (HEA) who request assistance, directly or through a designated third party, from the Department. The CEMS maintains the information for a number of purposes related to the duties and responsibilities of the Ombudsman and the FSA Enforcement Office, including: Verifying the identities of individuals; recording complaints and comments; tracking individual cases through final resolution; reporting trends; analyzing the data to recommend improvements in student financial assistance programs; and assisting in the informal resolution of disputes. In addition, the system of records described in this notice maintains records on individuals who have asserted defenses to the repayment of their Federal student loans, also known as ''borrower defenses,'' pursuant to the Department's regulations at 34 CFR 685.206. These records are maintained to carry out the responsibilities of the Department to receive, review, evaluate, process, and render decisions on the eligibility of individuals for relief under the borrower defense regulations, which may include the discharge of a William D. Ford Federal Direct Loan (Direct Loan) Program loan and further relief as determined by the Secretary, as well as the initiation of appropriate proceedings to require schools whose acts or omissions resulted in successful defenses against repayment to pay the Department the amounts of the loans to which the defenses apply.

The CEMS consists of a variety of records that identify individuals' complaints, requests for assistance, or other inquiries. Records include, but are not limited to: Written documentation

of an individual's complaint, request for assistance, or other comment or inquiry; and information pertaining to a student's or parent's student financial assistance program account(s) under title IV of the HEA, such as the individual's name, Social Security number, date of birth, address, telephone number(s), and FSA ID. Additionally, records may include the name, address, and phone numbers of school(s), lender(s), secondary holder(s) or lender(s), guaranty agency(ies), servicer(s), and private collection agency(ies), if applicable. The system of records also contains loan level information, and data submitted by individuals who have requested relief from Federal student loan repayment under the borrower defense to repayment regulations, as well as data that may be submitted by schools or other entities in connection with individuals' discharge requests.

The Department is modifying the section of the notice entitled ''AUTHORITY FOR MAINTENANCE OF THE SYSTEM'' to include 20 U.S.C. 1087e(h), which is the Department's authority to collect records on individuals who have requested relief under the borrower defense regulations.

The Department is modifying the section of the notice entitled ''PURPOSE(S) OF THE SYSTEM'' to include the duties and responsibilities of FSA to provide relief under the borrower defense regulations, including the receipt, review, evaluation, and processing of requests for relief under the borrower defense to repayment regulations, the rendering of decisions on the merits of such requests, and, where requests for borrower defense to repayment are successful, the determination of the relief that is appropriate to borrowers under the circumstances as well as the initiation of appropriate proceedings to require schools whose acts or omissions resulted in the successful defenses against repayment to pay the Department the amounts of the loans to which the defenses apply.

The Department is modifying the section of the notice entitled ''CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM'' to include individuals who request relief under borrower defense to repayment regulations from the Department.

The Department is modifying the section of the notice entitled ''CATEGORIES OF RECORDS IN THE SYSTEM'' to include individuals' requests for relief and related records under the borrower defense to repayment regulations and to indicate that records may contain other loan level data.

The Department is modifying the section of the notice entitled ''RECORD SOURCE CATEGORIES'' to include as record source categories third parties who provide data to the Department under the routine uses set forth below. The Department is also modifying this section to clarify that in addition to obtaining information from the individuals (*e.g.,* borrowers), the Department also may obtain information from the individuals' counsel or representatives, or from students or their parents (if the individual is a borrower and depending on whether the individual is a parent or student). This Section also has been revised by adding that the Department may obtain information from accreditors in addition to the sources previously listed, which were Federal agencies, State agencies, schools, lenders, private collection agencies, and guaranty agencies.

The Department is making several modifications to routine use (1) entitled ''Program Disclosure.'' First, the Department is including requests for relief under the borrower defense regulations as one of the types of requests for which the Department may disclose records and clarifying that the Department may disclose records where a request for borrower defense to repayment is successful in order to determine the relief that is appropriate under the circumstances as well as to initiate the appropriate proceeding to require the school whose acts or omissions resulted in the successful defense against repayment to pay the Department the amount of the loan to which the defense applies. Disclosing records where a request for borrower defense to repayment is successful in order to determine the relief that is appropriate under the circumstances was previously authorized by ''routine uses'' published in the ''Common Services for Borrowers (CSB)'' system of records notice, *see* 81 FR 60,683–60,691 (Sep. 2, 2016), and the Department is making this more explicit now. Second, the Department is revising this routine use to permit the Department to make disclosures when further information ''is relevant'' to, rather than ''is necessary to,'' the Department's resolution of the complaint, request, or other inquiry. Third, the Department is adding accreditors.

The Department is removing former routine use (2) entitled ''Disclosure for Use by Other Law Enforcement Agencies'' because the Department no longer intends to disclose any records under this routine use.

The Department is modifying routine use (3) entitled ''Litigation and Alternative Dispute Resolution (ADR) Disclosure'' to insert the word ''person'' in place of the word ''individual'' to avoid any confusion to the public because we did not intend the word ''individual'' to have the meaning of this term as defined in the Privacy Act.

The Department is also modifying routine use (5) entitled ''Contract Disclosure'' to remove the reference to ''Privacy Act safeguards as required under 5 U.S.C. 552a(m)'' to now require that all contractors agree to maintain safeguards to protect the security and confidentiality of the records in the system. The Department also has clarified that such safeguards will be agreed to as part of the contract, rather than before the contract is entered into.

The Department is removing former routine use (7) entitled ''Research Disclosure.'' Consistent with our commitment to protect personal data, we do not anticipate releasing student, borrower, or applicant-level data for purposes other than program administration.

The Department is modifying routine use (7) entitled ''Borrower Complaint Disclosure'' to include ''processing'' and ''reviewing'' of a complaint as a course through which the Department may disclose a record to better align with the language of routine use (8) entitled ''Borrower Defense to Repayment Disclosure''.

The Department is adding routine use (8) entitled ''Borrower Defense to Repayment Disclosure'' to clarify that disclosure of a record from this system of records is allowed in the course of reviewing, processing, investigating, fact-finding, or adjudicating a request for relief under the borrower defense regulations or in the course of the Department's enforcement activity to: Federal agencies, the student (if the student is not the borrower), the counsel or representative of the borrower or the student, or the school whose conduct is subject of the request for relief or the school's counsel or representative; a witness; or a designated fact-finder, mediator, or other person designated to resolve issues or decide the matter. The disclosure may only be made during the course of the review, processing, investigation, fact-finding, or adjudication of the request for relief.

Pursuant to the requirements in Office of Management and Budget Memorandum M–17–12 entitled ''Preparing for and Responding to a Breach of Personally Identifiable Information,'' the Department is also adding an additional routine use (11) in order to permit the Department to

disclose records from this system of records in the course of assisting another Federal agency or entity in responding to a breach of data. Lastly, the Department is modifying routine use (10) (previously routine use (11)) so that the routine use conforms with the requirements set forth in OMB Memorandum M–17–12 entitled ''Preparing for and Responding to a Breach of Personally Identifiable Information.''

The Department is updating the section entitled ''POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS'' to explain that the applicable Department records schedule is being amended, pending approval by the National Archives and Records Administration (NARA).

The sections entitled ''RECORD ACCESS PROCEDURES,'' ''CONTESTING RECORD PROCEDURES,'' and ''NOTIFICATION PROCEDURES'' are modified to define the ''necessary particulars'' needed to access, contest, or be notified of a record.

The Department has also added a section entitled ''HISTORY.''

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* Braille, large print, audiotape, or compact disc) on request to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations 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 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.

Dated: June 8, 2018.

James F. Manning,

Acting Chief Operating Officer, Federal Student Aid.

For the reasons discussed in the preamble, the Acting Chief Operating Officer of Federal Student Aid (FSA) of the U.S. Department of Education (Department) publishes a notice of a modified system of records to read as follows:

SYSTEM NAME AND NUMBER:

Customer Engagement Management System (CEMS) (18–11–11).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Salesforce Data Center, primary data center in 44521 Hastings Drive Ashburn, VA 20147. The system is accessible via the internet to different categories of users, including Department personnel, customers, and designated agents of the Department at any location where they have internet access.

SYSTEM MANAGER(S):

Ombudsman, Federal Student Aid, U.S. Department of Education, 830 First Street NE, Room 4111, Washington, DC 20202.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

20 U.S.C. 1018(f) and 1087e(h).

PURPOSE(S) OF THE SYSTEM:

The information maintained in this system will be used for a number of purposes related to the duties and responsibilities of the FSA Ombudsman; and, separately, to perform the duties and responsibilities of the Department to provide Federal student loan repayment relief, and certain further relief, under the borrower defense to repayment regulations at 34 CFR 685.206. The information will be used to: Verify the identities of individuals; record complaints and comments; track individual cases through final resolution; report trends; and analyze the data to recommend improvements in student financial assistance programs; and assist in the informal resolution of disputes. The information will also be used by the Department to receive, review, evaluate, and process requests for relief under the borrower defense to repayment regulations, to render decisions on the merits of such requests for relief, and, where requests for borrower defense to repayment are successful, to determine the relief that is appropriate to borrowers under the circumstances as well as to initiate appropriate proceedings to require schools whose acts or omissions resulted in the successful defenses against repayment to pay the Department the amounts of the loans to which the defenses apply.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains records on individuals who are, were, or may be participants in any of the Student Financial Assistance Programs under title IV of the Higher Education Act of 1965, as amended (HEA) who request assistance, directly or through a designated third party, from Federal Student Aid Enforcement Office or the FSA Ombudsman.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of a variety of records that identify the individuals' complaints, requests for assistance, requests for borrower defense relief, or other inquiries. Records include, but are not limited to: Written documentation of an individual's complaint, request for assistance, request for relief under the borrower defense regulations, or other comment or inquiry; and information pertaining to the individual's or the individual's parent's student financial assistance program account(s) under title IV of the HEA, such as the individual's name, Social Security number (SSN), date of birth, address, telephone number(s), and Federal Student Aid ID (FSA ID). Records may include the name, address, and phone numbers of the individual's counsel or representative, school(s), lender(s), secondary holder(s) or lender(s), guaranty agency(ies), servicer(s), and private collection agency(ies), if applicable, and, may contain other loan level data.

RECORD SOURCE CATEGORIES:

Information is obtained from individuals (*e.g.,* borrowers), their counsel or representatives, or students or their parents (when the individual is a borrower and depending on whether the individual is a parent or student), Federal agencies, State agencies, schools, lenders, private collection agencies, guaranty agencies, accreditors, and from other persons or entities from which data is obtained under routine uses set forth below.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records under the routine uses listed in this system of records without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. These disclosures may be made on a case-by-case basis or, if the Department has complied with the computer matching requirements of the Privacy Act of 1974, as amended (Privacy Act), under a computer matching agreement.

(1) *Program Disclosure.* The Department may disclose records to

Federal agencies, State agencies, accreditors, schools, lenders, guaranty agencies, servicers, and private collection agencies when further information about the complaint, request for assistance, request for Federal student loan repayment relief and other further relief under the borrower defense to repayment regulations, or other inquiry is relevant to the Department's resolution of the complaint, request, or other inquiry, and, where a request for borrower defense to repayment is successful, to determine the relief that is appropriate under the circumstances as well as to initiate the appropriate proceeding to require the school whose acts or omissions resulted in the successful defense against repayment to pay the Department the amount of the loan to which the defense applies.

(2) *Enforcement Disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulation, or order of a competent authority, the Department may disclose the relevant records to the appropriate agency, whether foreign, Federal, State, Tribal, or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive Order, rule, regulation, or order issued pursuant thereto.

(3) *Litigation and Alternative Dispute Resolution (ADR) Disclosure.*

(a) *Introduction.* In the event that one of the parties listed in sub-paragraphs (i) through (v) is involved in judicial or administrative litigation or ADR, or has an interest in such litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department, or any component of the Department;

(ii) Any Department employee in his or her official capacity;

(iii) Any Department employee in his or her individual capacity if the U.S. Department of Justice (DOJ) has been requested to or has agreed to provide or arrange for representation for the employee;

(iv) Any Department employee in his or her individual capacity where the Department has agreed to represent the employee; or

(v) The United States where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to the DOJ.* If the Department determines that disclosure of certain records to the DOJ is relevant and necessary to litigation or ADR, the Department may disclose those records as a routine use to the DOJ.

(c) *Adjudicative Disclosure.* If the Department determines that it is relevant and necessary to the litigation or ADR to disclose certain records to an adjudicative body before which the Department is authorized to appear, to a person, or an entity designated by the Department or otherwise empowered to resolve or mediate disputes, the Department may disclose those records as a routine use to the adjudicative body, person, or entity.

(d) *Disclosure to Parties, Counsel, Representatives, and Witnesses.* If the Department determines that disclosure of certain records to a party, counsel, representative, or witness is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative, or witness.

(4) *Disclosure to the DOJ.* The Department may disclose records to the DOJ to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the programs covered by this system.

(5) *Contract Disclosure.* If the Department contracts with an entity for the purposes of performing any function that requires disclosure of records in this system to employees of the contractor, the Department may disclose the records to those employees. As part of such a contract, the Department shall require the contractor to agree to maintain safeguards to protect the security and confidentiality of the records in the system.

(6) *Congressional Member Disclosure.* The Department may disclose records to a member of Congress from the record of an individual in response to an inquiry from the member made at the written request of that individual. The member's right to the information is no greater than the right of the individual who requested it.

(7) *Borrower Complaint Disclosure.* If a record is relevant and necessary to a borrower complaint regarding participants in any of Student Financial Assistance Programs under title IV of the HEA, the Department may disclose a record from this system of records in the course of processing, reviewing, investigating, fact-finding, or adjudicating the complaint to: Any party to the complaint; the party's counsel or representative; a witness; or a designated fact-finder, mediator, or other person designated to resolve issues or decide the matter. The disclosure may only be made during the course of the review, processing, investigation, fact-finding, or adjudication.

(8) *Borrower Defense to Repayment Disclosure.* If a record is relevant and necessary to an individual's request for relief from repayment of a Federal student loan or other relief under the borrower defense to repayment regulations, or the potential provision of such relief in connection with the Department's enforcement activities on any of the Student Financial Assistance Programs under title IV of the HEA, the Department may disclose a record from this system of records in the course of processing, reviewing, investigating, fact-finding, or adjudicating the request or in the course of the Department's enforcement activity to: Federal agency, the student (if the student is not the borrower), the counsel or representative of the borrower or the student, or the school whose conduct is subject of the request for relief or the school's counsel or representative; a witness; or a designated fact-finder, mediator, or other person designated to resolve issues or decide the matter. The disclosure may only be made during the course of the review, processing, investigation, fact-finding, or adjudication.

(9) *Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure.* The Department may disclose records from this system of records to the DOJ or Office of Management and Budget (OMB) if the Department concludes that disclosure is desirable or necessary in determining whether particular records are required to be disclosed under the FOIA or the Privacy Act.

(10) *Disclosure in the Course of Responding to a Breach of Data.* The Department may disclose records from this system of records to appropriate agencies, entities, and persons when: (a) The Department suspects or has confirmed that there has been a breach of the system of records; (b) the Department has determined that as a result of the suspected or confirmed breach, there is a risk of harm to individuals, the Department (including its information systems, programs, and operation), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(11) *Disclosure in Assisting another Agency in Responding to a Breach of*

Data. The Department may disclose records from this system to another Federal agency or Federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records will be maintained in an electronic database.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are indexed by Social Security number, name, date of birth, and case tracking number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

All records are retained and disposed of in accordance with Department Records Schedule 052: Ombudsman Case Files (N1–441–09–21) (ED 052). ED 052 is being amended, pending approval by the National Archives and Records Administration (NARA). Records will not be destroyed until NARA-approved amendments to ED 052 are in effect, as applicable.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to and use of these records by Department employees and agents shall be limited to those persons whose official duties require access. This includes staff members of the Office of the Student Loan Ombudsman, Enforcement Office staff members, and other Department employees and agents. All physical access to the site where this system of records is maintained, is controlled and monitored by security personnel who check each individual entering the building for his or her employee or visitor badge.

The computer system offers a high degree of resistance to tampering and circumvention. This security system limits data access to staff on a ''need to know'' basis, and controls individual users' ability to access and alter records within the system. All users of this system of records are given unique user IDs with personal identifiers. All interactions by individual users with the system are recorded.

RECORD ACCESS PROCEDURES:

If you wish to gain access to a record regarding you in the system of records, contact the system manager at the address listed above. You must provide necessary particulars such as your name, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name. Your request must meet the requirements of 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURES:

If you wish to contest the content of a record regarding you in the system of records, contact the system manager with the information described in the record access procedures. Your request must meet the requirements of 34 CFR 5b.7.

NOTIFICATION PROCEDURES:

If you wish to determine whether a record exists regarding you in the system of records, contact the system manager at the address listed above. You must provide necessary particulars such as your name, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals of with the same name. Your request must meet the requirements of 34 CFR 5b.5, including proof of identity.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The system of records notice entitled ''Office of the Student Loan Ombudsman Records'' (18–11–11) was published in the **Federal Register** on December 27, 1999 (64 FR 72384, 72399–72400). The ''Office of the Student Loan Ombudsman Records'' system of records notice was most recently altered and republished in full in the **Federal Register** on March 8, 2016 (81 FR 12081).

The records that will be maintained in the CEMS system of records that are about individuals who have asserted defenses to the repayment of their Federal student loans, also known as ''borrower defenses,'' pursuant to the Department's regulations at 34 CFR 685.206, previously were covered by the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16), which was first published in the **Federal Register** on January 23, 2006 (71 FR 3503), subsequently updated on September 12, 2014 (79 FR 54685), and last altered on September 2, 2016 (81 FR 60683).

[FR Doc. 2018–12700 Filed 6–12–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Request for Information (RFI) on Identifying Priorities for Reducing Barriers to Deployment of Hydrogen Infrastructure

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) published a Request for Information (RFI) on Identifying Priorities for Reducing Barriers to Deployment of Hydrogen Infrastructure on EERE Exchange to gather information on priority areas for reducing barriers to deployment of hydrogen technologies, with a particular focus on hydrogen infrastructure.

DATES: Responses to the RFI must be received no later than 5:00 p.m. (ET) on August 10, 2018.

ADDRESSES: Interested parties are to submit comments electronically to *FY18FCTOBARRIERSRFI@EE.DOE.GOV.* Responses must be provided as attachments to an email. Include ''Deployment Barriers RFI'' as the subject of the email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.,* zipped) to ensure message delivery. Responses must be provided as a Microsoft Word (.docx) attachment to the email, and 12 point font, 1 inch margins. Only electronic responses will be accepted. The complete RFI document is located at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Questions may be addressed to *FY18FCTOBARRIERSRFI@EE.DOE.GOV.* Further instruction can be found in the RFI document posted on EERE Exchange.

SUPPLEMENTARY INFORMATION: DOE posted on its website an RFI to solicit feedback from industry, academia, research laboratories, government agencies, and other stakeholders on critical barriers to deployment of hydrogen infrastructure. The goal of the RFI is to identify these barriers and potential courses-of-action to address them to reduce deployment time and cost in implementing hydrogen technologies and to support the implementation of large-scale applications. Deployment of hydrogen

station regulatory compliance costs and time for regulatory processing have been shown to be substantial. Courses-of-action may include areas such as: Identifying gaps in existing regulations, codes and standards; streamlining regulatory, permitting, and certification processes; reducing unneeded compliance actions; or consolidating regulatory requirements. The RFI [DE–FOA–0001948] is available at: *https://eere-exchange.energy.gov/.*

Confidential Business Information

Because information received in response to this RFI may be used to structure future programs, funding and/or otherwise be made available to the public, respondents are strongly advised to not include any information in their responses that might be considered business sensitive, proprietary, or otherwise confidential. If, however, a respondent chooses to submit business sensitive, proprietary, or otherwise confidential information, it must be clearly and conspicuously marked as such in the response as detailed in the RFI [DE–FOA–0001948] at: *https://eere-exchange.energy.gov/.*

Issued in Washington, DC, on June 7, 2018.

Sunita Satyapal,

Director, Fuel Cell Technologies Office.

[FR Doc. 2018–12699 Filed 6–12–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review and comment.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its Procurement Collection, OMB Control Number 1910–4100. This information collection request covers information necessary to administer and manage DOE's procurement and acquisition programs.

DATES: Comments regarding this collection must be received on or before July 13, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 395–4650.

ADDRESSES: Written comments should be sent to the: DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building Room 10102, 735 17th Street NW, Washington, DC 20503.

If you wish access to the collection of information, without charge, contact the person listed as soon as possible. Sharon Archer, Procurement Analyst, MA–61/L'Enfant Plaza Building, U.S. Department of Energy, 950 L'Enfant Plaza SW, Washington, DC 20024, *Sharon.Archer@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Sharon Archer, by email: *Sharon.Archer@hq.doe.gov,* or by telephone at (202) 287–1739.

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) *OMB No.* 1910–4100 (Renewal); (2) *Information Collection Request Title:* Procurement Information Collection; (3) *Type of Request:* Renewal; (4) *Purpose:* Under 48 CFR part 952 and Subpart 970.52, DOE must collect certain types of information from those seeking to do business with the Department or those awarded contracts by the Department. This information collection is necessary for the solicitation, award, administration, and closeout of DOE procurement contracts. (5) *Annual Estimated Number of Respondents:* 7,387; (6) *Annual Estimated Total Burden Hours:* 666,082; (7) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $56,616,970.

Statutory Authority: 42 U.S.C. 2201.

Issued in Washington, DC, on May 31, 2018.

John Bashista,

Director, Office of Acquisition Management.

[FR Doc. 2018–12698 Filed 6–12–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Proposed New Survey or Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Notice and request for comments.

SUMMARY: EIA is requesting a three-year extension of EIA–882T, ''Generic Clearance for Questionnaire Testing, Evaluation, and Research.'' EIA–882T provides EIA with the authority to utilize qualitative and quantitative methodologies to pretest questionnaires and validate the quality of data collected on EIA's surveys. EIA uses EIA–882T to meet its obligation to publish, and otherwise make available independent, high-quality statistical data to federal government agencies, state and local governments, the energy industry, researchers, and the general public.

DATES: EIA must receive all comments on this proposed information collection no later than August 13, 2018. If you anticipate any difficulties in submitting your comments by the deadline, contact the person listed in the **ADDRESSES** section of this notice as soon as possible.

ADDRESSES: Send your comments to Brian Hewitt, U.S. Energy Information Administration, 1000 Independence Avenue SW, EI–21 Washington, DC 20585. If you prefer, you can email them to: *brian.hewitt@eia.gov.*

FOR FURTHER INFORMATION CONTACT: If you need additional information, send your request to Brian Hewitt, U.S. Energy Information Administration, 1000 Independence Avenue SW, EI–21, Washington, DC 20585. If you prefer, you can email *brian.hewitt@eia.gov* or contact him by telephone at 202–586–5045.

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1905–0186;

(2) *Information Collection Request Title:* Generic Clearance for Questionnaire Testing, Evaluation, and Research;

(3) *Type of Request:* Renewal;

(4) *Purpose:* The U.S. Energy Information Administration (EIA) is requesting a three-year approval from the Office of Management and Budget (OMB) to utilize qualitative and quantitative methodologies to pretest questionnaires and validate the quality of the data that is collected on EIA and DOE survey forms. Through the use of these methodologies, EIA will conduct research studies to improve the quality of energy data being collected, reduce or minimize survey respondent burden, and increase agency efficiency. This authority would also allow EIA to improve data collection in order to meet the needs of EIA's customers while also staying current in the evolving nature of the energy industry.

The specific methods proposed for the coverage by this clearance are described below. Also outlined is the legal authority for these voluntary information gathering activities.

The following methods are proposed:

Pilot Surveys. Pilot surveys conducted under this clearance will generally be methodological studies, and will always employ statistically representative samples. The pilot surveys will replicate all components of the methodological design, sampling procedures (where possible), and questionnaires of the full scale survey. Pilot surveys will normally be utilized when EIA undertakes a complete redesign of a particular data collection methodology or when EIA undertakes data collection in new energy areas, such as HGL production, alternative fueled motor vehicles, and other emerging areas of the energy sector where data collection would provide utility to EIA.

Cognitive Interviews. Cognitive interviews are typically one-on-one interviews in which the respondent is usually asked to ''think aloud'' or is asked ''retrospective questions'' as he or she answers questions, reads survey materials, defines terminology, or completes other activities as part of a typical survey process. A number of different techniques may be involved including, asking respondents what specific words or phrases mean or asking respondents probing questions to determine how they estimate, calculate, or determine specific data elements on a survey. The objectives of these cognitive interviews are to identify problems of ambiguity or misunderstanding, examine the process that respondents follow for reporting information, assess survey respondents' ability to report new information, or identify other difficulties respondents have answering survey questions in order to reduce measurement error from estimates based on a survey.

Respondent Debriefings. Respondent debriefings conducted under this clearance will generally be methodological or cognitive research studies. The debriefing form is administered after a respondent completes a questionnaire either in paper format, electronically, or through in-person interviews. The debriefings contain probing questions to determine how respondents interpret the survey questions, how much time and effort was spent completing the questionnaire, and whether they have problems in completing the survey/questionnaire. Respondent debriefings also are useful in determining potential issues with data quality and in estimating respondent burden.

Usability Testing. Usability tests are similar to cognitive interviews in which a respondent is typically asked to ''think aloud'' or asked ''retrospective questions'' as he or she reviews an electronic questionnaire, website, visual aid, or hard copy survey form. The objective of usability testing is to check that respondents can easily and intuitively navigate electronic survey collection programs, websites, and other survey instruments to submit their data to EIA.

Focus Groups. Focus groups, in person or online, involve group sessions guided by a moderator who follows a topic guide containing questions or subjects focused on a particular issue rather than adhering to a standardized cognitive interview protocol. Focus groups are useful for exploring issues concerning the design of a form and the meaning of terms from a specific group of respondents, data users, or other stakeholders of EIA data.

(5) *Annual Estimated Number of Respondents:* 1,870;

(6) *Annual Estimated Number of Total Responses:* 1,870;

(7) *Annual Estimated Number of Burden Hours:* 1,915;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* There are no additional costs associated with these survey methods other than the burden hours. The information is maintained in the normal course of business. The annual cost in burden hours to the respondents is estimated to be $144,946 (1,915 burden hours times $75.69 per hour), which represents a reduction of 85 burden hours from the prior renewal of this collection. Therefore, other than the cost of burden hours, EIA estimates that there are no additional costs for generating, maintaining, and providing the information.

Comments are invited on whether or not: (a) The proposed collection of information is necessary for the proper performance of agency functions, including whether the information will have a practical utility; (b) EIA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, is accurate; (c) EIA can improve the quality, utility, and clarity of the information it will collect; and (d) EIA can minimize the burden of the collection of information on respondents, such as automated collection techniques or other forms of information technology.

Statutory Authority: Section 13(b) of the Federal Energy Administration Act of 1974, Pub. L. 93–275, codified as 15 U.S.C. 772(b) and the DOE Organization Act of 1977, Pub. L. 95–91, codified at 42 U.S.C. 7101 *et seq.*

Issued in Washington, DC, on May 29, 2018.

Nanda Srinivasan,

Director, Office of Survey Development and Statistical Integration, U.S. Energy Information Administration.

[FR Doc. 2018–12696 Filed 6–12–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL18–171–000]

Notice of Complaint: Kathryn E. Leonard v. Deepwater Wind Block Island, LLC, Narragansett Electric Company, Inc., Rhode Island Public Utilities Commission

Take notice that on June 7, 2018, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Kathryn E. Leonard (Complainant) filed a formal complaint against Deepwater Wind Block Island, LLC (Deepwater Wind), Narragansett Electric Company, Inc., and Rhode Island Public Utilities Commission (jointly Respondents) alleging that, Rhode Island Public Utility Commission on August 16, 2010, as directed by the Rhode Island General Assembly, approved a 20-year Purchase Power Agreement between Deepwater Wind and National Grid that appears to constitute a violation of the FPA, all as more fully explained in the complaint.

Complainant certifies that copies of the complaint were served on the contacts for the Rhode Island Public Utility Commission as listed on the Commission's list of Corporate Officials, as well as contacts for National Grid and Deepwater Wind.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions 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 protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This 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 there is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). 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 June 27, 2018.

Dated: June 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–12666 Filed 6–12–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP18–859–000.
Applicants: Colorado Interstate Gas Company, L.L.C.
Description: Colorado Interstate Gas Company, L.L.C. submits tariff filing per 154.403(d)(2): LUF Qtrly Filing to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5117.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–860–000.
Applicants: Kinder Morgan Louisiana Pipeline LLC.
Description: Kinder Morgan Louisiana Pipeline LLC submits tariff filing per 154.403: Periodic Rate Adjustment—7/1/18 to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5179.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–861–000.
Applicants: Equitrans, L.P.
Description: Equitrans, L.P. submits tariff filing per 154.204: Scheduling Priority Exemption for Reservation Charge Credits to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5180.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–862–000.
Applicants: Ruby Pipeline, L.L.C.
Description: Ruby Pipeline, L.L.C. submits tariff filing per 154.403(d)(2): Filing to Update FLU and EPC to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5189.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–863–000.
Applicants: Discovery Gas Transmission LLC.
Description: Discovery Gas Transmission LLC submits tariff filing per 154.403(d)(2): 2018 FL&U Submittal to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5202.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–864–000.
Applicants: Kinder Morgan Louisiana Pipeline LLC.
Description: Kinder Morgan Louisiana Pipeline LLC submits tariff filing per 154.204: Amendment to Gas Quality Provision to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5211.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–865–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Amendment to Neg Rate Agmt (Vicksburg 36347–4) to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5213.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–866–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Cap Rel Neg Rate Agmt (Petrohawk 41455 to Sequent 49576 & Texla 49578) to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5216.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–867–000.
Applicants: Texas Gas Transmission, LLC.
Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: Cap Rel Neg Rate Agmts (RE Gas 35433, 34955 to BP 37202, 37203) to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5217.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–868–000.
Applicants: Arlington Storage Company, LLC.
Description: Arlington Storage Company, LLC submits tariff filing per 154.204: Filing of Revised Tariff Records to be effective 6/4/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5227.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–869–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.204: Negotiated Rates—Cherokee AGL—Replacement Shippers—Jun 2018 to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5239.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–870–000.
Applicants: Garden Banks Gas Pipeline, LLC.
Description: Garden Banks Gas Pipeline, LLC submits tariff filing per 154.204: Auger Platform FT–2 Dedications to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5255.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–871–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Tennessee Gas Pipeline Company, L.L.C. submits tariff filing per 154.204: KM Lease Charges to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5287.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–872–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Tennessee Gas Pipeline Company, L.L.C. submits tariff filing per 154.204: Volume No. 2—Seneca Resources Corp—Amend No.2 SP315568 to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5288.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–873–000.
Applicants: Tallgrass Interstate Gas Transmission, L.
Description: Tallgrass Interstate Gas Transmission, LLC submits tariff filing per 154.204: NC 2018–05–31 CSU to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5298.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–874–000.
Applicants: Rockies Express Pipeline LLC.
Description: Rockies Express Pipeline LLC submits tariff filing per 154.204:

Neg Rate 2018–05–31 ARM to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5322.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–875–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: El Paso Natural Gas Company, L.L.C. submits tariff filing per 154.601: Negotiated Rate Agreement Update (Conoco June_Aug 18) to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5332.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–876–000.
Applicants: Rockies Express Pipeline LLC.
Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Neg Rate 2018–05–31 E2W to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5336.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–877–000.
Applicants: MoGas Pipeline LLC.
Description: MoGas Pipeline LLC submits tariff filing per 154.312: MoGas Section 4 Rate Filing to be effective 7/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5348.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP18–878–000.
Applicants: Northern Natural Gas Company.
Description: Northern Natural Gas Company submits tariff filing per 154.204: 20180531 Negotiated Rate to be effective 6/1/2018.
Filed Date: 5/31/18.
Accession Number: 20180531–5373.
Comments Due: 5 p.m. ET 6/12/18.

Docket Numbers: RP01–382–028.
Applicants: Northern Natural Gas Company.
Description: Northern Natural Gas Company submits Carlton Reimbursement Report under RP01–382.
Filed Date: 6/1/18.
Accession Number: 20180601–5219.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–879–000.
Applicants: Equitrans, L.P.
Description: Equitrans, L.P. submits tariff filing per 154.204: Negotiated Capacity Release Agreements—6/1/2018 to be effective 6/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5040.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–880–000.
Applicants: Viking Gas Transmission Company.
Description: Viking Gas Transmission Company submits tariff filing per 154.204: Interim Filing to Reduce FLRP—June 2018 to be effective 7/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5090.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–881–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.204: Cap Rel Neg Rate Agmts (Newfield 18 releases eff 6–1–2018) to be effective 6/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5145.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–882–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Cap Rel Neg Rate Agmts (Atlanta Gas 8438 to various eff 6–1–2018) to be effective 6/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5147.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–883–000.
Applicants: Rockies Express Pipeline LLC.
Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Neg Rate 2018–06–01 Rice to EQT (3Ks) to be effective 6/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5149.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–884–000.
Applicants: ANR Pipeline Company.
Description: ANR Pipeline Company submits tariff filing per 154.601: ANR EQT Non-Conforming Amendments to be effective 6/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5217.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–885–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Columbia Gas Transmission, LLC submits tariff filing per 154.601: TCO EQT Negotiated Rate Amendments to be effective 6/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5218.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–886–000.
Applicants: Enable Gas Transmission, LLC.
Description: Enable Gas Transmission, LLC submits tariff filing per 154.204: Negotiated Rate Filing—June 2018—Newfield 1011021 to be effective 6/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5239.
Comments Due: 5 p.m. ET 6/13/18.

Docket Numbers: RP18–887–000.
Applicants: Eastern Shore Natural Gas Company.
Description: Eastern Shore Natural Gas Company submits tariff filing per 154.204: Fuel Retention and Cash-Out Adjustment to be effective 7/1/2018.
Filed Date: 6/1/18.
Accession Number: 20180601–5276.
Comments Due: 5 p.m. ET 6/13/18.
Comments Due: 5 p.m. ET 6/18/18.

Docket Numbers: RP18–510–000.
Applicants: KPC Pipeline, LLC.
Description: KPC Pipeline, LLC submits Compliance Filing of Additional Information Concerning Proposed Fuel Reimbursement Percentage Rates under RP18–510.
Filed Date: 6/5/18.
Accession Number: 20180605–5166.
Comments Due: 5 p.m. ET 6/18/18.

Docket Numbers: RP18–889–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: Tenaska Marketing Ventures Amendment to NRA Filing to be effective 6/5/2018.
Filed Date: 6/5/18.
Accession Number: 20180605–5000.
Comments Due: 5 p.m. ET 6/18/18.

Docket Numbers: RP18–890–000.
Applicants: Northwest Pipeline LLC.
Description: Northwest Pipeline LLC submits tariff filing per 154.204: Buy and Sell Gas to Support Flows for Inline Inspections Filing to be effective 7/5/2018.
Filed Date: 6/5/18.
Accession Number: 20180605–5078.
Comments Due: 5 p.m. ET 6/18/18.

Docket Numbers: RP18–891–000.
Applicants: Eastern Shore Natural Gas Company.
Description: Eastern Shore Natural Gas Company submits tariff filing per 154.204: Non-Conforming Letter Agreements-Easton/CUC–MD to be effective 6/5/2018.
Filed Date: 6/6/18.
Accession Number: 20180606–5000.
Comments Due: 5 p.m. ET 6/18/18.

Docket Numbers: RP15–517–001.
Applicants: Vector Pipeline L.P.
Description: Vector Pipeline L.P. submits tariff filing per 154.203: Negotiated Rate RP15–517 Compliance Filing to be effective 6/1/2018 under RP15–517.
Filed Date: 6/7/18.
Accession Number: 20180607–5033.
Comments Due: 5 p.m. ET 6/19/18.

Docket Numbers: RP18–789–000.

Applicants: Cheniere Corpus Christi Pipeline, LP.

Description: Cheniere Corpus Christi Pipeline, LP submits tariff filing per: Section 157.20(c)(2) Compliance in Docket Nos. CP12–508–000, *et al.*—Eff 6/1/18 to be effective N/A.

Filed Date: 6/7/18.

Accession Number: 20180607–5020.

Comments Due: 5 p.m. ET 6/19/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–12665 Filed 6–12–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18–332–000]

Notice of Intent To Prepare an Environmental Assessment for the Proposed El Paso Natural Gas Company, LLC. South Mainline Expansion Project, and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the South Mainline Expansion Project involving construction and operation of facilities by El Paso Natural Gas Company, L.L.C. (EPNG) in Hudspeth and El Paso Counties, Texas; Luna County, New Mexico; and Cochise County, Arizona. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts.

Your input will help the Commission staff determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Daylight Time on July 9, 2018.

If you sent comments on this project to the Commission before the opening of this docket on April 27, 2018, you will need to file those comments in Docket No. CP18–332–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

EPNG provided landowners with a fact sheet prepared by the FERC entitled An Interstate Natural Gas Facility On My Land? What Do I Need To Know? This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC website (*www.ferc.gov*).

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's website (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on *eRegister.* If you are filing a comment on a particular project, please select Comment on a Filing as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP18–332–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

Summary of the Proposed Project

EPNG's project would consist of:

- Construction of an approximately 17-mile-long, 30-inch-diameter loop line [1] adjacent to existing EPNG Line No. 1100 and Line No. 1103 between mileposts 174.5 and 191.5 in El Paso and Hudspeth Counties, Texas.
- Construction of the new 13,220-horsepower Red Mountain Compressor Station at approximate milepost 301.2 of Line No. 1100 and Line No. 1103 in Luna County, New Mexico.
- Construction of the new 13,220-horsepower Dragoon Compressor Station to be co-located with EPNG's existing Willcox Compressor Station at approximate milepost 406.9 of Line No. 1100 and Line No. 1103 in Cochise County, Arizona.

Appendix 1 shows the general location of the project facilities.[2]

Land Requirements for Construction

The three project locations proposed by EPNG include approximately 418.4 combined acres of land, all of which

[1] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

[2] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE, Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

would be temporarily disturbed during construction. Operational and maintenance areas (permanent disturbances) for these three locations would be approximately 162.0 acres. Land requirements for each proposed facility are summarized below:

Pipeline Loop

Most of the centerline of the proposed new 17-mile-long pipeline loop would be sited 30 feet south of EPNG's existing Line No. 1100, in an expanded easement. From mileposts (MP) 189.2 to 191.5 (within the Homestead Meadows residential area), the pipeline would be sited 20 feet south of Line 1100, wholly within the existing EPNG easement. During construction, EPNG would use a typical construction work area of approximately 80 feet in width. However, to account for the additional pipeline depth and workspace requirements in the sand dune area (MP 188.5 to MP 189.2), EPNG proposes a construction area 190 feet in width. No additional construction work area outside of the existing easement is proposed in the residential area. The total area disturbed during pipeline construction, including contractor yards and staging areas, would be 279.0 acres. For operation of the loop, EPNG proposes to maintain a 60-foot-wide permanent right-of-way for most of its length, except in the area of the sand dunes, where a 100-foot-wide permanent right-of-way would be maintained.

Red Mountain Compressor Station

The proposed Red Mountain Compressor Station would be entirely within the EPNG-owned land parcel which also contains the previously abandoned Deming Compressor Station. Construction of the new compressor facilities would temporarily disturb approximately 78.2 acres within the existing site, with 6.2 acres being permanently maintained for the new aboveground facilities.

Dragoon Compressor Station

The proposed Dragoon Compressor station and its access road would be on the same site that currently contains EPNG's existing Willcox Compressor Station. Construction of the new compressor facilities would temporarily disturb approximately 61.2 acres within the existing site, with approximately 6.4 acres being permanently maintained for the new aboveground facilities.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [3] to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- land use;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- socioeconomics;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2 of this notice.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[4] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

[3] We, us, and our refer to the environmental staff of the Commission's Office of Energy Projects.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Offices (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[5]

We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project.

We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies of the EA will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the

[5] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

attached Information Request (appendix 2).

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on General Search and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* CP18–332). Be sure you have selected an appropriate date range.

For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public sessions or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: June 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–12667 Filed 6–12–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–1708–000.
Applicants: Copenhagen Wind Farm, LLC.
Description: Supplement to May 31, 2018 Copenhagen Wind Farm, LLC tariff filing.
Filed Date: 6/6/18.
Accession Number: 20180606–5151.
Comments Due: 5 p.m. ET 6/27/18.

Docket Numbers: ER18–1751–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: GIA and Distribution Service Agmt O.L.S. Energy-Chino SA No. 1025–1026 to be effective 7/1/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5001.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1752–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: First Revised ISA SA No. 4138; Queue No. AC1–072 to be effective 5/8/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5004.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1753–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 2827R4 Kansas Power Pool & Westar Meter Agent Agreement to be effective 6/1/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5031.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1754–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA SA No. 5108; Queue No. AC2–175 to be effective 10/28/2017.
Filed Date: 6/7/18.
Accession Number: 20180607–5036.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1755–000.
Applicants: Duke Energy Progress, LLC.
Description: Petition of Duke Energy Progress, LLC for Waiver of Tariff Provisions.
Filed Date: 6/6/18.
Accession Number: 20180606–5160.
Comments Due: 5 p.m. ET 6/27/18.

Docket Numbers: ER18–1756–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Removal of Requirement to Perform Stand Alone Scenario in DISIS to be effective 8/7/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5041.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1757–000.
Applicants: NextEra Energy Transmission Southwest, LLC, Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: NextEra Energy Transmission Southwest Formula Rate to be effective 12/31/9998.
Filed Date: 6/7/18.
Accession Number: 20180607–5051.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1758–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–06–07_Termination of SA 2933 ITC Transmission-Michigan Wind 3 GIA (J321) to be effective 5/9/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5052.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1759–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: First Amended LGIA Palen SEGS II, LLC Almasol Generating Station SA No. 98 to be effective 6/1/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5066.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1760–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Revised ISA SA No. 4355; Queue No. Z2–011/AD1–109 to be effective 5/10/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5071.
Comments Due: 5 p.m. ET 6/28/18.

Docket Numbers: ER18–1761–000.
Applicants: Allegheny Energy Supply Company, LLC.
Description: Tariff Cancellation: Cancel Rate schedule FERC No. 3 to be effective 5/3/2018.
Filed Date: 6/7/18.
Accession Number: 20180607–5081.
Comments Due: 5 p.m. ET 6/28/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–12664 Filed 6–12–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Proposed Allocation of Olmsted Powerplant Replacement Project

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of proposed allocation of Olmsted Powerplant Replacement Project.

SUMMARY: Western Area Power Administration (WAPA) Colorado River Storage Project (CRSP) Management Center, a Federal power marketing agency of the Department of Energy, announces its Olmsted Powerplant Replacement Project (Olmsted) Proposed Allocation of Energy. The Final 2018 Olmsted Power Marketing Plan and Call for Applications was published on October 11, 2017, and set forth that an application for an allocation of energy from Olmsted was due by December 11, 2017. WAPA has reviewed and considered the applications received and this **Federal Register** notice outlines WAPA's proposed allocations.

DATES: All comments must be received by the end of the comment period to be assured of consideration. The comment period on the proposed allocation of power begins June 13, 2018 and ends July 13, 2018. WAPA will accept written comments any time during the 30-day comment period.

ADDRESSES: All written comments regarding the proposed allocation of power should be directed to the following address: Mr. Brent Osiek, Vice President of Power Marketing for CRSP, CRSP Management Center, Western Area Power Administration, 299 South Main Street, Suite 200, Salt Lake City, UT 84111. Comments may also be faxed to (801) 524–5017 or emailed to: *osiek@wapa.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Brent Osiek, Vice President of Power Marketing for CRSP, (801) 524–5495; or Mr. Lyle Johnson, Public Utilities Specialist, (801) 524–5585. Written requests for information should be sent to CRSP Management Center, Western Area Power Administration, 299 South Main Street, Suite 200, Salt Lake City, UT 84111; faxed to (801) 524–5017; or emailed to: *osiek@wapa.gov.*

SUPPLEMENTARY INFORMATION: The United States acquired the Olmsted Powerplant in 1990 through condemnation proceedings in order to secure the water rights associated with the Olmsted Powerplant deemed essential to the Central Utah Project (CUP). The CUP is a participating project of the Colorado River Storage Project. As part of the condemnation proceedings, PacifiCorp continued Olmsted operations until 2015; after that time, the operation of the facility became the responsibility of the Bureau of Reclamation.

The existing Olmsted Powerplant greatly exceeded its operational life, and a replacement facility was needed for the generation of power and preservation of associated non-consumptive water rights. On February 4, 2015, the Implementation Agreement (Agreement) for Olmsted was signed by Central Utah Water Conservancy District (District); the Department of the Interior, Bureau of Reclamation; and WAPA (Participants). The Agreement sets forth the responsibilities of the Participants and identifies funding of Olmsted. The District will construct, operate, maintain, and replace the Olmsted Powerplant and incidental facilities in connection with its CUP operations, including power generation.

WAPA is responsible for marketing the Olmsted energy, which is anticipated to be available in the late summer of 2018. Power production will be incidental to the delivery of water and will only be available when water is present. Therefore, only energy, without capacity, will be available for marketing. It is expected that the annual energy production from Olmsted will average around 27,000,000 kWh per year. The Final 2018 Olmsted Power Marketing Plan and Call for Applications was published on October 11, 2017 (82 FR 47201), and set forth that an application for an allocation of energy from Olmsted was due by December 11, 2017.

Olmsted Proposed Allocation of Energy

Pursuant to the Final Power Marketing Criteria, allocations of energy from Olmsted were made based on a percentage of annual generation rather than fixed quantities of energy. Olmsted is a ''take all, pay all'' project; the annual revenue requirement does not depend on the amount of energy available each year. Customers with an allocation will receive a share of the energy and will annually pay a proportional share of the operation, maintenance, and replacement (OM&R) expenses in 12 monthly installments.

Applications were received from four entities representing a total of 14 eligible applicants. In considering the Power Marketing Criteria, priority was given to the District due to its role in the construction, operation, maintenance, and replacement of Olmsted. The District will receive 30 percent of Olmsted's annual generation.

Olmsted will be electrically interconnected to Provo City's (Provo) distribution and transmission facilities. Provo is a participant of the Utah Municipal Power Agency (UMPA), a joint-action agency responsible for supplying the wholesale power needs to Provo and other municipal electric utilities in the area. UMPA, a long-term power customer of WAPA, has agreed to accept all Olmsted energy as it is generated and, under a scheduling and displacement agreement with WAPA, provide Olmsted customers with their respective Olmsted allocation amounts from a portion of UMPA's allocation of Salt Lake City Area Integrated Projects (SLCA/IP) resources, which is also marketed by WAPA. This arrangement will allow the Olmsted recipients more flexibility as it will be easier to schedule this SLCA/IP resource, which is essentially exchanged for Olmsted generation, and it allows the use of existing scheduling and transmission wheeling arrangements. In consideration for providing these arrangements, UMPA will receive a 30 percent allocation of Olmsted generation.

After consideration of the allocations to the District and UMPA, WAPA determined it would use the remaining Olmsted energy to increase the allocations of those applicants that have the lowest percentages of their current loads served by Federal power. Four of the applicants receive less than 10 percent of their energy resources from Federal power. All of the other applicants currently receive over 20 percent of their energy requirements from Federal allocations. Therefore, WAPA awarded 10 percent of the Olmsted generation to the four applicants receiving less than 10 percent of their energy from Federal sources. The following table shows the proposed allocation percentages of the annual energy production of Olmsted:

Applicant	Percentage
Central Utah Water Conservancy District	30
Utah Municipal Power Agency	30
Lehi City, Utah	10
Kaysville City, Utah	10
Weber Basin Water Conservancy District	10
Springville City, Utah	10

WAPA will respond to the comments received regarding the Olmsted Proposed Allocation of Energy and publish its final allocations after the public comment period ends. If any adjustments or corrections are necessary in a recipient's percentage allocation, the allocations of all other recipients

may change. WAPA plans to enter into contracts with customers after publication of the Final Allocation of Power **Federal Register** notice.

Availability of Information

Documents developed or retained by WAPA during this public process will be available, by appointment, for inspection and copying at the CRSP Management Center, 299 South Main Street, Suite 200, Salt Lake City, Utah. Any comments received during the 30-day comment period will be posted to WAPA's website at the following address: *https://www.wapa.gov/regions/CRSP/PowerMarketing/Pages/power-marketing.aspx.*

Procedural Requirements

Environmental Compliance

In compliance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321–4347), the Council on Environmental Quality Regulations (40 CFR parts 1500–1508), and DOE NEPA Regulations (10 CFR part 1021), WAPA issued a Finding of No Significant Impact (FONSI) on January 13, 2017. The FONSI and other NEPA compliance documentation may be found at *https://www.wapa.gov/regions/CRSP/environment/Pages/environment.aspx.*

Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601, *et seq.,* requires a Federal agency to perform a regulatory flexibility analysis whenever the agency is required by law to publish a general notice of proposed rulemaking for any proposed rule unless the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. In defining the term ''rule,'' the RFA specifies that a ''rule'' does not include ''a rule of particular applicability relating to rates [and] services . . . or to valuations, costs or accounting, or practices relating to such rates [and] services . . . .'' 5 U.S.C. 601. WAPA has determined that this action relates to rates or services offered by WAPA and, therefore, is not a rule within the purview of the RFA.

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this **Federal Register** notice by the Office of Management and Budget is required.

Dated: May 30, 2018.

Mark A. Gabriel,

Administrator.

[FR Doc. 2018–12697 Filed 6–12–18; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2018–0229; FRL–9979–22–OARM]

Proposed Information Collection Request; Comment Request; Monthly Progress Reports (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Monthly Progress Reports (Renewal)'' (EPA ICR No. 1039.15, OMB Control No. 2030–0005) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through December 31, 2018. 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: Comments must be submitted on or before August 13, 2018.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OARM–2018–0229 online using *www.regulations.gov* (our preferred method), by email to *oei.docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

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: Thomas Valentino, Policy Training and Oversight Division, Office of Acquisition Management (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–4522; email address: *valentino.thomas@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 *https://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Appropriate Government surveillance of contractor performance is required to give reasonable assurance that efficient methods and effective cost controls are being used for various cost-reimbursable and fixed-rate contracts. Per 48 CFR 1552.211 regulations, on a monthly basis the Agency requires contractors to provide the Contracting Officer's Representative (COR) with a report detailing: (a) What was accomplished on the contract for that period, (b) expenditures for the same period of time, and (c) what is expected to be accomplished on the contract for the next month. Responses to the information collection are mandatory for contractors and are required for the contractors to receive monthly payments.

Form Numbers: EPA Form 1900–68.

Respondents/Affected Entities: Private sector.

Respondent's Obligation to Respond: Mandatory per 48 CFR 1552.211.

Estimated Number of Respondents: 337 (total).

Frequency of Response: Monthly.

Total Estimated Burden: 97,056 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total Estimated Cost: $9,074,736 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in Estimates: There is an increase of 19,650 hours (97,056 − 77,406) in the total estimated respondent burden compared with the ICR currently approved by OMB because there are approximately 337 contracts and orders requiring response in 2018 instead of only 266 in 2014. This figure has increased to 337 due in part to shorter-value and shorter-length contracts being awarded due to budget uncertainty; *e.g.,* continuing funding resolutions, sequestration budget cuts.

Dated: May 24, 2018.

Pamela D. Legare,

Deputy Director, Office of Acquisition Management.

[FR Doc. 2018–12712 Filed 6–12–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–0728; Docket No. CDC–2018–0047]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the National Notifiable Diseases Surveillance System (NNDSS). The NNDSS is the nation's public health surveillance system that monitors the occurrence and spread of diseases and conditions that are nationally notifiable or under standard surveillance.

DATES: CDC must receive written comments on or before August 13, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0047 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, 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. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments 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 Leroy A. Richardson, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. 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;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.
5. Assess information collection costs.

Proposed Project

National Notifiable Diseases Surveillance System—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The National Notifiable Diseases Surveillance System (NNDSS) is based on data collected at the state, territorial and local levels as a result of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Each year, the Council of State and Territorial Disease Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance.

CDC requests a three-year approval for a Revision for the NNDSS, OMB Control No. 0920–0728, Expiration Date 02/28/2021. This Revision includes requests for approval to: (1) Receive case notification data for Salmonella enterica serotype Paratyphi (S. Paratyphi) A, B, or C Infections should they become nationally notifiable or be placed under standardized surveillance; (2) receive case notification data for Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP–CRE) which is now nationally notifiable; (3) receive case notification data for Candida auris (C. auris) which is now under standardized surveillance; and (4) receive disease-specific data elements for CP–CRE.

The NNDSS currently facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: Public health departments in every U.S. state,

New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau). This information is shared across jurisdictional boundaries and both surveillance and prevention and control activities are coordinated at regional and national levels.

Approximately 90% of case notifications are encrypted and submitted to NNDSS electronically from already existing databases by automated electronic messages. When automated transmission is not possible, case notifications are faxed, emailed, uploaded to a secure network or entered into a secure website. All case notifications that are faxed, emailed, and uploaded are done so in the form of an aggregate weekly or annual report, not individual cases. These different mechanisms used to send case notifications to CDC vary by the jurisdiction and the disease or condition. Private personally identifiable information (PII) is collected from automated electronic messages and information can be retrieved by PII. In addition, some combinations of submitted data elements could potentially be used to identify individuals. Private information is not be disclosed unless otherwise compelled by law. All data are treated in a secure manner consistent with the technical, administrative, and operational controls required by the Federal Information Security Management Act of 2002 (FISMA) and the 2010 National Institute of Standards and Technology (NIST) Recommended Security Controls for Federal Information Systems and Organizations. Weekly tables of nationally notifiable diseases are available through CDC WONDER and *data.cdc.gov.* Annual summaries of finalized nationally notifiable disease data are published on CDC WONDER and *data.cdc.gov* and disease-specific data are published by individual CDC programs.

The burden estimates include the number of hours that the public health department uses to process and send case notification data from their jurisdiction to CDC. Specifically, the burden estimates include separate burden hours incurred for automated and non-automated transmissions, separate weekly burden hours incurred for modernizing surveillance systems as part of NNDSS Modernization Initiative (NMI) implementation, separate burden hours incurred for annual data reconciliation and submission, and separate one-time burden hours incurred for the addition of new diseases and data elements. The burden estimates also include the one-time burden for reporting jurisdictions for the addition of case notification data for CP–CRE and C. auris and disease-specific data elements for CP–CRE. The estimated annual burden for the 233 respondents is 18,619 hours. The cost of the information collection is $787,846. The total burden hours increased from 18,529 to 18,619 since the last revision because of the addition of diseases and disease-specific data elements.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
States	Weekly (Automated)	50	52	20/60	867
States	Weekly (Non-Automated)	10	52	2	1,040
States	Weekly (NMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750
States	One-time Addition of Diseases and Data Elements.	50	1	10	485
Territories	Weekly (Automated)	1	52	20/60	17
Territories	Weekly, Quarterly (Non-Automated)	5	56	20/60	93
Territories	Weekly (NMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of Diseases and Data Elements.	1	1	10/60	1
Freely Associated States	Weekly, Quarterly (Non-Automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15

Jeffrey M. Zirger,

Acting 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. 2018–12637 Filed 6–12–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2285]

Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling—Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers.'' This guidance provides information for manufacturers, packers, and distributors and their representatives (collectively ''firms'') of drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively ''medical products''), about how FDA evaluates their medical product communications that present information that is not contained in the FDA-required labeling for the product but that may be

consistent with the FDA-required labeling for the product. The Agency is issuing this guidance to explain FDA's current thinking on commonly asked questions regarding such communications to provide clarity for firms. FDA is also 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.

DATES: The announcement of the guidance is published in the **Federal Register** on June 13, 2018. Submit written comments on the collection of information by July 13, 2018.

ADDRESSES: To ensure 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 ''Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers; Guidance for Industry.'' Also include the FDA docket number found in brackets in the heading of this document.

You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2285 for ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; Division of Small Manufacturers, International and Consumer Assistance, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or to Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kristin Davis, Office of Policy, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–796–0418; or Elizabeth Pepinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3248, Silver Spring, MD 20993–0002, 301–796–1200; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Ana Loloei Marsal, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002, 301–796–8774; or Thomas Moskal, Center for Veterinary Medicine, Food and Drug Administration, 7519

Standish Pl. (HFV–216), Rockville, MD 20855, 240–402–6251.

Regarding the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., 10A–12M, North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers.'' This guidance provides information for firms about how FDA evaluates their medical product communications (that fall within the scope of FDA's regulatory authority) that present information that is not contained in the FDA-required labeling [1] for the product but that may be consistent with the FDA-required labeling for the product.

FDA determines whether a medical product is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling submitted with the product's marketing application or submission (and for devices, also during the classification process). In making this determination, FDA evaluates whether the conditions of use in the proposed labeling are supported by the required levels and types of evidence of safety and effectiveness and whether the benefits of using the product under those specific conditions of use outweigh the risks of the product. After FDA approves, clears, or licenses a medical product, the FDA-required labeling sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing, and it provides directions and information on how to use the product safely and effectively under those conditions.

Medical product firms have told FDA that they are interested in communicating, including in their promotional materials, data and information about the approved/cleared/licensed uses of their products that are not contained in their products' FDA-required labeling. We are aware that firms have questions about how FDA determines whether such communications are consistent with the FDA-required labeling.

The guidance describes FDA's thinking when examining the consistency of a firm's product communications with that product's own FDA-required labeling. As explained in the guidance, if a firm communicates information that is not contained in its product's FDA-required labeling but that is determined to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use, different from the use(s) for which the product is legally marketed. Establishing a product's intended uses is an element in establishing certain violations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Public Health Service Act. However, firms' communications about their products that are consistent with the products' FDA-required labeling but that are false or misleading may subject a firm to enforcement action under the FD&C Act. Thus, the guidance not only describes FDA's thinking on communications that are consistent with the FDA-required labeling, but also provides general recommendations intended to aid firms in complying with requirements in the FD&C Act and FDA's implementing regulations for conveying information that is consistent with the FDA-required labeling in a truthful and non-misleading way. The general recommendations provided in the guidance for conveying information in a truthful and non-misleading way are applicable only to drug and device labeling and prescription drug and restricted device advertising that are consistent with the FDA-required labeling. Communication of information that is not consistent with the FDA-required labeling is outside the scope of these recommendations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on firms' communications for their medical products that may be consistent with the FDA-required labeling. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection for OMB review and clearance.

Title: Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling; OMB Control No. 0910—NEW.

The guidance includes third-party disclosure recommendations regarding information that firms should include in communications that contain information not found in the FDA-required labeling for their medical products but that are consistent with the FDA-required labeling (as explained in the guidance) if they choose to publicly disseminate such materials. The guidance recommends that various aspects of study design and methodology for studies relied on in such communications be disclosed to provide material contextual information (*e.g.,* type of study, study objectives, product dosage/use regimens, control(s) used, patient population studied), and that material limitations related to the study design, methodology, and results also be disclosed in a clear and prominent manner to help ensure that the communications are not false or misleading. Additionally, the guidance recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. Finally, the guidance recommends that firms disclose material contextual information from the FDA-required labeling in these communications, such as data and information from studies in the FDA-required labeling that are relevant to the data or information presented in the communication (*e.g.,* if a communication provides post-market information about the types and rates of occurrence of adverse events that have been observed in practice, the communication should also include information from the FDA-required labeling about the types and rates of occurrence of adverse reactions observed in clinical trials to provide context).

In the **Federal Register** of January 19, 2017 (82 FR 6575), we published a notice announcing the availability of the draft guidance document and included an analysis under the PRA of the information collection burden associated with our recommendations. No comments were received in response to the four information collection topics solicited in the notice.

According to FDA data, approximately 162,000 FDA-regulated

[1] As used in the guidance, the term FDA-required labeling includes the labeling reviewed and approved by FDA as part of the medical product marketing application review process. For products not subject to premarket approval, but instead subject to premarket notification (510(k)) requirements or exempt from premarket review, the term FDA-required labeling includes the labeling that provides adequate directions for use and other information required to appear on the label or in labeling.

promotional materials are prepared by approximately 500 firms annually. Of these materials, we estimate approximately 5 percent contain unique presentations of information consistent with FDA-required labeling, as described in the guidance, submitted by approximately 64 percent (or 324) of the firms. Anticipating that the number of these FDA-regulated promotional materials will soon increase to 6 percent, we estimate the 324 firms will prepare and disseminate annually 9,720 FDA-regulated promotional materials that contain unique presentations of information that is consistent with the FDA-required labeling, as described in the guidance, and that therefore are recommended to include the proposed third party disclosures. Based on our experience reviewing FDA-regulated promotional materials for medical products, we estimate it will take respondents approximately 4 hours per unique presentation to prepare and incorporate the disclosures recommended in the guidance, if they choose to disseminate this information.

We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of information	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling	324	30	9,720	4	38,880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA is issuing this final guidance subject to OMB approval of the collection of information. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the collection of information, including OMB control number(s) for newly approved collections.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *https://www.regulations.gov.*

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12631 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1307]

Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' This guidance provides answers to common questions regarding the communication of health care economic information (d) about approved prescription drugs and approved or cleared medical devices by medical product manufacturers, packers, distributers, and their representatives (firms) to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis (collectively referred to as payors). This guidance also provides answers to common questions about both firms' dissemination of information to payors about medical products that are not yet approved or cleared for any use and firms' dissemination of information to payors about unapproved uses of approved or cleared medical products. The Agency is issuing this guidance to explain FDA's current thinking on frequently asked questions regarding these topics in order to provide clarity for firms and payors. FDA is also 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.

DATES: The announcement of the guidance is published in the **Federal Register** on June 13, 2018. Submit written comments on the collection of information by July 13, 2018.

ADDRESSES: To ensure 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 ''Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities.'' Also include the FDA docket number found in brackets in the heading of this document.

You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1307 for ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or to the Office of Communication, Education and Radiation Programs, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kristin Davis, Office of Policy, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–796–0418; Sheila Ryan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3320, Silver Spring, MD 20993–0002, 301–796–1200; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Ana Loloei Marsal, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002, 301–796–8774.

Regarding the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., 10A–12M, North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and review staff entitled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' This guidance provides answers to common questions regarding firms' communications of HCEI about their approved prescription drugs to payors. The guidance also provides answers to common questions regarding firms' communications of HCEI about their approved or cleared medical devices to payors. In addition, the guidance addresses common questions relating to firms' dissemination to payors of information about medical products [1] that are not yet approved or cleared for any use and about unapproved uses of approved/cleared medical products. For purposes of this guidance, the term ''payors'' collectively refers to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis that are responsible for making product selection or acquisition, formulary management, and/or coverage and reimbursement decisions on a population basis regarding drugs and/or devices on behalf of health care organizations, which may include entities such as integrated health care delivery networks, hospitals, and hospital systems.

FDA is aware that payors seek a range of information on effectiveness, safety, and cost-effectiveness of approved/cleared medical products, including information from firms, to help support their medical product selection, formulary management, and/or coverage and reimbursement decisions on a

[1] The term ''medical product'' refers to both drugs and devices.

population basis. This information may differ from and may be in addition to the information FDA reviews in order to make drug and device approval or clearance decisions. Because coverage and reimbursement decisions by payors impact many patients, FDA believes it is critical that HCEI provided by firms to payors about their approved drugs and approved/cleared devices be truthful and non-misleading.

With respect to HCEI regarding approved drugs, section 502(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(a)), as amended by section 114 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and section 3037 of the 21st Century Cures Act (Pub. L. 114–255), includes a provision regarding communication of HCEI about such drugs to payors. Section 502(a) of the FD&C Act indicates that HCEI provided to payors carrying out their responsibilities for the selection of drugs for coverage or reimbursement shall not be considered to be false or misleading if the HCEI relates to an FDA-approved indication for the drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the FDA-approved labeling for the drug. Section III.A of this guidance provides FDA's current thinking on key concepts in section 502(a) of the FD&C Act and recommendations for how firms can communicate HCEI about approved drugs to payors in accordance with this section to help ensure that payors have information needed to make informed drug selection, formulary management, and/or coverage and reimbursement decisions and to help ensure that the information is not false or misleading. Section III.A also discusses how FDA's requirements for submission of promotional materials apply to HCEI about approved drugs disseminated by firms to payors. If a firm disseminates HCEI about an approved drug in accordance with this guidance, FDA does not intend to consider such information false or misleading. In addition, FDA does not intend to use HCEI about approved drugs disseminated consistent with this guidance as evidence of a new intended use.

When FDA published a notice announcing the availability of the draft guidance document in the **Federal Register** of January 19, 2017 (82 FR 6568), the Agency specifically requested comments from interested parties on the extent to which the principles provided in section III.A of the draft guidance could be applicable to communications of HCEI about approved/cleared devices (82 FR 6568 at 6571). We also stated that, to the extent that interested parties believe that different considerations should apply to medical devices or that guidance is needed on additional issues with respect to medical device firms' communications of HCEI about approved/cleared medical devices to payors, FDA is interested in input on those topics as well (*Id.*). FDA received 23 comments on the draft guidance; 3 comments expressed support for applying the recommendations in section III.A of the guidance to medical devices and no comments opposed applying these recommendations to medical devices. In response to this feedback, section III.B of the guidance provides FDA's recommendations for how firms can communicate HCEI about approved or cleared devices to payors to help ensure that device firms' communication of HCEI to payors is not false or misleading. These recommendations generally follow the recommendations in section III.A of the guidance. If a device firm disseminates HCEI about an approved or cleared device in accordance with this guidance, FDA does not intend to consider such information false or misleading. In addition, FDA does not intend to use HCEI about approved or cleared devices disseminated consistent with this guidance as evidence of a new intended use.

FDA also recognizes that due in part to their need, in some situations, to plan for and make coverage and reimbursement decisions far in advance of the effective date of such decisions, payors are also interested in receiving information from drug and device firms about medical products that are not yet approved or cleared by FDA for any use, and about unapproved uses of approved/cleared medical products. Section III.C of the guidance discusses FDA's thinking with respect to communication by firms to payors of information about unapproved products [2] and about unapproved uses of approved/cleared medical products. The draft guidance provided similar recommendations, but the relevant section only addressed communications related to unapproved products. As noted above, FDA received 23 comments on the draft guidance; 17 of these comments requested that the Agency also provide recommendations for firms' communications to payors of information about unapproved uses of approved/cleared medical products. No comments opposed providing recommendations on this topic. In response to these comments, section III.C of this guidance provides FDA's recommendations on firms' dissemination to payors of information about both unapproved products and about unapproved uses of approved/cleared medical products. As with firms' communications to payors of HCEI about approved prescription drugs and approved or cleared devices, it is essential that information provided by firms about their unapproved products and about unapproved uses of their approved/cleared medical products be truthful and non-misleading. Therefore, section III.C also lays out a series of recommendations to help achieve these goals.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on drug and device manufacturer communications with payors, formulary committees, and similar entities. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection for OMB review and clearance:

Title: Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities; OMB Control No. 0910—NEW.

The information collection supports Agency guidance and includes Third-Party Disclosure recommendations regarding information that firms should include in HCEI for prescription drugs if they choose to disseminate such materials (''HCEI materials'') to payors, in accordance with section 502(a) of the FD&C Act. Specifically, FDA recommends that various aspects of study design and methodology of an economic analysis (*i.e.,* type of analysis, modeling technique, patient population, perspective/viewpoint, treatment

[2] As used in this guidance, the term ''unapproved products'' refers to drugs and devices that are not yet approved/cleared by FDA for any use (but which must be approved/cleared to be legally marketed), including products for which firms have submitted or plan to submit a new drug application, a biologics license application (including an application submitted under the 351(k) pathway), an abbreviated new drug application, a premarket approval application, a 510(k) submission, a De Novo submission under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)), or a Humanitarian Device Exemption application.

comparator, time horizon, outcome measures, cost estimates, and assumptions); factors that limit generalizability of an economic analysis; limitations to an economic analysis; and sensitivity analyses, if applicable, be included in HCEI materials disseminated to payors to allow for informed decision-making.

Furthermore, FDA recommends that firms include other information when disseminating HCEI materials, as applicable, to provide a balanced and complete presentation. Such information includes a statement of the FDA-approved indication of the drug and a copy of the most current FDA-approved labeling. Under section 502(a) of the FD&C Act, firms must also include a conspicuous and prominent statement to describe any material differences between the HCEI and the FDA-approved labeling. HCEI materials should also disclose whether certain studies or data sources were omitted from an economic analysis and how the omission of those studies or data sources may alter the conclusions presented in the analysis. Moreover, FDA recommends that HCEI materials disclose important risk information associated with the approved use of the drug, and pursuant to section 502(a) of the FD&C Act, must disclose any additional risk information related to assumptions that vary from the approved labeling. Finally, HCEI materials should disclose potential financial or affiliation biases to the extent reasonably known by firms at the time of dissemination.

The guidance provides similar recommendations for HCEI materials disseminated to payors about approved or cleared devices.

If firms choose to make communications to payors about unapproved products or unapproved uses of approved/cleared products, FDA recommends that firms include a clear statement with their communications that the product or use is not approved/cleared and that the safety or effectiveness of the product or use has not been established. In addition, FDA recommends providing information related to the stage of product development (*e.g.,* the status of any study(ies) in which a product/new use is being investigated and how it relates to the overall product development plan; whether a marketing application for the product or new use has been submitted to FDA or when such a submission is planned). FDA also recommends that communications that include factual presentations of results from studies also describe material aspects of study design and methodology and disclose material limitations related to the study design, methodology, and results. Moreover, FDA recommends that firms provide followup information to payors if previously communicated information becomes materially outdated as a result of significant changes or as a result of new information regarding the product or its review status.

Description of Respondents: For information that should be included when HCEI about approved prescription drugs is disseminated to payors, respondents to this collection of information are firms that manufacture prescription human drugs products, including biological products; for information that should be included when HCEI about approved or cleared medical devices is disseminated to payors, respondents to this collection of information are firms that manufacture medical devices; for information that should be included in communications with payors about unapproved products and about unapproved uses of approved/cleared products, respondents to this collection of information are firms that manufacture prescription human drug products, including biological products, and medical devices.

As noted, in the **Federal Register** of January 19, 2017, we published a notice announcing the availability of the draft guidance document and included an analysis under the PRA of the information collection burden associated with recommendations found in the draft guidance. Although no comments were received in response to the four information collection topics solicited in the notice, we revised the guidance as discussed above. These revisions resulted in a significant increase to the number of respondents to the information collection and also recommended new data elements. However, because our estimate reflects the average burden of the information collection distributed among all respondents, we believe any increase resulting from revisions to the guidance would be nominal.

Based on the post-marketing submissions of promotional materials using Form FDA 2253 received in calendar year 2016 for approved human prescription drugs, including prescription biological products, FDA estimates that approximately 440 manufacturers will disseminate 4,400 distinct HCEI materials for approved human prescription drugs annually. FDA estimates that approximately 236 manufacturers will disseminate 2,360 distinct HCEI materials for approved/cleared devices annually. FDA estimates it will take firms approximately 20 hours to compile and draft the information that this final guidance recommends should be included when disseminating HCEI materials for approved human prescription drugs and approved/cleared devices. Based on the number of human prescription drugs and devices approved/cleared and the number of efficacy supplements approved/cleared (*i.e.,* approving/clearing a new use for an approved/cleared product) in a calendar year, FDA estimates that approximately 717 manufacturers will prepare 1,434 distinct communications of information to payors about their unapproved products or unapproved uses of approved/cleared products annually. FDA estimates it will take firms approximately 0.5 hour to compile and draft the information that this final guidance recommends should be provided with communications to payors about unapproved products or unapproved uses of approved/cleared products. Additionally, FDA estimates that 50 percent of the firms will spend approximately 2 hours to compile and provide 718 distinct communications of followup information regarding previously communicated information to payors about their unapproved products or unapproved uses of approved/cleared products annually. We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of information	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved prescription drugs.	440	10	4,400	20	88,000

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of information	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved or cleared medical devices.	236	10	2,360	20	47,200
Recommended information to be included when firms choose to disseminate information about unapproved products or unapproved uses of approved or cleared products.	717	2	1,434	.5 (30 minutes)	717
Followup information to payors regarding previously communicated about unapproved products or unapproved uses of approved or cleared products.	359	2	718	2	1,436
Total					137,353

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 314.81(b)(3)(i) (Form FDA 2253) have been approved under OMB control number 0910–0001.

FDA is issuing this final guidance subject to OMB approval of the collections of information. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the collections of information, including OMB control number(s) for newly approved collections.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *https://www.regulations.gov.*

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12632 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2065]

Alternative or Streamlined Mechanisms for Complying With the Current Good Manufacturing Practice Requirements for Combination Products; Proposed List Under the 21st Century Cures Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: As required by the 21st Century Cures Act (Cures Act), the Food and Drug Administration (FDA or Agency) is proposing a list of alternative or streamlined mechanisms for complying with the current good manufacturing practice (CGMP) requirements for combination products. Combination products are products composed of two or more different types of medical products (drug, device, and/or biological product).

DATES: Submit either electronic or written comments on this notice by September 11, 2018 to ensure that the Agency considers your comment on this proposed list before it begins work on the final list.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 11, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–2065 for ''Alternative or Streamlined Mechanisms for Complying with Current Good Manufacturing Practice (CGMP) Requirements for Combination Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Melissa Burns, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5125, Silver Spring, MD 20993, 301–795–5616, *melissa.burns@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In December 2016, the Cures Act (Pub. L. 114–255) was signed into law. Section 3038(c) of the Cures Act mandated that FDA publish in the **Federal Register** a list identifying types of combination products and manufacturing processes for which ''good manufacturing processes'' may be adopted that vary from the requirements set forth in § 4.4 (21 CFR 4.4) or that FDA proposes can satisfy the requirements in § 4.4 through ''alternative or streamlined mechanisms,'' and to review this list periodically. In accordance with this statutory mandate, FDA is publishing a proposed list in section II of this document, which addresses processes for single-entity and co-packaged combination products that can satisfy requirements in § 4.4 through alternative or streamlined mechanisms (hereafter ''mechanisms'').

On January 22, 2013, FDA issued a final rule on CGMP requirements for combination products (see 78 FR 4307 and part 4 (21 CFR part 4, subpart A)). Prior to issuance of the final rule, although CGMP regulations were in place to establish requirements for drugs, devices, biological products, and human cells, tissues, or cellular or tissue-based products (HCT/Ps), there were no regulations to clarify and explain the application of these CGMP requirements to combination products. The final rule clarified which CGMP requirements apply to combination products. It also established a transparent and streamlined regulatory framework for combination product manufacturers to use when demonstrating compliance with applicable CGMP requirements.

A combination product is a product composed of two or more different types of medical products (*i.e.,* a combination of a drug, device, and/or biological product). The drugs, devices, and biological products included in combination products are referred to as ''constituent parts'' of the combination product. Combination products include ''single-entity'' combination products that are physically, chemically, or otherwise combined or mixed and produced as a single entity (§ 3.2(e)(1) (21 CFR 3.2(e)(1)) (*e.g.,* prefilled syringes and drug-eluting stents) and ''co-packaged'' combination products where two or more separate products are packaged together in a single package or as a unit and composed of drug and device products, device and biological products, or biological and drug products (§ 3.2(e)(2)) (*e.g.,* a surgical or first-aid kit).[1] Section 4.4 outlines how manufacturers of single-entity and co-packaged combination products (hereafter ''CP manufacturers'') can demonstrate compliance with applicable CGMP requirements, including through implementation of a streamlined approach to meet the requirements of both the drug CGMP and the device Quality System (QS) regulation by designing and implementing a CGMP operating system that demonstrates compliance with either of the following:

• The drug CGMP regulations in parts 210 and 211 (21 CFR parts 210 and 211) and the following specified provisions from the device QS regulation (§ 4.4(b)(1), ''drug CGMP-based streamlined approach''): (1) § 820.20 (21 CFR 820.20) Management responsibility, (2) § 820.30 (21 CFR 820.30) Design controls, (3) § 820.50 (21 CFR 820.50) Purchasing controls, (4) § 820.100 (21 CFR 820.100) Corrective and preventive action, (5) § 820.170 (21 CFR 820.170) Installation, and (6) § 820.200 (21 CFR 820.200) Servicing; or

• The device QS regulation in part 820 (21 CFR part 820) and the following specified provisions from the drug CGMP regulations (§ 4.4(b)(2), ''device QS regulation-based streamlined approach''): (1) § 211.84 (21 CFR 211.84) Testing and approval or rejection of components, drug product containers, and closures; (2) § 211.103 (21 CFR 211.103) Calculation of yield; (3) § 211.132 (21 CFR 211.132) Tamper-evident packaging requirements for

[1] There are also ''cross-labeled'' combination products (§ 3.2(e)(3) and (4)). With respect to cross-labeled combination products, part 4, subpart A was intended to clarify only that the CGMP requirements applicable to the drugs, devices, or biological products also apply to these types of articles when they are constituent parts of such combination products. Constituent parts of cross-labeled combination products need only comply with the requirements otherwise applicable to that type of product (*e.g.,* 21 CFR parts 210 and 211 for a drug constituent part or 21 CFR part 820 for a device constituent part). The ''streamlined approach'' and related mechanisms described in this notice are generally not relevant or applicable to cross-labeled combination products. However, to the extent that the constituent parts of a cross-labeled combination product are manufactured at the same facility, the manufacturing process would be akin to when the manufacture of the constituent parts of a co-packaged combination product occurs at the same facility. Accordingly, as discussed in the combination product CGMP guidance (Ref. 1), for cross-labeled combination products manufactured at the same facility, the Agency does not intend to object to the use of a streamlined CGMP operating system for the manufacture of the combination product rather than distinct systems for the manufacture of each constituent part that is occurring at that facility.

over-the-counter (OTC) human drug products; (4) § 211.137 (21 CFR 211.137) Expiration dating; (5) § 211.165 (21 CFR 211.165) Testing and release for distribution; (6) § 211.166 (21 CFR 211.166) Stability testing; (7) § 211.167 (21 CFR 211.167) Special testing requirements; and (8) § 211.170 (21 CFR 211.170) Reserve samples.

If the combination product includes a biological product constituent part, the CGMP operating system must also demonstrate compliance with applicable CGMP requirements for biological products in parts 600 through 680 (21 CFR parts 600 through 680), and if the combination product includes an HCT/P, the CGMP operating system must also demonstrate compliance with the applicable current good tissue practice requirements in part 1271 (21 CFR part 1271).

Following publication of the final rule, FDA reviewed data and rationales provided by manufacturers who proposed various means of addressing CGMP considerations for combination products. FDA also considered feedback on its draft guidance on CGMP requirements for combination products, published in January 2015, in which stakeholders requested further guidance on circumstances in which flexible approaches may be available and how to engage with FDA on them. The final ''Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products'' includes discussion of existing mechanisms to comply with the final rule and of circumstances in which FDA did not intend to object to manufacturers applying practices that vary from the requirements set forth in the rule (Ref. 1). The Agency continues to apply a risk-based approach to evaluating methods for ensuring the quality of combination products and to welcome proposals from manufacturers for how to enhance the efficiency of development and manufacturing activities, while ensuring the safety and effectiveness of the combination products produced.

II. Proposed List of Mechanisms for Complying With § 4.4 CGMP Requirements for Combination Products

A. Introduction

The following is a proposed list of mechanisms for demonstrating compliance with relevant combination product CGMP requirements, as described below. Where applicable, reference is made to sections of the ''Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products'' for additional information (Ref. 1). FDA will continue to evaluate this list in light of Agency experience and stakeholder input. Manufacturers are welcome to propose other approaches not described, and FDA continues to encourage dialogue with the Agency on various means of demonstrating CGMP compliance for combination products.

For each mechanism described below, CP manufacturers should consider what documentation would be sufficient to support that the mechanism, including the specific approach for implementing it, assures appropriate control of the manufacture of the combination product to ensure safety and effectiveness of the product. Appropriate evidence and an explanation of the rationale to support the approach should be accessible at the manufacturing facility for review during facility inspections. For additional discussion on how to interact with FDA regarding the mechanisms described below, see section III.

B. Mechanisms for Complying With Drug CGMP Requirements (Part 211) Specified in § 4.4 [2]

FDA interprets the mechanisms identified in the sections below as a means to demonstrate compliance with the specified part 211 requirements identified in § 4.4:

1. Section 211.165 Testing and Release for Distribution

Use of product samples that are not finished combination products (but that are representative of the finished combination product with respect to the characteristics and attributes being tested) when performing testing required by § 211.165 to determine whether the drug constituent part meets final specifications. To meet the requirements of § 211.165, the CP manufacturer would need to establish, including where appropriate through bridging studies and other quantitative means, that any differences in the manufacturing process for the representative samples as compared to the finished combination product do not affect the drug constituent part. For example, as part of product release testing, drug-eluting lead manufacturers could perform release testing for identity, potency, or other quality attributes on a representative lead tip assembly that contains the drug constituent part, but does not contain the full electronic and mechanical assembly, so long as they can establish that the differences in the manufacturing process do not impact the drug constituent part and the sample is representative of the finished combination product with respect to the quality attributes being tested.

(See also Section IV.B.5 of Reference 1 for additional information on testing and release for combination products.)

2. Section 211.166 Stability Testing

Use of bracketing and matrixing approaches to stability studies for combination products. Principles for bracketing and matrixing approaches to meet the requirements of § 211.166 have already been addressed by the Agency with regard to drug products (Ref. 2), and such principles can also be applied to combination products. For example, when assessing stability for a prefilled syringe that is marketed in various fill volumes, one of the approaches that a CP manufacturer could utilize, if appropriate, is bracketing based on the smallest and the largest fill volume of product configurations. In determining the extremes for a bracketing approach and/or when justifying the use of a matrix design for single-entity combination products, it is important that the drug-device interactions and variations in the manufacturing processes are considered. For co-packaged combination products, such approaches can be applied to the drug constituent part of the product.

Leveraging stability data for an already marketed combination product. Such mechanisms can be considered when the new combination product is a modification of an already marketed product and the modification does not impact the stability of the drug constituent part. For example, when developing new lengths of a drug-coated catheter product for which the catheter materials, drug coating, manufacturing process, and packaging configurations are largely unchanged from existing marketed sizes, the CP manufacturer would generally be able to leverage existing stability data to establish initial product shelf life or to support reduced stability data requirements, so long as characteristics of the product that could impact stability (materials, packaging configuration, etc.) remain the same. However, if the device constituent part of a drug-coated catheter includes a new material that is in contact with the drug coating, for example, new stability studies would generally be needed under § 211.166.

[2] Several drug CGMP mechanisms included in this proposed list depend upon use of a more broadly defined batch. FDA notes that approaches that depend upon broadly defined batches may increase the number of distributed products implicated when corrective actions are necessary to address postmarket issues.

(See also Section IV.B.6 of Reference 1 for additional information on stability requirements for combination products.)

3. Section 211.167 Special Testing Requirements

Defining ''batch'' based on the drug constituent part rather than the finished combination product for purposes of special testing requirements for pyrogens and endotoxins. For example, a manufacturer of a combination product that has a sub-assembly coated with a drug, which is then incorporated into several ''batches'' or ''lots'' of the overall combination product, may be able to define a batch for purposes of pyrogen and endotoxin testing as a batch of that sub-assembly for purposes of meeting the requirements of § 211.167. As with the other mechanisms described in this list, this mechanism would only potentially be available if there would be no impact on the drug constituent part from subsequent manufacturing processes, including when the constituent parts are combined to produce the final combination product. CP manufacturers should consider whether such risks may be introduced later in the production process (after the batch has been defined). This approach will most frequently apply for co-packaged combination products or single-entity combination products for which only a component or sub-assembly of the overall product is in contact with the drug constituent part.

(See also Section IV.B.7 of Reference 1 for additional information on special testing requirements for combination products.)

4. Section 211.170 Reserve Samples

Keeping reserve samples that are representative of the finished combination product. CP manufacturers may use validated surrogates as representative samples to meet the requirements of § 211.170, provided the surrogate is appropriate, both in terms of the manufacturing process and the characteristics of the container closure. For example, maintaining only a sub-assembly of a coated single-entity combination product or only the drug constituent part of a co-packaged combination product as a reserve sample would generally be permissible under the regulation when: (1) All manufacturing process steps after the coating step or the fill for the drug constituent part are shown not to affect the drug constituent part, (2) the immediate container closure has essentially the same characteristics as that for the drug constituent part as packaged in the combination product for distribution, and (3) the representative samples are suitable for all required testing of the drug constituent part for which the reserve samples are being kept.

Using samples from representative lots of a larger batch for retention of reserve samples. To meet the requirements of § 211.170, CP manufacturers may be able to use bracketing and matrixing approaches to retain reserve samples from certain lots to adequately represent the broadly defined batch of the combination product. For example, CP manufacturers might be able to retain reserve samples of appropriately varied sizes of a drug-coated combination product from within a broadly defined batch that includes multiple lots of different sizes.

(See also Section IV.B.8 of Reference 1 for additional information on reserve sample requirements for combination products.)

C. Mechanisms for Complying With Device Quality System Requirements (Part 820) Specified in § 4.4

FDA interprets the mechanisms identified in the sections below as a means to demonstrate compliance with the specified part 820 requirements identified in § 4.4:

1. Section 820.30 Design Controls

Using existing pharmaceutical development practices and documentation that align with the design control principles and requirements of § 820.30. Robust pharmaceutical development practices would address many design control requirements to assure compliance with § 820.30, where applicable. CP manufacturers need to demonstrate how development processes and terminology align with design control principles and requirements in § 820.30, when required, including, where necessary, developing additional design control elements. When evaluating the adequacy of existing pharmaceutical development processes, particular attention should be given to postmarket management of design changes to the combination product and the alignment of change control practices with the principles and requirements of § 820.30, as applicable.

2. Exemption of Combination Products From Device QS Regulation

Exemption of the combination product from all or certain provisions of the device QS regulation (part 820) if the device constituent part of the combination product is itself exempt from such requirements and use of the device constituent part falls within the scope of the relevant exemption, including with respect to the device constituent part's intended use. Some devices are exempt from all or certain provisions of the device QS regulation (see, for example, liquid medication dispensers such as cups and droppers that fall within the scope of § 880.6430 (21 CFR 880.6430), provided the use of the device is not a new intended use or does not otherwise raise different safety and effectiveness questions (see, for example, limitations to the exemption under 21 CFR 880.9). Consistent with this, for the combination product to be exempt from the associated provisions of the device QS regulation, we interpret this exemption to mean that the use of the device in the combination product must not be a new intended use or otherwise raise different safety and effectiveness questions for the device. This circumstance will most frequently apply to co-packaged combination products. For example, an oral dosing syringe (a liquid medication dispenser under § 880.6430) that is co-packaged with a drug may be exempt from certain provisions of the device QS regulation (and hence the combination product may also be exempt from such provisions); however, incorporation of such a dispenser into a primary container closure system or co-packaging of such a dispenser with an emergency-use product, for example, may constitute a new intended use for the dispenser or raise different safety and effectiveness questions for the dispenser, such that the relevant exemption would not apply.

(See also Section III.C.3 of Reference 1 for additional information on the exemption from provisions of the device QS regulation for combination products.)

III. Interacting With FDA on Mechanisms for Complying With CGMP for Combination Products

1. Process for Interacting With FDA

In some cases, CP manufacturers may interact with FDA to gain approval or otherwise notify FDA of a manufacturing change. In other cases, although a submission or notification is not required, CP manufacturers may want to discuss potential use of CGMP mechanisms with FDA. CP manufacturers are encouraged to interact early with FDA on contemplated CGMP mechanisms.

- *Pre-Submissions and Meeting Requests.* CP manufacturers who want to obtain FDA feedback prior to submitting a premarket application or a postmarket supplement or who otherwise want to obtain feedback on

their approach may interact with FDA via the existing established process applicable to the lead Center[3] for the combination product. For combination products reviewed under a new drug application (NDA) or a biologics license application (BLA), such interactions will generally be through Type C meetings (Ref. 3).[4] For combination products reviewed under an abbreviated new drug application (ANDA), these interactions will generally be through pre-ANDA meetings (Ref. 4).[5] For combination products reviewed under a device premarket submission (*e.g.,* a premarket approval application (PMA), de novo classification, or premarket notification (510(k)), these interactions will generally be via the pre-submission process (Ref. 5).

Regardless of the type of submission, such interactions should be focused on a general discussion of the mechanism and CGMP approach the CP manufacturer wishes to pursue and associated justification to support the approach. Only representative data is typically appropriate in these interactions; complete data should be included in the subsequent premarket submission or postmarket supplement, if required, and/or be maintained at the manufacturing facility, as appropriate.[6]

• *Premarket Review.* CP manufacturers should include in their original submission for NDAs, BLAs, ANDAs, and PMAs information on any mechanisms for complying with CGMP requirements. For PMAs, this information should be included in the manufacturing section of the PMA. For information regarding where to place information in NDAs, BLAs, or ANDAs, refer to ''eCTD Technical Conformance Guide'' (Ref. 6).

• *Postmarket Supplements or Notifications to FDA.* Postmarket changes to implement a combination product CGMP mechanism for NDAs, ANDAs, BLAs, and PMAs, may require submission of a supplement or notification to FDA.[7] CP manufacturers should consult related guidances relevant to the type of constituent part of the combination product (Refs. 7 to 9).[8] If a CP manufacturer has questions on the appropriate submission type or the need for a submission, they can contact the lead Center for assistance.

2. Content Suggestions

When submitting information on a CGMP mechanism, along with any submission requirements applicable to the submission type, the following content should be included:

• *Applicable CGMP regulation.* Identify the CGMP regulation applicable to the described mechanism. For example, if a submission includes a mechanism related to stability testing, indicate that § 211.166 is the applicable CGMP requirement.

• *Applicable Products.* If the mechanism is to be applied to multiple products and/or product configurations, list all related sizes, strengths, etc., as well as all related application numbers.

• *Related Interactions with FDA.* If the CP manufacturer has had previous interactions with FDA relevant to the proposed mechanism, either for the product addressed in the submission or for related products, the CP manufacturer should provide reference to those interactions. Where applicable, the CP manufacturer may cross-reference previously submitted information.

• *Justification and Scientific Data.* Include a rationale to support that the proposed mechanism assures adequate manufacturing control to ensure product safety and effectiveness. When describing a CGMP mechanism in a premarket or postmarket submission, the description should be accompanied by data necessary to support the approach. When proposing a change from a CGMP approach that was reviewed previously by FDA, such justification should include analysis of how the proposed approach compares to the previously reviewed approach as an effective manufacturing control, including representative data, as appropriate, to substantiate the analysis.

3. FDA Engagement

CP manufacturers are encouraged to discuss combination product CGMP mechanisms with FDA. Any questions on how to engage FDA in such discussions should be directed to the lead Center for the product or the Office of Combination Products, as needed.

4. FDA Review

FDA may review information from a CP manufacturer related to a mechanism for complying with CGMP requirements for combination products in premarket applications, postmarket supplements or notifications, pre-submissions and meetings, and during facility inspections. FDA may determine that the data and rationale presented by a CP manufacturer for a particular mechanism are insufficient to demonstrate that the mechanism, as proposed or implemented, meets the applicable CGMP requirement. FDA generally will notify the CP manufacturer and/or applicant in writing of any such determination.

IV. Other Issues for Consideration

We have developed this proposed list of mechanisms based on information submitted to FDA by CP manufacturers as well as FDA experience with manufacturing processes and CGMP compliance approaches that have been shown through appropriate data and rationales to support the manufacture of safe and effective products. FDA requests comment from stakeholders who believe there are additional types of combination products and/or manufacturing processes where different approaches may be appropriate. When providing such feedback, the suggested approach should be:

• Applicable to a type or range of combination products (*e.g.,* not just a single CP manufacturer's product). Commenters should indicate to which types of combination products or manufacturing processes they believe the suggested approach should apply.

• Supported by adequate data and rationales to demonstrate that such an approach would continue to support manufacturing of safe and effective combination products. Commenters should summarize the data and rationale that support the suggested approach.

Any confidential information submitted to FDA via the docket should be appropriately identified (see *Instructions* above, in **ADDRESSES**).

V. Paperwork Reduction Act

This notice refers to previously approved collections of information

[3] A combination product is assigned to an Agency center (Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, or Center for Devices and Radiological Health) that will have primary jurisdiction (*i.e.,* the ''lead Center'') for that combination product's review and regulation. Assignment of a combination product to a lead Center is based on a determination of which constituent part provides the primary mode of action of the combination product (21 U.S.C. 353(g)).

[4] When final, this guidance will represent the FDA's current thinking on this topic.

[5] When final, this guidance will represent the FDA's current thinking on this topic.

[6] Note that when discussing a mechanism for complying with CGMP requirements for which the CP manufacturer is leveraging information in master file(s), the master file holder must submit a letter of authorization to permit FDA to review such information (see 21 CFR 314.420(d) and 21 CFR 814.20(c)). The specific information within the master file that is being leveraged should be clearly identified to FDA.

[7] Requirements for postmarket supplements are contained, for example, in 21 CFR 314.70 (NDAs), 21 CFR 601.12 (BLAs), and 21 CFR 814.39 (PMAs). Any questions on whether FDA review is required for a postmarket CGMP mechanism should be directed to the lead Center.

[8] With reference to Ref. 8, when final, this guidance will represent the FDA's current thinking on this topic.

found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We note that the information collected under the underlying CGMP regulations for drugs, devices, and biological products, including current good tissue practices for HCT/Ps, found in parts 211, 820, 600 through 680, and 1271, have already been approved and are in effect. The provisions of part 211 are approved under the OMB control number 0910–0139. The provisions of part 820 are approved under OMB control number 0910–0073. The provisions of parts 606 and 640 are approved under OMB control number 0910–0116. The provisions of part 610 are approved under OMB control number 0910–0116 and OMB control number 0910–0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910–0543.

We note that the information collected under the related submission types have already been approved and are in effect. The collections of information regarding formal meetings with sponsors and applicants have been approved under OMB control number 0910–0429. The collections of information regarding new drug approvals (NDA) and abbreviated new drug applications (ANDA) have been approved under OMB control number 0910–0001. The collections of information regarding pre-ANDAs have been approved under OMB control number 0910–0797. The collections of information regarding pre-submissions have been approved under OMB control number 0910–0756. The collections of information regarding PMAs have been approved under OMB control number 0910–0231. The collections of information for premarket notification (510(k)) have been approved under OMB control number 0910–0120. The collections of information for the de novo classification process have been approved under OMB control number 0910–0844. The collections of information regarding biologics license applications have been approved under OMB control number 0910–0338.

VI. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. ''Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products,'' January 2017. *https://www.fda.gov/RegulatoryInformation/Guidances/ucm126198.htm.*
2. ''Guidance for Industry: Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products,'' January 2003. *https://www.fda.gov/downloads/Drugs/Guidances/ucm073379.pdf.*
3. ''Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products,'' December 2017. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf.*
4. ''Draft Guidance for Industry: Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA,'' October 2017. *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm578366.pdf.*
5. ''Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff,'' September 2017. *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf.*
6. ''eCTD Technical Conformance Guide,'' November 2017. *https://www.fda.gov/downloads/Drugs/UCM465411.pdf.*
7. ''Guidance for Industry: Changes to an Approved NDA or ANDA,'' April 2004. *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm077097.pdf.*
8. ''Draft Guidance for Industry: Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products,'' December 2017. *https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM590118.pdf.*
9. ''Guidance for Industry and FDA Staff: 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes,'' April 2011. *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080194.pdf.*

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12634 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0223]

Humanitarian Device Exemption Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Humanitarian Device Exemption (HDE) Program.'' This draft guidance concerns the HDE program as a whole and, among other topics, it explains the criteria FDA considers to determine if ''probable benefit'' has been demonstrated as part of the Agency's decision-making process regarding marketing authorization for a humanitarian use device (HUD). The draft guidance also incorporates recent amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) that affect the HDE program and answers other common questions that we receive about the program. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–0223 for ''Humanitarian Device Exemption (HDE) Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Humanitarian Device Exemption (HDE) Program'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6524; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this draft guidance to clarify to industry and FDA staff the current review practices for the HDE program. This draft guidance answers common questions about the HDE program and responds to a requirement in the 21st Century Cures Act (Cures Act, Pub. L. 114–255) to define the criteria for establishing ''probable benefit'' as that term is used in section 520(m)(2)(C) of the FD&C Act (21 U.S.C. 360j(m)(2)(C)).

This draft guidance incorporates recent amendments to the FD&C Act that affect the HDE program. Specifically, section 3052 of the Cures Act modified the eligibility for an HDE by increasing the threshold number of patients affected by the disease or condition that a HUD is designed to treat or diagnose to ''not more than 8,000 individuals in the United States.'' Further, section 3056 the Cures Act removed the requirement that institutional review committees, *i.e.,* institutional review boards (IRBs), that supervise the clinical testing of HUDs or approve the use of HUDs in clinical care be local.

Additionally, the FDA Reauthorization Act of 2017 (Pub. L. 115–52) amended section 520(m) of the FD&C Act to provide that the use of a device under an HDE at a facility to treat or diagnose patients may be approved by an IRB or an appropriate local committee. Previously, section 520(m)(4) of the FD&C Act only allowed an IRB to perform this function. FDA is providing an interpretation of the term ''appropriate local committee'' in this draft guidance, and we welcome comment on the characteristics that should define an appropriate local committee for purposes of the HDE program.

This draft guidance supplants the draft guidance, ''Humanitarian Device Exemption (HDE): Questions and Answers—Draft Guidance for HDE Holders, IRBs, Clinical Investigators, and Food and Drug Administration Staff,'' issued on March 18, 2014. When final, this guidance will supersede the guidance, ''Guidance for HDE holders, IRBs, Clinical Investigators, and Food and Drug Administration Staff, HDE Regulation: Questions and Answers,'' issued on July 8, 2010, available online at: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM110203.*

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the Humanitarian Device Exemption Program. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by

downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Humanitarian Device Exemption (HDE) Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17040 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 10 have been approved under OMB control number 0910–0191; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control numbers 0910–0755 and 0910–0130; the collections of information in 21 CFR part 54 have been approved under OMB control number 0910–0396; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information regarding Information to Accompany HDE Applications and Annual Distribution Number Reporting Requirements have been approved under OMB control number 0910–0661; and the collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12633 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2032]

Limited Population Pathway for Antibacterial and Antifungal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Limited Population Pathway for Antibacterial and Antifungal Drugs.'' This guidance provides information on the implementation of the limited population pathway provision of the 21st Century Cures Act (Cures Act), which established the limited population pathway for antibacterial and antifungal drugs (LPAD pathway).

DATES: Submit either electronic or written comments on the draft guidance by August 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2032 for ''Limited Population Pathway for Antibacterial and Antifungal Drugs; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Walinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 240–402–4075; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Limited Population Pathway for Antibacterial and Antifungal Drugs.'' Section 506(h)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(h)(5)) requires FDA to issue guidance ''describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs.'' This guidance provides this information and is intended to assist sponsors in the development of certain new antibacterial and antifungal drugs for approval under the LPAD pathway. This guidance also is intended to assist sponsors in developing labeling, including prescribing information, patient labeling, and carton/container labeling, that incorporates certain statements required by section 506(h) of the FD&C Act, added by section 3042 of the Cures Act. This guidance satisfies the requirements under section 506(h)(5) of the FD&C Act.

The LPAD pathway is intended to encourage the development of certain antibacterial and antifungal drugs to help address the critical public health and patient care concern that has resulted from the current decline in antibacterial drug research and development as serious antibacterial and antifungal drug-resistant infections increase. FDA is committed to using the tools at its disposal, including the LPAD pathway, to help encourage the development of safe and effective drug products that address unmet needs of patients with serious bacterial and fungal infections.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the LPAD pathway. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 314 for the submission of new drug applications (NDAs) under the LPAD pathway, including the submission of labeling under § 314.50(e)(2)(ii) and (l)(1)(i) and advertisements and promotional labeling under § 314.81(b)(3)(i), has been approved under OMB control number 0910–0001. The submission of biologics license applications (BLAs) under the LPAD pathway has been approved under OMB control number 0910–0338.

The submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The submission of medication guides under 21 CFR part 208 has been approved under OMB control number 0910–0393. The submission of prescription drug advertisements under 21 CFR 202.1 has been approved under OMB control number 0910–0686.

The collection of information in the draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors and Applicants for PDUFA Products'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm590547.pdf*), including requests for pre-NDA and pre-BLA meetings and other meetings pertaining to the LPAD pathway, has been approved under OMB control number 0910–0429.

The collection of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm358301.pdf*), including fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation has been approved under OMB control number 0910–0765.

The collection of information in 21 CFR part 312, including submissions under subpart E, has been approved under OMB control number 0910–0014. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12635 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1893]

Patient-Focused Drug Development: Collecting Comprehensive and Representative Input; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' This guidance (Guidance 1) is the first of a series of four methodological guidance documents that FDA committed to develop to address in a stepwise manner how to collect and submit information from patients and caregivers for medical product development and regulatory decision making.

DATES: Submit either electronic or written comments on the draft guidance by September 11, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1893 for ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–6525, Fax: 301–847–8443, *Meghana.Chalasani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing availability of a draft guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' This guidance (Guidance 1) is the first of a series of four guidance documents that FDA committed to develop to address in a stepwise manner how stakeholders (patients, researchers, medical product developers, and others) can collect and submit information from patients and caregivers for medical product development and regulatory decision making. This series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform medical product development and regulatory decision making. The purpose of Guidance 1 is to present methods for collecting information on the patient experience that is representative of the intended population to inform the development and evaluation of medical products

throughout the medical product lifecycle. In addition, this document discusses methods on how to operationalize and standardize the collection, analysis, and dissemination of patient experience data. Guidance 1 also includes a glossary of terms that will be used in one or more of the series of four guidance documents.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Additional Information

Section 3002 of Title III, Subtitle A of the 21st Century Cures Act (Pub. L. 114–255) directs FDA to develop patient-focused drug development guidance to address a number of areas, including under section 3002(c)(1) (methodological approaches), which are relevant and objective and ensure that such data are accurate and representative of the intended population, that a person seeking to collect patient experience data to inform regulatory decision making may use.

In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section I.J.1. of the commitment letter, ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making,'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12636 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Tuesday, July 10, 2018, from 8:30 a.m. until 5:00 p.m., and Wednesday, July 11, 2018, from 8:30 a.m. until 4:00 p.m.

ADDRESSES: 6001 Executive Boulevard, Conference Room A, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 8:30 a.m., on Tuesday, July 10, 2018, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS and SOH subcommittees will present their recommendations regarding the description of ''key information,'' as required by the revised Common Rule at § 46.116(a)(5)(i). This will be followed by a discussion of the application of the revised Common Rule's exemptions at 46.104(d) to FDA-regulated research, and recommendations on the interpretation of § 46.104(d)(1) and (2) for HHS funded research.

The Wednesday, July 11, meeting will begin at 8:30 a.m. The SAS subcommittee will present and discuss recommendations on the interpretation of ''reasonably available'' at § 46.408(b), as well as discuss issues surrounding payment to subjects for participation in research. Modifications to the previous day's work will be discussed and finalized. The meeting will adjourn at approximately 4:00 p.m., July 11, 2018.

Time for public comment sessions will be allotted both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to topics currently being addressed by the SACHRP. Individuals submitting written statements as public comment should provide their comments by email to *SACHRP@hhs.gov* or by fax to (240) 453–6909 at least five business days prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated SACHRP point of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: June 7, 2018.

Julia G. Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2018–12662 Filed 6–12–18; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) is hereby giving notice that the charter for the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (Committee) has been renewed.

FOR FURTHER INFORMATION CONTACT: Emmeline Ochiai, Designated Federal Official, Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Room LL–100, Rockville, MD 20852, (240) 453–8255 (telephone), (240) 453–8281 (fax). Additional information is available on the Healthy People website at *http://www.healthypeople.gov.*

SUPPLEMENTARY INFORMATION: The Committee is a discretionary federal advisory committee. Under 42 U.S.C. 300u, the Secretary of Health and Human Services (the Secretary) has authority to undertake and support necessary activities and programs to (a) incorporate appropriate health education components into our society, especially into all aspects of education and health; (b) increase the application and use of health knowledge, skills, and practices by the general population in its patterns of daily living; and (c) establish systematic processes for the exploration, development, demonstration, and evaluation of innovative health promotion concepts. Under Title XVII, Section 1701 of the Public Health Service Act, the Secretary is given authority to formulate national goals and a strategy to achieve such goals, with respect to health information and health promotion, preventive health services, and education in the appropriate use of health care. In 1979, the Department of Health and Human Services (HHS) established the *Healthy People* initiative to develop a framework for improving the health of all people in the United States. *Healthy People* provides evidence-based, ten-year national objectives for improving the health of all Americans. *Healthy People* offers a strategic agenda to align health promotion and disease prevention activities in communities around the country. It includes measurable objectives with targets to be reached by the end of each decade. The Committee is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C., App.), which sets forth standards for the formation and use of federal advisory committees. The Committee advises and makes recommendations to the Secretary on matters regarding the development and implementation of Healthy People 2030, the nation's disease prevention and health promotion objectives for 2030.

To carry out is charge, the Committee will provide advice about the *Healthy People 2030,* the Leading Health Indicators, implementation, and actions for achieving *Healthy People 2030* goals and objectives. The Committee's advice must assist the Secretary in reducing the number of objectives while ensuring that *Healthy People 2030* identifies the most critical public health issues that are high-impact priorities supported by current, national data sets. The Committee will take into account new scientific evidence, resource documents, the needs of *Healthy People* stakeholders, and the value of assessing progress over the course of the decade. Furthermore, the Committee will advise the Secretary on strategies the department can use to maximize stakeholder use of Healthy People 2030 and ensure implementation of *Healthy People 2030.*

On May 21, 2018, the Secretary approved renewal of the Committee's charter. The new charter was effected and filed with the appropriate Congressional committees and the Library of Congress on June 1, 2018. Renewal of the Committee's charter gives authorization for the Committee to continue to operate until June 1, 2020.

A copy of the Committee's charter is available on the Committee's website at *https://www.healthypeople.gov/2020/About-Healthy-People/Development-Healthy-People-2030/Advisory-Committee.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *https://facadatabase.gov.*

Donald Wright,

Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion).

[FR Doc. 2018–12661 Filed 6–12–18; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Review of Applications Addressing Population-Based Model Organisms in a GxE Context and Predisposition to Complex Diseases.

Date: June 25–26, 2018.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Fairfield Inn & Suites Durham Southpoint, 7807 Leonardo Drive, Durham, NC 27713.

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, 530 Davis Drive, Suite 3171, Research Triangle Park, NC 27709, (919) 541–2824, *worth@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; R13 Conference Grants Applications.

Date: June 27, 2018.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIEHS/National Institute of Health, Keystone Building, 530 Davis Drive, Suite 1001, Research Triangle Park, NC 27709, Durham, NC 27703 (Telephone Conference Call).

Contact Person: Laura A. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and

Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, 919–541–2824, *laura.thomas@nih.gov.*

Name of Committee: Summer Research Education Experience Programs; R25National Institute of Environmental Health Sciences Special Emphasis Panel.

Date: June 28, 2018.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institute of Health, Keystone Building, 530 Davis Drive, Suite 1002, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Linda K. Bass, Ph.D., Scientific Review Officer, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, 530 Davis Drive, Suite 3074, Research Triangle Park, NC 27709, (919) 541–2824, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: June 8, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12675 Filed 6–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Integrative Health: Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the ZAT1 VS (10) meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Institutional Research Training Grants—T32.

Date: July 19, 2018.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Viatcheslav A. Soldatenkov, MD, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities National Center for Complementary and Integrative Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, *soldatenkovv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: June 7, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12673 Filed 6–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Sleep Disorders and Circadian Clock Disruption in Alzheimers Disease and other Dementias of Aging.

Date: July 2–3, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *selmanom@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AIDS and AIDS-related applications.

Date: July 6, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, Bethesda, MD 20892, 301–451–5953, *tuoj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Retinal Circuitry, Signaling and Physiology.

Date: July 6, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Vanessa S. Boyce, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 451–2853, *vanessa.boyce@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Digestive Sciences.

Date: July 11, 2018.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Martha Garcia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892, 301–435–1243, *garciamc@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training in Comparative and Veterinary Medicine.

Date: July 11, 2018.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Development of Large Animal Reporter Systems for Testing Somatic Cell, Genome Editing Tools (U24).

Date: July 11, 2018.

Time: 11:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–435–1206, *komissar@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Immune Mechanism: Activation, Regulation and Tolerance.

Date: July 11, 2018.

Time: 12:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Patrick K. Lai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892, 301–435–1052, *laip@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 7, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12671 Filed 6–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; SEP for Medications Development.

Date: June 27, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4242, MSC 9550, Bethesda, MD 20892, 301–827–5833, *ivan.navarro@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3 (Clinical Trials Optional).

Date: August 16, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4242, MSC 9550, Bethesda, MD 20892, 301–827–5833, *ivan.navarro@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: June 7, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12674 Filed 6–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used To Detect and Measure Botulinum Neurotoxin

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used to detect and measure botulinum neurotoxin (BoNT). Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods that are used to detect the presence of BoNT and measure potency of BoNT preparations.

DATES: *Receipt of information:* Deadline is July 11, 2018.

ADDRESSES: Data and information should be submitted electronically to *niceatm@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (984) 287–3118.

SUPPLEMENTARY INFORMATION:

Background: NICEATM fosters the evaluation and promotion of alternative test methods for regulatory use. As part of this activity, NICEATM supports efforts to develop, validate, and implement alternative approaches for biologics tests, including those used to detect the presence of BoNT and measure potency of BoNT preparations. Tests to detect and measure BoNT are required by multiple federal agencies for regulatory and other decision contexts. Currently, the standard test for these endpoints is a mouse lethality assay that can use large numbers of animals.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to detect the presence of BoNT and measure potency of BoNT preparations. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo test methods currently used by federal agencies for regulatory and other decision contexts. NICEATM also requests available data from in vivo BoNT tests used for similar applications as the proposed alternative, such as distinguishing between BoNT serotypes in biological matrix samples or measuring the potency of therapeutic BoNT preparations.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is July 11, 2018. Responses to this notice will be posted at: *https://ntp.niehs.nih.gov/go/*bont. Persons submitting responses will be identified on the web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information

submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides authority for ICCVAM and NICEATM involvement in activities relevant to the development of alternative test methods.

Information about NICEATM and ICCVAM can be found at *http://ntp.niehs.nih.gov/go/niceatm* and *http://ntp.niehs.nih.gov/go/iccvam.*

Dated: June 6, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018–12726 Filed 6–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency; DHS.

ACTION: Notice; correction.

SUMMARY: On April 5, 2018, FEMA published in the **Federal Register** a changes in flood hazard determination notice that contained an erroneous table. This notice provides corrections to that table, to be used in lieu of the information published at 83 FR 14646–14650. The table provided here represents the changes in flood hazard determinations and communities affected for City of Appleton, Outagamie County, Wisconsin.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

Correction

In the changes in flood hazard determination notice published at 83 FR 14646–14650 in the April 5, 2018, issue of the **Federal Register**, FEMA published a table with erroneous information. This table contained inaccurate information as to the effective date of modification and community identification number for the City of Appleton, Outagamie County, Wisconsin featured in the table. In this document, FEMA is publishing a table containing the accurate information. The information provided below should be used in lieu of that previously published.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation (Acting), Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Wisconsin: Outagamie	City of Appleton (17–05–3854P).	The Honorable Timothy Hanna, Mayor, City of Appleton City Hall, 100 North Appleton Street, Appleton, WI 54911.	City Hall, 100 North Appleton Street, Appleton, WI 54911.	Feb. 16, 2018	555542

[FR Doc. 2018–12643 Filed 6–12–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4339–DR; Docket ID FEMA–2018–0001]

Puerto Rico; Amendment No. 8 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the Commonwealth of Puerto Rico (FEMA–4339–DR), dated September 20, 2017, and related determinations.

DATES: This amendment was issued May 23, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated May 23, 2018, the President amended the cost-sharing arrangements regarding Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), in a letter to Brock Long, Administrator, Federal Emergency Management Agency, Department of Homeland Security, under Executive Order 12148, as follows:

I have determined that the damage in the Commonwealth of Puerto Rico resulting from Hurricane Maria during the period of September 17 to November 15, 2017, is of sufficient severity and magnitude that special cost-sharing arrangements are warranted regarding Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act'').

Therefore, I amend my declarations of September 20, 2017, September 26, 2017, November 2, 2017, and February 23, 2018, to authorize a 90-day extension of the period of 100 percent Federal funding for emergency power restoration and a 120-day extension of the period of 100 percent Federal funding for emergency temporary power support and Sheltering and Temporary Essential Power (STEP).

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–12639 Filed 6–12–18; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4361–DR; Docket ID FEMA–2018–0001]

Kentucky; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Kentucky (FEMA–4361–DR), dated April 26, 2018, and related determinations.

DATE: This amendment was issued May 25, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Kentucky is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 26, 2018.

Pendleton County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–12638 Filed 6–12–18; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2018–0032]

DHS Data Privacy and Integrity Advisory Committee

AGENCY: Privacy Office, DHS.

ACTION: Committee management; notice of committee charter renewal.

SUMMARY: The Secretary of Homeland Security has determined that the renewal of the Data Privacy and Integrity Advisory Committee is necessary and in the public interest in connection with the Department of Homeland Security's performance of its duties. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

DATES: The committee's charter is effective May 24, 2018, and expires May 24, 2020.

ADDRESSES: If you desire to submit comments on this action, they must be submitted by (60 days after publication of Notice). Comments must be identified by DHS Docket Number (DHS–2018–0032) and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PrivacyCommittee@dhs.gov.* Include the Docket Number (DHS–2018–0032) in the subject line of the message.
- *Fax:* (202) 343–4010, ATTN: Sandra Taylor.
- *Mail:* Sandra Taylor, Designated Federal Officer, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, 245 Murray Lane SW, Mail Stop 0655, Washington, DC 20528.

Instructions: All submissions must include the words ''Department of Homeland Security'' and DHS–2018–0032, 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 or to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sandra Taylor, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, Department of Homeland Security, 245 Murray Lane SW, Mail Stop 0655, Washington, DC 20528, by telephone (202) 343–1717, by fax (202) 343–4010, or by email to *privacycommittee@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: Purpose and Objective: Under the authority of 6 U.S.C. 451, the Secretary of Homeland Security renewed the charter of the Data Privacy and Integrity Advisory Committee as a discretionary committee, which shall operate in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix. The Committee provides advice at the request of the Secretary of Homeland Security and the DHS Chief Privacy Officer on programmatic, policy, operational, administrative, and technological issues within the DHS that relate to personally identifiable information (PII), as well as data integrity and other privacy-related matters.

Dated: June 7, 2018.

Philip S. Kaplan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2018–12668 Filed 6–12–18; 8:45 am]

BILLING CODE 9110–9L–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000.L63100000. HD0000.18XL1116AF.HAG 18–0108]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management (BLM), Oregon State Office, Portland, Oregon, 30 calendar days from the date of this publication. The surveys, which were executed at the request of the BLM, are necessary for the management of these lands.

DATES: Protests must be received by the BLM by July 13, 2018.

ADDRESSES: A copy of the plats may be obtained from the Public Room at the Bureau of Land Management, Oregon State Office, 1220 SW 3rd Avenue, Portland, Oregon 97204, upon required payment. The plats may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Marshal Wade, Branch of Geographic Sciences, Bureau of Land Management, 1220 SW 3rd Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact the above individual during normal business hours. The FRS 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: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management, Oregon State Office, Portland, Oregon:

Willamette Meridian, Oregon

Tps. 38 & 39 S, R. 4 E, accepted April 6, 2018
T. 15 S, R. 11 E, accepted April 6, 2018
T. 39 S, R. 2 E, accepted April 6, 2018
T. 31 S, R. 9 W, accepted April 23, 2018
T. 23 S, R. 6 W, accepted April 23, 2018
T. 19 S, R. 5 W, accepted April 23, 2018
T. 29 S, R. 5 W, accepted April 23, 2018
T. 17 S, R. 7 W, accepted May 3, 2018
T. 7 S, R. 3 E, accepted May 3, 2018
T. 13 S, R. 6 W, accepted May 3, 2018
T. 31 S, R. 9 W, accepted May 7, 2018

Willamette Meridian, Washington

T. 15 N, R. 27 E, accepted May 3, 2018
T. 15 N, R. 27 E, accepted May 3, 2018
T. 33 N, R. 17 E, accepted May 3, 2018

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the Chief Cadastral Surveyor for Oregon/Washington, Bureau of Land Management. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be filed before the scheduled date of official filing for the plat(s) of survey being protested. Any notice of protest filed after the scheduled date of official filing will be untimely and will not be considered. A notice of protest is considered filed on the date it is received by the Chief Cadastral Surveyor for Oregon/Washington during regular business hours; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the Chief Cadastral Surveyor for Oregon/Washington within 30 calendar days after the notice of protest is filed. If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the next business day following dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Marshal Wade,

Acting Chief Cadastral Surveyor of Oregon/Washington.

[FR Doc. 2018–12714 Filed 6–12–18; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–25647; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before May 19, 2018, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by June 28, 2018.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before May 19, 2018. Pursuant to Section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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.

Nominations submitted by State Historic Preservation Officers:

ALASKA

Kenai Peninsula Borough

Ch'u'itnu Historic District, Address Restricted, Tyonek vicinity, SG100002618

FLORIDA

Alachua County

Proctor, Carlos and Marjorie Log House and Cottage, 2250 NW 8th Ave., Gainesville, SG100002620

IOWA

Pottawattamie County

Farnsworth, Shepard and Emma, House, 301 S 8th St., Council Bluffs, SG100002621

KANSAS

Dickinson County

Vine Street Historic, 301 to 415 N Vine & 808–810 NW 3rd Sts., Abilene, SG100002622

Douglas County

O'Sullivan, John and Anna Farmstead (Agriculture-Related Resources of Kansas MPS), 710 E 100 Rd., Overbrook vicinity, MP100002623

Kearny County

Deerfield State Bank, 602 Main St., Deerfield, SG100002625

Leavenworth County

Stonehaven Farm, 19801 Tonganoxie Dr., Tonganoxie vicinity, SG100002626

Lyon County

Mouse, Snowden S., Service Station and Tourist Home (Roadside Kansas MPS), 413 E 6th Ave. & 526 N Exchange St., Emporia, MP100002627

McPherson County

McPherson, Community Building, 122 E. Marlin, McPherson, SG100002628

Shawnee County

Shiloh Baptist Church, 1201 SW Buchanan St., Topeka, SG100002629

MARYLAND

Dorchester County

Hughes A.M.E. Chapel, 4201 Maple Dam Rd., Cambridge vicinity, SG100002630

OREGON

Douglas County

Moores, Dr. Robert R. and Mary Helen, House, 1247 SE Kane St., Roseburg, SG100002632

SOUTH DAKOTA

Fall River County

Hot Springs Historic District (Boundary Decrease), Various, Hot Springs, BC100002634

Yankton County

Yankton Historic Commercial District (Boundary Decrease), Various, Yankton, BC100002635

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations and supports listing the properties in the National Register of Historic Places.

CALIFORNIA

Marin County

Point Reyes Naval Radio Compass Station, 23250 Sir Francis Drake Blvd., Inverness vicinity, SG100002619

MARYLAND

Washington County

Antietam National Battlefield, N of Sharpsburg off MD 45, Sharpsburg, AD66000038

UTAH

Grand County

Johnson Ranch House, Hastings Rd. 21 mi NW of Crescent Junction, Crescent Junction vicinity, SG100002636

Authority: Section 60.13 of 36 CFR part 60.

Dated: May 22, 2018.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program and Keeper, National Register of Historic Places.

[FR Doc. 2018–12630 Filed 6–12–18; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1012 (Enforcement Proceeding)]

Certain Magnetic Data Storage Tapes and Cartridges Containing the Same; Notice of Institution of Formal Enforcement Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has instituted a formal enforcement proceeding relating to the March 8, 2018 cease and desist orders issued in the above-referenced investigation.

FOR FURTHER INFORMATION CONTACT: Amanda P. Fisherow, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted the original investigation on July 1, 2016, based on a complaint filed by Fujifilm Corporation of Tokyo, Japan, and Fujifilm Recording Media U.S.A., Inc. of Bedford, Massachusetts (collectively, ''Fujifilm''). 81 FR 43243–44 (July 1, 2016). Pertinent to this action, the complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the sale for importation, importation, and sale within the United States after importation of certain magnetic data storage tapes and cartridges containing the same by reason of infringement of claims 1, 4–9, 11 and 14 of U.S. Patent No. 6,641,891 (''the '891 patent''). The Commission's Notice of Investigation named as respondents Sony Corporation of Tokyo, Japan; Sony Corporation of America of New York, New York; and Sony Electronics Inc. of San Diego, California (collectively, ''Sony''). The Office of Unfair Import Investigations (''OUII'') was also named as a party to the investigation.

On March 8, 2018, the Commission found a section 337 violation as to the '891 patent and issued a limited exclusion order and cease and desist orders (''CDOs'') to each of the Sony respondents. 83 FR 11245–47 (March 14, 2018). The CDOs prohibit Sony from importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting

United States agents or distributors for certain magnetic data storage tapes and cartridges containing the same that infringe the '891 patent.

On May 9, 2018, Fujifilm filed a complaint requesting that the Commission institute a formal enforcement proceeding under Commission Rule 210.75 to investigate alleged violation of the CDOs by Sony. On May 23, 2018, Sony filed a letter requesting that the Commission determine not to institute the enforcement proceeding. On May 30, 2019, Fujifilm filed a response.

Having examined the enforcement complaint, the supporting documents, and the pre-institution correspondence, the Commission has determined to institute a formal enforcement proceeding, pursuant to 19 CFR 210.75(a), to determine whether a violation of the March 8, 2018 CDOs issued in the original investigation has occurred and to determine what, if any, enforcement measures are appropriate. The named respondents are the three Sony entities from the original investigation and Sony Storage Media Solutions Corporation of Tokyo, Japan; Sony Storage Media Manufacturing Corporation of Miyagi, Japan; Sony DADC US Inc. of Terre Haute, Indiana; and Sony Latin America Inc. of Miami, Florida. OUII is also named as a party. The Commission has not ruled on the issues raised in the pre-institution correspondence submitted by the parties.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 7, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–12655 Filed 6–12–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Convertible Sofas and Components Thereof, DN 3321;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Sauder Manufacturing Company on June 7, 2018. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain convertible sofas and components thereof. The complaint names as a respondent: Krug, Inc. of Canada. The complainant requests that the Commission issue a limited exclusion order, a cease and desist order, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3321) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electonic Filing Procedures, Electronic Filing Procedures).[1] Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: June 7, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–12651 Filed 6–12–18; 8:45 am]

BILLING CODE 7020–02–P

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Alcami Wisconsin Corporation

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before August 13, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been delegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on May 3rd, 2018, Alcami Wisconsin Corporation, W130 N10497 Washington Dr., Germantown, WI 53022 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Alfentanil	9737	II

The company plans to provide bulk active pharmaceutical ingredient to support clinical trials.

Dated: June 6, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–12684 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Gazelle A. Craig, D.O.; Decision and Order

On September 20, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Gazelle A. Craig, D.O. (hereinafter, Respondent), of Houston, Texas. GX 2 (Order to Show Cause). The Show Cause Order proposed the revocation of Respondent's Certificate of Registration on the ground that she does ''not have authority to handle controlled substances in the State of Texas, the [S]tate in which . . . [she is] registered with the DEA.'' *Id.* at 1 (citing 21 U.S.C. 823(f) and 824(a)(3)).

As to the Agency's jurisdiction, the Show Cause Order alleged that Respondent holds DEA Certificate of Registration No. FC1384306, which authorizes her to dispense controlled substances in schedules II through V as a practitioner, at the registered address of Gulfton Community Health Center, 6306 Gulfton St., Suite 101, Houston, Texas 77081. *Id.* The Show Cause Order alleged that this registration expires on August 31, 2018. *Id.*

As the substantive ground for the proceeding, the Show Cause Order alleged that Respondent is ''without authority to handle controlled substances in the State of Texas, the [S]tate in which . . . [she is] registered . . . with the DEA.'' *Id.* It further alleged that, on July 28, 2017, the Texas Medical Board temporarily suspended Respondent's medical license and that the Texas Medical Board order remains in effect. *Id.* The Show Cause Order asserted that Respondent is ''required to possess authority from a [S]tate in order to obtain or retain a DEA Registration. . . . [and c]onsequently, the DEA must revoke . . . [her registration] based upon [her] lack of authority to handle controlled substances in the State of Texas.'' *Id.* at 1–2.

The Show Cause Order notified Respondent of her right to request a hearing on the allegations or to submit a written statement while waiving her right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of the opportunity to submit a Corrective Action Plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

According to the Declaration of a DEA Diversion Investigator (hereinafter, DI), on September 20, 2017, he mailed the Show Cause Order to Respondent's ''residential address . . . where . . . [he] had previously interacted with . . . [her] in conjunction with a search warrant.'' GX 3, at 1–2 (DI Declaration, Dec. 5, 2017). Attached to his Declaration was a ''copy of the return receipt [card] showing that the certified mail . . . was delivered on October 3, 2017.'' *Id.* at 2. However, the return receipt card was signed by someone other than Respondent.[1] GX 3, Attachment D, at 1.

On November 21, 2017, the Office of Administrative Law Judges (OALJ) received a Request for Hearing from an attorney representing Respondent.[2] GX 4, at 1. Therein, Respondent admitted that her ''license to practice medicine in the [S]tate of Texas is suspended,'' but represented that ''she maintains an active and unrestricted license to practice medicine in the State of New York.'' *Id.* at 1. Respondent also represented that, ''[o]n or about September 2017, [she] modified her practice address'' from Houston, Texas to New York, NY, and that she ''has modified her registration to reflect her practice address as the address indicated above to the State of New York.'' *Id.* Respondent further stated that prior to modifying her practice address to her Houston location, she practiced at the New York address she referenced in her Request. *Id.* Under the heading of ''CORRECTIVE ACTION PLAN,'' the Hearing Request stated that Respondent ''submits this modification of her practice address as a corrective action plan to the continuation of her DEA controlled substance registration.'' *Id.*

Upon receipt of Respondent's Hearing Request, the matter was assigned to Administrative Law Judge (ALJ) Charles Wm. Dorman, who issued an order captioned as ''Briefing Schedule for Lack of State Authority Allegations.'' GX 6, at 1. In this order, the ALJ noted the respective dates of the Show Cause Order and the receipt of the Hearing Request and further directed the Government to ''submit evidence of the date of service of the'' Show Cause Order ''by December 5, 2017.'' *Id.* The ALJ also ordered that if the Government moved to terminate the proceeding, it must file its motion ''by the same date'' and that Respondent's response was due ''by 2:00 p.m. Eastern Standard Time . . . on December 12, 2017.'' *Id.*

According to the ALJ's Termination Order (Dec. 14, 2017), on December 5, 2017, ''[t]he Government timely filed'' its Termination Request wherein ''it argued that . . . Respondent filed her Hearing Request more than 30 days after the date of service of the'' Show Cause Order. *Id.* The ALJ further noted that, ''[as] of the date of'' his Termination Order, ''Respondent had not filed a response to the Government's Termination Request.'' *Id.* at 2.

As grounds for finding waiver, the ALJ noted that ''[a]lthough there is no evidence of when the Respondent received the'' Show Cause Order that was sent by regular mail to her registered location, ''the fact that [it] was not returned as undeliverable establishes the presumption of receipt.'' *Id.* (citing *Net Wholesale,* 70 FR 24626 (2005)). The ALJ then noted that ''given that it was mailed on September 20, [2017,] it is highly likely that it was delivered before October 15, 2017.'' *Id.* at 2. The ALJ further noted, that ''[n]otwithstanding this uncertainty, there is evidence that the Respondent received the [Show Cause Order] at her residential address on October 3, 2017.'' *Id.* The ALJ explained that, ''[b]ased on this date, the Hearing Request should have been filed by November 3, 2017, in order to be timely,'' but ''[t]he Hearing Request . . . was not received by the OALJ, and therefore not filed, until November 21, 2017.'' *Id.* The ALJ thus found that ''Respondent's hearing Request was filed more than 30 days after the [Show Cause Order] was served.'' *Id.*

The ALJ then noted that ''[f]ailing to show good cause for an untimely hearing request constitutes a waiver of the right to a hearing.'' *Id.* (citing *Shannon L. Gallentine,* 76 FR 45864, 45864 (2011); *Gilbert E. Johnson,* 75 FR 65663, 65663–64 (2010)). Because Respondent did not file a response to the Government's Termination Request, the ALJ found that Respondent failed to show good cause to excuse the untimely filing of her Hearing Request and had waived her right to a hearing. *Id.* The ALJ thus granted the Government's motion and terminated the proceedings before his Office. *Id.*

On December 22, 2017, the Government filed its Request for Final Agency (RFAA) along with an investigative record in support of its proposed action. RFAA, at 6. Therein, the Government seeks revocation of Respondent's Certificate of Registration on the ground that she is registered in the State of Texas, where she no longer has authority to dispense controlled substances. *Id.* at 4–6. While the Government further notes that Respondent attempted to change the address of her registration to a location in New York State, it argues that her ''attempt to change addresses . . . was made only after being served with the [Show Cause Order and] should not serve as a basis to prevent revocation of her'' Registration. *Id.* at 4. The Government further argues that ''pursuant to 21 CFR 1301.51(c), this attempted modification is to be treated as an application for a registration.'' *Id.*

Having considered the record in its entirety, I grant the Government's Request to revoke Respondent's Certificate of Registration. While I agree with the Government that Respondent's attempt to modify her registered location to an address in the State of New York is to be treated as a new application, I find that this application remains pending before the Agency. I also conclude that because the Government seeks revocation of her existing registration solely on the basis that Respondent lacks authority to dispense controlled substances in Texas, her application for registration in New York must be the subject of separate proceedings.

The Waiver Finding

As discussed above, the ALJ found that ''there is evidence that the Respondent received the [Show Cause Order] at her residential address on October 3, 2017,'' and ''[b]ased on this date, the Hearing Request should have been filed by November 3, 2017, in order to be timely.'' GX 6, at 2 (citing 21 CFR 1301.43(a)). The ALJ also found that Respondent's Hearing Request was untimely based on the fact that it was not received by his Office until November 21, 2017. *Id.* Notwithstanding that the return receipt card is signed by someone other than Respondent and that under the Agency's regulations, the timeliness of a hearing request is based on the request being filed ''within 30 days after the date of receipt of the order to show cause,'' 21 CFR 1301.43(a), I agree with each of the ALJ's findings.

While DEA has not specifically addressed the issue of when the clock starts to run for purposes of assessing the timeliness of a hearing request where someone other than the subject of a Show Cause Order signs the return receipt card, the federal courts have long recognized that ''a '*strong*

[1] In proceedings before the Administrative Law Judge, the Government submitted evidence that it also mailed the Show Cause Order by regular first class mail to Respondent's registered address on September 20, 2017 and that this mailing was not returned as undeliverable. GX 6, at 2.

[2] While the hearing request was dated November 15, 2017, under DEA's regulation, ''[d]ocuments shall be dated and deemed filed upon receipt by the Hearing Clerk.'' 21 CFR 1316.45. The Show Cause Order also notified Respondent that ''[m]atters are deemed filed upon receipt by the Hearing Clerk.'' GX 2, at 2.

presumption' of receipt applies when notice is sent by certified mail, because it creates actual evidence of delivery in the form of a receipt.'' *Lupyan* v. *Corinthian Colleges Inc.,* 761 F.3d 14 (3d Cir. 2014) (quoting *Santana Gonzales* v. *Att'y Gen.,* 506 F.3d 274, 279 (3d Cir. 2007). To similar effect, the Fifth Circuit has explained that ''[p]roof that a letter properly directed was placed in a U.S. post office mail receptacle creates a presumption that it reached its destination in the usual time and was actually received by the person to whom it was addressed.'' *Beck* v. *Somerset Technologies, Inc.,* 882 F.2d 993, 996 (5th Cir. 1989). As the Fifth Circuit further explained in discussing the evidence of delivery in *Beck:*

> The record contains a copy of the properly addressed letter, a certified mail receipt and signed return post cards. Accordingly, we hold there was sufficient evidence to create a presumption that the letter was received . . . in the due course of the mail. Thus, the burden of producing evidence of non-delivery shifted to Beck.

Id.

To be sure, this rule '' 'is not a conclusive presumption of law.' '' *Lupyan,* 761 F.3d at 319 (quoting *Rosenthal* v. *Walker,* 111 U.S. 185, 193 (1884)). ''Rather, it is a rebuttable 'inference of fact.' '' *Id.; see also Beck,* 882 F.2d at 996; [3] *Cf. Morgan* v. *Potter,* 489 F.3d 195, 197 n.1 (5th Cir. 2005) (noting that while ''the presumption can certainly be overcome,'' plaintiff provided no evidence to establish the date she claimed to have received right to sue letter and ''never made such a claim or presented such evidence to the district court'').

In this matter, while the ALJ provided Respondent with the opportunity to respond to the Government's Termination Request, she has entirely failed to respond, let alone provide evidence to rebut the presumption that she received the Show Cause Order on the date the mailing was signed for. Because I find that the mailing was properly addressed to Respondent's residence and delivered on October 3, 2017, and Respondent produced no evidence to rebut the presumption that she received the mailing on this date, I find that Respondent received the Show Cause Order on October 3, 2017. I further find that more than 30 days have since passed since the date of service of the Show Cause Order, and that Respondent has waived both her right to a hearing as well as her right to submit a written statement of position on the matters of fact and law asserted in the Show Cause Order while waiving her right to a hearing. 21 CFR 1301.43(a), (c), (d).[4] I make the following additional finding of fact.

Findings of Fact

Respondent's DEA Registration

Respondent is the holder of DEA Certificate of Registration No. FC1384306, pursuant to which she is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of Gulfton Community Health Center, 6306 Gulfton St., Suite 101, Houston, TX 77081. GX 1. This registration does not expire until August 31, 2018. *Id.*

According to the Acting Unit Chief of the Agency's Registration and Program Support Section, on three different occasions following service of the Show Cause Order, Respondent attempted to change her registered location from the above address to an address in New York, NY. GX 5. According to the Acting Unit Chief, Respondent was unable to change her registered location and remains registered at the Houston, Texas location. *Id.* I further find, however, that Respondent's attempts to modify her registered location are deemed applications for a new registration in the State of New York. 21 CFR 1301.51(c) (''The request for modification shall be handled in the same manner as an application for registration.'').

The Status of Respondent's Texas License

On July 28, 2017, a Disciplinary Panel of the Texas Medical Board entered an Order of Temporary Suspension (hereinafter, Board's Order) of Respondent's Texas Medical License. GX 3, at Attachment A. The Board's Order ''remain[s] in effect until it is superseded by a subsequent Order of the Texas Medical Board.'' *Id.* at 5.

The Board's Order was based on fact findings related to Respondent's operation of an unregistered pain management clinic. *Id.* at 2. These findings included that, on August 31, 2016, the Board filed a Complaint with the Texas Office of Administrative Hearings alleging that Respondent and her prescriptive delegates ''prescribed controlled medications to ten patients in a manner inconsistent with public health [and] welfare, failed to meet the standard of care in the care and treatment of the patients, . . . failed to keep adequate medical records for the patients,'' and ''failed to supervise her prescriptive delegates adequately.'' *Id.* The Board's Order also found that the Board's expert had reviewed ten patient cases and concluded that ''Respondent's prescriptions for controlled substances were not provided for a legitimate medical purpose.'' *Id.*

Next, the Board's Order found that, on July 6, 2017, Respondent was indicted in the United District Court for the Southern District of Texas on felony charges of conspiracy to distribute and dispense controlled substances unlawfully, as well as aiding and abetting the unlawful distribution and dispensing of controlled substances at her pain clinic. *Id.* The Board's Order also found that following her arrest, Respondent signed an Order Setting Conditions of Release, which ''restricts [her] from employment in a pain management clinic[ ] [and] from writing prescriptions for any schedule II or IV drug, and from writing prescriptions for any opioid in schedule II.'' *Id.* Based on a Prescriber Activity Report obtained from the State's Prescription Monitoring Program, the Board's Order found that since her release from custody on July 10, 2017, ''eight prescriptions for schedule IV controlled substances (Carisoprodol and Alprazolam) and 21 prescriptions for Promethazine/Codeine syrup were issued under her DEA registration number.'' *Id.* at 3. Based on the Prescriber Activity Report, the Board's Order also found that from

[3] In *Vincent G. Colosimo,* an applicant for registration was issued a Show Cause Order which was served by Certified Mail addressed to his proposed registered location. 79 FR 20911, 20912 (2014). The applicant filed a hearing request which was received by the OALJ one day late and therefore deemed untimely by the ALJ, who ordered the parties to address whether there was good cause to excuse the late filing. *Id.*

Thereafter, the Government argued that the respondent's Hearing Request was untimely and that he had not shown good cause. *Id.* The respondent filed a statement wherein he asserted that the mailing containing the Show Cause Order had been signed for by another person at his office, that because it appeared to be of a legal nature, the mailing was sent to his employer's administrative office, and that he had only received it shortly before the due date of his hearing request. *Id.; see also Vincent G. Colosimo,* ALJ Termination Order, at 4. The ALJ nonetheless terminated the proceeding finding that the respondent had failed to show good cause for the untimely filing of his hearing request. *Colosimo,* 79 FR at 20912.

The Government then submitted a Request for Final Agency Action. *Id.* On review, the Administrator vacated the ALJ's termination order and rejected the Government's Request for Final Agency Action. The Administrator explained that while the respondent had not supported by affidavit the various factual assertions he had made in response to the ALJ's order directing the parties to address the timeliness of the hearing request, she further ''held that if those assertions were supported, [respondent would] demonstrate good cause.'' *Id.* Of note, the Agency did not hold that the date of receipt commenced on the date on which the respondent actually received the Show Cause Order rather than the date on which the certified mail was received at the respondent's proposed registration location. *Id.*

[4] I also agree with the ALJ's finding that Respondent has failed to show good cause to excuse the untimely filing of her Hearing Request and has therefore waived her right to a hearing for this reason as well.

April 26, 2016 through July 26, 2017, Respondent issued over 10,300 prescriptions for Hydrocodone/Acetaminophen 10/325 mg and over 10,400 prescriptions for Carisoprodol 350 mg. *Id.* at 2.

The Board thus found that ''Respondent's continuation in the practice of medicine poses a continuing threat to public welfare.'' *Id.* at 3. Based on these findings, the Panel found ''an imminent peril to the public health, safety, or welfare that requires immediate effect of'' its Order, *id.,* and temporarily suspended Respondent's medical license. *Id.* at 5.

I take official notice of the online records of the Texas Medical Board. *See* 5 U.S.C. 556(e). According to the Board's records, the temporary suspension of Respondent's medical license remains in effect as of the date of this Decision and Order.[5]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA), ''upon a finding that the registrant . . . has had . . . [her] State License or registration suspended [or] revoked by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term '' 'practitioner' [to] mean[ ] a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which [s]he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which . . . [she] practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess State authority in order to be deemed a practitioner under the CSA, the Agency has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever she is no longer authorized to dispense controlled substances under the laws of the State in which she practices. *See, e.g., Hooper, supra,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988); *Blanton, supra,* 43 FR at 27617.

Under the Texas Controlled Substances Act, a ''practitioner'' includes a ''physician'' who is licensed ''to dispense . . . or administer a controlled substance in the course of professional practice.'' Tex. Controlled Substances Act § 481.002(39)(A). Under the Texas Medical Practice Act, a ''physician'' is ''a person licensed to practice medicine,'' Tex. Occ. Code § 151.002(a)(12), and ''practicing medicine'' means the ''diagnosis, treatment, or offer to treat a . . . disease . . . by any system or method.'' *Id.* § 151.002(a)(13). Moreover, a ''person may not practice medicine in th[e] state unless the person holds a license issued under'' the Medical Practice Act, *id.* § 155.001, and ''[a] person commits an offense if the person practices medicine in this state in violation of'' the Act. *Id.* § 165.152.(a).

As found above, Respondent's Texas medical license remains temporarily suspended. I therefore find that Respondent is currently without authority to dispense controlled substances under the laws of Texas, the State in which she is registered with the Agency.

Moreover, because ''the controlling question'' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a DEA registration ''is currently authorized to handle controlled substances in the [S]tate,'' *Hooper,* 76 FR at 71371 (quoting *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997)), the Agency has long held that revocation is warranted even where a practitioner has lost his state authority by virtue of the State's use of summary process and the State has yet to provide a hearing to challenge the suspension. *Bourne Pharmacy,* 72 FR 18273, 18274 (2007); *Wingfield Drugs,* 52 FR 27070, 27071 (1987). Thus, it is of no consequence that the Texas Board has employed summary process in suspending Respondent's state license. *See Judson J. Somerville, M.D.,* 82 FR 21408, 21410 (2017); *Rezik A. Saqer,* 81 FR 22122, 22126 (2016). What is consequential is that Registrant is no longer currently authorized to dispense controlled substances in Texas, the State in which she is registered. *See Somerville,* 82 FR at 18274; *Saqer,* 81 FR 22126. I will therefore order that her registration be revoked.

While this Order resolves the issue of Respondent's entitlement to maintain her DEA registration, as found above, Respondent attempted to modify her registered address to a location in the State of New York. As the Government acknowledges, these requests for modification are treated as new applications for registration. RFAA, at 4; *see also* 21 CFR 1301.51(c). The record submitted to my Office provides no indication that the Government sought denial of these applications (which were submitted subsequent to the service of the Show Cause Order) in this proceeding, and in any event, the ground offered by the Government for revoking her Texas registration, which rests exclusively on the summary suspension of her Texas Medical License, does not support denial of her New York applications. Those applications remain pending before the Agency and must be the subject of a separate proceeding if the Government seeks to deny them.[6]

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. FC1384306, issued to Gazelle Craig, M.D., be, and it hereby is, revoked. This Order is effective immediately.[7]

[5] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration within 15 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Respondent files a motion, the Government shall have seven calendar days to file a response.

[6] Because Respondent's Corrective Action Plan is simply to modify her registered location to the New York address, I conclude that consideration of her plan should be considered by the Government in the course of evaluating her New York applications.

[7] Based on the Texas Board's finding that Respondent poses ''an imminent peril to the public health, safety, or welfare that requires immediate effect of'' the suspension order, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

Dated: June 1, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018–12686 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Johnson Matthey Pharmaceutical Materials Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before August 13, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on January 1, 2018, Johnson Matthey Pharmaceutical Materials Inc., 25 Patton Road, Devens, MA 01434 applied to be registered as a bulk manufacturer for the basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Methylphenidate	1724	II
Nabilone	7379	II
Hydrocodone	9193	II
Levorphanol	9220	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II

The company plans to utilize this facility to manufacture small quantities of the listed controlled substances in bulk for distribution to its customers as well as to conduct analytical testing in support of the company's primary manufacturing facility in West Deptford, New Jersey.

Dated: June 6, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–12685 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by-the Drug Enforcement Administration (DEA) as importers of various classes of schedule I or II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

Company	FR docket	Published
PerkinElmer, Inc	83 FR 9337	March 5, 2018.
Stepan Company	83 FR 9337	March 5, 2018.
Noramco, Inc	83 FR 12408	March 21, 2018.
Sanyal Biotechnology	83 FR 12407	March 21, 2018.
S&B Pharma, Inc	83 FR 13523	March 29, 2018.
Siegfried USA, LLC	83 FR 13521	March 29, 2018.
Lannett Company, Inc	83 FR 13520	March 29, 2018.

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or II controlled substances to the above listed companies.

Dated: May 30, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–12670 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Cambrex Charles City

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before July 13, 2018. Such persons may also file a written request for a hearing on the application on or before July 13, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been delegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on March 10, 2018, Cambrex Charles City, 1205 11th Street, Charles City, IA 50616 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Phenylacetone	8501	II
Coca Leaves	9040	II
Opium, raw	9600	II
Poppy Straw Concentrate	9670	II

The company plans to import the listed controlled substances for internal use, and to manufacture bulk intermediates for sale to its customers.

Dated: June 6, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–12683 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Bellwyck Clinical Services

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before July 13, 2018. Such persons may also file a written request for a hearing on the application on or before July 13, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on April 4, 2018, Bellwyck Clinical Services, 8946 Global Way, West Chester, OH 45069 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Methylphenidate	1724	II
Oxycodone	9143	II

The company plans to import the listed controlled substances in dosage form to conduct clinical trials.

Approval of permit applications will occur only when the registrant's activity is consistent with what is authorized under to 21 U.S.C.952 (a)(2).

Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: June 6, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–12682 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Restek Corporation

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before July 13, 2018. Such persons may also file a written request for a hearing on the application on or before July 13, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on February 20, 2018, Restek Corporation, 110 Benner Cr., Bellefonte, PA 16823 applied to be registered as an importer of the Schedule I controlled substance Tetrahydrocannibinols (7370).

The company plans to import the controlled substance in bulk for the manufacture of analytical reference material which, in its final form, is an exempted product.

Dated: June 6, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–12680 Filed 6–12–18; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meeting of Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meeting.

SUMMARY: The National Endowment for the Humanities will hold six meetings of the Humanities Panel, a federal advisory committee, during July 2018. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

ADDRESSES: The meetings will be held at Constitution Center at 400 7th Street SW, Washington, DC 20506, unless otherwise indicated.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meeting:

1. *Date:* July 24, 2018. This meeting will discuss applications on the topics of American Literature and Studies, the Arts, and Media, for the Awards for Faculty grant program, submitted to the Division of Research Programs.

2. *Date:* July 24, 2018. This meeting will discuss applications on the topics of Literature, History, and the Arts, for the NEH-Mellon Fellowships, submitted to the Division of Research Programs.

3. *Date:* July 25, 2018. This meeting will discuss applications on the topics of Literature, Philosophy, and Religion, for the Awards for Faculty grant program, submitted to the Division of Research Programs.

4. *Date:* July 26, 2018. This meeting will discuss applications on the topics of History and Politics, for the Awards for Faculty grant program, submitted to the Division of Research Programs.

5. *Date:* July 26, 2018. This meeting will discuss applications for Fellowships for Advanced Social Science Research on Japan, submitted to the Division of Research Programs.

6. *Date:* July 27, 2018. This meeting will discuss applications on the topics of American History and Studies, and Social Sciences, for the Awards for Faculty grant program, submitted to the Division of Research Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: June 7, 2018.

Elizabeth Voyatzis,

Committee Management Officer.

[FR Doc. 2018–12653 Filed 6–12–18; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–289 and 50–320; NRC–2018–0115]

Exelon Generation Company, LLC; Three Mile Island Nuclear Station, Units 1 and 2; Suspension of Security Measures in an Emergency or During Severe Weather

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption from regulatory requirements in response to an August 1, 2017,

request from Exelon Generation Company, LLC (Exelon or the licensee). The exemption allows a certified fuel handler (CFH), besides a licensed senior operator, to approve the emergency suspension of security measures for Three Mile Island Nuclear Station (TMI), Units 1 and 2, during certain emergency conditions or during severe weather. Although the exemption is effective upon receipt, the actions permitted by the exemption may not be implemented until both the ''Certification of Permanent Cessation of Operations'' and the ''Certification of Permanent Fuel Removal'' have been submitted. While Exelon submitted a Certification of Permanent Cessation of Operations for TMI, Unit 1, the Certification of Permanent Fuel Removal has not yet been submitted. Since the TMI, Unit 2, license had already been modified to allow possession but not operation before the effective date of the rule requiring these certifications; the certifications have been deemed submitted.

DATES: The exemption was issued on June 13, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0115 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 Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0115. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@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 it is mentioned in this document. In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- *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: Justin C. Poole, Office of Nuclear Reactor Regulation; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2048; email: *Justin.Poole@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Exelon is the holder of Renewed Facility Operating License No. DPR–50 for TMI, Unit 1. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. Exelon maintains the security planning responsibilities for TMI, Unit 2, through a service agreement with Unit 2's owner, First Energy Corporation. The TMI facility consists of pressurized-water reactors located in Dauphin County, Pennsylvania.

By letter dated June 20, 2017 (ADAMS Accession No. ML17171A151), the licensee submitted a Certification of Permanent Cessation of Operations for TMI, Unit 1. In this letter, Exelon provided notification to the NRC of its intent to permanently cease power operation at TMI, Unit 1, no later than September 30, 2019.

TMI, Unit 2, has a possession-only license. Unit 2 is currently maintained in accordance with the NRC-approved SAFSTOR condition known as post-defueling monitored storage. This is a method in which a nuclear facility is placed and maintained in a condition that allows it to be safely stored and subsequently decontaminated.

In accordance with title 10 of the *Code of Federal Regulations* (10 CFR) 50.82(a)(1)(i) through (iii), and 10 CFR 50.82(a)(2), 10 CFR part 50 licenses for TMI will no longer authorize reactor operation, placement, or retention of fuel in the respective reactor vessel after certifications of permanent cessation of operations and permanent removal of fuel from the reactor vessel are docketed. It is expected that fuel will be permanently removed from TMI, Unit 1, by September 30, 2019.

By letter dated July 10, 2017 (ADAMS Accession No. ML17191A451), TMI requested NRC approval of its Certified Fuel Handler Training and Retraining Program. By letter dated December 29, 2017 (ADAMS Accession No. ML17228A729), the NRC approved the Certified Fuel Handler Training and Retraining Program for TMI.

II. Request/Action

On August 1, 2017 (ADAMS Accession No. ML17213A097), Exelon requested an exemption from 10 CFR 73.55(p)(1)(i) and (ii) pursuant to 10 CFR 73.5. The proposed exemption would authorize that the suspension of security measures must be approved, as a minimum, by either a licensed senior operator or a CFH at TMI only after the certifications required under 10 CFR 50.82(a)(1) have been submitted.

The regulations in 10 CFR 73.55(p)(1)(i) and (ii) require, in part, that the suspension of security measures during emergencies or severe weather be approved by a licensed senior operator. Exelon requested an exemption from these rules to allow either a licensed senior operator or a CFH to approve the suspension of security measures during emergencies or severe weather.

The NRC's security rules have long recognized the potential need to suspend security or safeguards measures under certain conditions. Accordingly, 10 CFR 50.54(x) and (y), first published in 1983, allow a licensee to take reasonable steps in an emergency that deviate from license conditions when those steps are ''needed to protect the public health and safety'' and there are no conforming comparable measures (48 FR 13970; April 1, 1983). As originally issued, the deviation from license conditions must be approved by, as a minimum, a licensed senior operator. In 1986, in its final rule, ''Miscellaneous Amendments Concerning the Physical Protection of Nuclear Power Plants'' (51 FR 27817; August 4, 1986), the Commission issued 10 CFR 73.55(a), stating in part:

> In accordance with Section 50.54(x) and (y) of Part 50, the licensee may suspend any safeguards measures pursuant to Section 73.55 in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specification that can provide adequate or equivalent protection is immediately apparent. This suspension must be approved as a minimum by a licensed senior operator prior to taking action.

In 1996, the NRC made a number of regulatory changes to address decommissioning. One of the changes was to amend 10 CFR 50.54(x) and (y) to authorize a non-licensed operator called a ''certified fuel handler,'' in addition to a licensed senior operator, to approve such protective steps. Specifically, in addressing the role of the CFH during emergencies, the Commission stated in the proposed rule, ''Decommissioning of Nuclear Power Reactors'' (60 FR 37379; July 20, 1995):

The Commission is proposing to amend 10 CFR 50.54(y) to permit a certified fuel handler at nuclear power reactors that have permanently ceased operations and permanently removed fuel from the reactor vessel, subject to the requirements of Sec. 50.82(a) and consistent with the proposed definition of ''Certified Fuel Handler'' specified in Sec. 50.2, to make these evaluations and judgments. A nuclear power reactor that has permanently ceased operations and no longer has fuel in the reactor vessel does not require a licensed individual to monitor core conditions. A certified fuel handler at a permanently shutdown and defueled nuclear power reactor undergoing decommissioning is an individual who has the requisite knowledge and experience to evaluate plant conditions and make these judgments.

In the final rule (61 FR 39298; July 29, 1996), the NRC added the following definition to 10 CFR 50.2: Certified fuel handler means, ''for a nuclear power reactor facility, a non-licensed operator who has qualified in accordance with a fuel handler training program approved by the Commission.'' However, the decommissioning rule did not propose or make parallel changes to 10 CFR 73.55(a), and did not discuss the role of a non-licensed CFH.

In the final rule, ''Power Reactor Security Requirements'' (74 FR 13926; March 27, 2009), the NRC relocated the security suspension requirements from 10 CFR 73.55(a) to 10 CFR 73.55(p)(1)(i) and (ii). The role of a CFH was not discussed in the rulemaking, so the suspension of security measures in accordance with 10 CFR 73.55(p) continue to require approval, as a minimum, by a licensed senior operator, even for a site that otherwise no longer operates.

III. Discussion

Under 10 CFR 73.5, the Commission may, upon application by any interested person or upon its own initiative, grant an exemption from the requirements of 10 CFR part 73, when the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. As explained below, the proposed exemption is lawful, will not endanger life or property or the common defense and security, and is otherwise in the public interest.

A. Authorized by Law

The exemption would permit a CFH at TMI, besides a licensed senior operator, to approve the suspension of security measures during emergencies or severe weather. Although the exemption is effective upon receipt, the actions permitted by the exemption may not be implemented until both the ''Certification of Permanent Cessation of Operations'' and the ''Certification of Permanent Fuel Removal'' have been submitted in accordance with 10 CFR 50.82(a)(1). While Exelon submitted a Certification of Permanent Cessation of Operations for TMI, Unit 1, the Certification of Permanent Fuel Removal has not yet been submitted. Per 10 CFR 50.82(a)(1)(iii), since TMI, Unit 2, had already modified its license to allow possession but not operation before the effective date of the rule, the certifications have been deemed submitted. The licensee intends to align these regulations with 10 CFR 50.54(y) by authorizing a CFH, in addition to a licensed senior operator, to approve the suspension of security measures during emergencies or severe weather.

Per 10 CFR 73.5, the NRC is authorized to grant specific exemptions from the requirements of 10 CFR part 73. Issuance of this exemption is consistent with the Atomic Energy Act of 1954, as amended, and not otherwise inconsistent with NRC regulations or other applicable laws. Therefore, the exemption is authorized by law.

B. Will Not Endanger Life or Property or the Common Defense and Security

The NRC staff determined that the requested exemption would not endanger life or property, or the common defense and security. The requested exemption would permit a CFH, besides a licensed senior operator, to approve suspension of security measures during emergencies or severe weather. The NRC staff finds that the exemption does not endanger life or property, or the common defense and security for the reasons discussed below.

First, 10 CFR 73.55(p)(2) continues to require that ''[s]uspended security measures must be reinstated as soon as conditions permit.''

Second, the suspension of security measures for emergencies under 10 CFR 73.55(p)(1)(i) will continue to be invoked only ''when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent.'' Thus, the exemption would not prevent the licensee from meeting the underlying purpose of 10 CFR 73.55(p)(1)(i), to protect public health and safety.

Third, the suspension of security measures for severe weather under 10 CFR 73.55(p)(1)(ii) will continue to be used only when ''the suspension of affected security measures is immediately needed to protect the personal health and safety of security force personnel, and no other immediately apparent action consistent with the license conditions and technical specifications can provide adequate or equivalent protection.'' The requirement in 10 CFR 73.55(p)(1)(ii) to receive input from the security supervisor or manager will remain. Therefore, the exemption would not prevent the licensee from meeting the underlying purpose of 10 CFR 73.55(p)(1)(ii) to protect the health and safety of the security force.

Additionally, by letter dated December 29, 2017, the NRC approved Exelon's Certified Fuel Handler Training and Retraining Program for TMI. The NRC staff found that, among other things, the program addresses the safe conduct of decommissioning activities, safe handling and storage of spent fuel, and the appropriate response to plant emergencies. Because a CFH is sufficiently trained and qualified under an NRC-approved program, the NRC staff considers a CFH to have sufficient knowledge of operational and safety concerns, such that allowing a CFH to suspend security measures during emergencies or severe weather will not result in undue risk to public health and safety.

In addition, since the exemption request allows a CFH the same authority currently given to the licensed senior operator under 10 CFR 73.55(p)(1)(i) and (ii), no change is required to physical security. Since no change is required to physical security, the exemption would not reduce the overall effectiveness of the physical security plan and would not adversely impact Exelon's ability to physically secure the site or protect special nuclear material at TMI, and thus, would not have an effect on the common defense and security. The NRC staff has concluded that the exemption does not reduce security measures currently in place to protect against radiological sabotage. Therefore, allowing a CFH, besides a licensed senior operator, to approve the suspension of security measures during an emergency or severe weather, will not endanger life, property, or the common defense and security.

C. Otherwise in the Public Interest

Exelon's proposed exemption would allow a CFH, besides a licensed senior operator, to approve suspension of security measures during an emergency when ''immediately needed to protect the public health and safety'' or severe weather when ''immediately needed to protect the personal health and safety of security force personnel.'' Without the exemption, the licensee cannot

implement changes to its security plan comparable to the authority given to the CFH under 10 CFR 50.54(y), which authorizes a CFH to approve the temporary suspension of security measures during an emergency or severe weather. If the exemption is not granted, TMI will be required to have a licensed senior operator available to approve suspension of security measures during severe weather and emergencies for a permanently shutdown plant, even though TMI would no longer require a licensed senior operator after the certifications required by 10 CFR 50.82(a)(1)(i) and (ii) were submitted.

This exemption is in the public interest for two reasons. First, without the exemption, there is uncertainty regarding how the licensee will invoke temporary suspension of security measures that may be needed for protecting public health and safety or the safety of the security force during emergencies and severe weather given the inconsistencies between the requirements in 10 CFR 73.55(p)(1)(i) and (ii) and 10 CFR 50.54(y). The exemption would allow the licensee to make decisions pursuant to 10 CFR 73.55(p)(1)(i) and (ii) without having to maintain a staff of licensed senior operators. The exemption would also allow the licensee to have an established procedure in place to allow a trained CFH to suspend security measures in the event of an emergency or severe weather. Second, the consistent and efficient regulation of nuclear power plants serves the public interest. This exemption would assure consistency between the security regulations in 10 CFR part 73 and 10 CFR 50.54(y) and the requirements concerning licensed operators in 10 CFR part 55.

The NRC staff has determined that granting the licensee's proposed exemption would allow the licensee to designate a CFH with qualifications appropriate for a permanently shutdown and defueled reactor, to approve the suspension of security measures during an emergency. This role of the CFH to protect the public health and safety, and during severe weather to protect the safety of the security force, is consistent with the similar authority provided by 10 CFR 50.54(y). Therefore, the exemption is in the public interest.

D. Environmental Consideration

The NRC's approval of the exemption to security requirements belongs to a category of actions that the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Specifically, the exemption is categorically excluded from further analysis under 10 CFR 51.22(c)(25).

Under 10 CFR 51.22(c)(25), the granting of an exemption from the requirements of any regulation of chapter 10 is a categorical exclusion provided that (i) there is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve recordkeeping requirements; reporting requirements; inspection or surveillance requirements; equipment servicing or maintenance scheduling requirements; education, training, experience, qualification, requalification or other employment suitability requirements; safeguard plans, and materials control and accounting inventory scheduling requirements; scheduling requirements; surety, insurance or indemnity requirements; or other requirements of an administrative, managerial, or organizational nature.

The Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, has determined that the granting of the exemption request involves no significant hazards consideration because allowing a CFH, besides a licensed senior operator, to approve the security suspension at a defueled shutdown power plant does 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 exempted security regulation is unrelated to any operational restriction. Accordingly, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite, and no significant increase in individual or cumulative public or occupational radiation exposure. The exempted regulation is not associated with construction, so there is no significant construction impact. The exempted regulation does not concern the source term (*i.e.,* potential amount of radiation in an accident) nor mitigation. Thus, there is no significant increase in the potential for, or consequences of, a radiological accident. The requirement to have a licensed senior operator approve departure from security actions is viewed as involving safeguards, materials control, and managerial matters.

Therefore, pursuant to 10 CFR 51.22(b) and (c)(25), no environmental impact statement or environmental assessment need be prepared in connection with the approval of this exemption request.

IV. Conclusions

The NRC has determined that, pursuant to 10 CFR 73.5, this exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants the licensee's request for an exemption from the requirements of 10 CFR 73.55(p)(1)(i) and (ii) to authorize that the suspension of security measures must be approved, as a minimum, by either a licensed senior operator or a certified fuel handler at TMI during emergency or severe weather, once the certifications required under 10 CFR 50.82(a)(1) have been submitted.

The exemption is effective upon receipt.

V. Availability of Documents

The documents identified in the following table are available to interested persons.

Title	Date	ADAMS accession No.
Exelon letter to NRC, "Certification of Permanent Cessation of Power Operations for Three Mile Island Nuclear Station, Unit 1".	6/20/2017	ML17171A151
Exelon letter to NRC, Three Mile Island Nuclear Station, Unit 1, "Request for Approval of Certified Fuel Handler Training Program".	7/10/2017	ML17191A451

Title	Date	ADAMS accession No.
Exelon letter to NRC, Three Mile Island Nuclear Station, Units 1 and 2, ''Request for Exemption from Specific Provisions in 10 CFR 73.55(p)(1)(i) and (p)(1)(ii) Related to the Suspension of Security Measures in an Emergency or During Severe Weather''.	8/01/2017	ML17213A097
NRC letter to Exelon, ''Three Mile Island Nuclear Station, Unit 1—Approval of Certified Fuel Handler Training and Retraining Program''.	12/29/2017	ML17228A729

Dated at Rockville, Maryland, this 7th day of June 2018.

For the Nuclear Regulatory Commission.

Joseph G. Giitter,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–12652 Filed 6–12–18; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2016–111]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 15, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service has filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The requests(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2016–111; *Filing Title:* USPS Notice of Amendment to Priority Mail Contract 192, Filed Under Seal; *Filing Acceptance Date:* June 7, 2018; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Jennaca D. Upperman; *Comments Due:* June 15, 2018.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–12695 Filed 6–12–18; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83392; File No. SR–FINRA–2018–022]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Tier Size Pilot of Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities)

June 7, 2018.

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 May 31, 2018, 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 and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to amend FINRA Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities) to extend the Tier Size Pilot, which currently is scheduled to expire on June 7, 2018, until December 7, 2018.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

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 proposes to amend FINRA Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities) (the ''Rule'') to extend, until December 7, 2018, the amendments set forth in File No. SR–FINRA–2011–058 (''Tier Size Pilot'' or ''Pilot''), which currently are scheduled to expire on June 7, 2018.[4]

The Tier Size Pilot was filed with the SEC on October 6, 2011,[5] to amend the minimum quotation sizes (or ''tier sizes'') for OTC Equity Securities.[6] The goals of the Pilot were to simplify the tier structure, facilitate the display of customer limit orders, and expand the scope of the Rule to apply to additional quoting participants. During the course of the Pilot, FINRA collected and provided to the SEC specified data with which to assess the impact of the Pilot tiers on market quality and limit order display.[7] On September 13, 2013, FINRA provided to the Commission an assessment on the operation of the Tier Size Pilot utilizing data covering the period from November 12, 2012 through June 30, 2013.[8] As noted in the 2013 Assessment, FINRA believed that the analysis of the data generally showed that the Tier Size Pilot had a neutral to positive impact on OTC market quality for the majority of OTC Equity Securities and tiers; and that there was an overall increase of 13% in the number of customer limit orders that met the minimum quotation sizes to be eligible for display under the Pilot tiers. In the 2013 Assessment, FINRA recommended adopting the tiers as permanent, but extended the Pilot period to allow more time to gather and analyze data after the November 12, 2012 through June 30, 2013 assessment period.[9]

On April 20, 2018, FINRA proposed a rule change to adopt the pilot tiers as permanent. The Commission published that proposal in the **Federal Register** for notice and comment on May 7, 2018, and the comment period expired on May 29, 2018.[10] The Commission received one comment letter in response to the Proposal.[11] The purpose of the instant filing is to extend the operation of the Tier Size Pilot until December 7, 2018, to provide additional time for the Commission to consider FINRA's proposal to adopt the pilot tiers as permanent and comments received.

FINRA has filed the proposed rule change for immediate effectiveness. The operative date of the proposed rule change will be June 7, 2018.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[12] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA also believes that the proposed rule change is consistent with the provisions of Section 15A(b)(11) of the Act.[13] Section 15A(b)(11) requires that FINRA rules include provisions governing the form and content of quotations relating to securities sold otherwise than on a national securities exchange which may be distributed or published by any member or person associated with a member, and the persons to whom such quotations may be supplied.

FINRA believes that the extension of the Tier Size Pilot until December 7, 2018, is consistent with the Act in that it would provide the Commission with additional time to consider FINRA's proposal to adopt the pilot tiers as permanent and comments received.

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.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative prior to 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii),[17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Commission is waiving the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because such waiver will allow the pilot program to continue without interruption. Therefore, the Commission

[4] *See* Securities Exchange Act Release No. 82153 (November 22, 2017), 82 FR 56300 (November 28, 2017) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2017–035).

[5] *See* Securities Exchange Act Release No. 65568 (October 14, 2011), 76 FR 65307 (October 20, 2011) (Notice of Filing of File No. SR–FINRA–2011–058).

[6] ''OTC Equity Security'' means any equity security that is not an ''NMS stock'' as that term is defined in Rule 600(b)(47) of SEC Regulation NMS; provided, however, that the term OTC Equity Security shall not include any Restricted Equity Security. *See* FINRA Rule 6420.

[7] FINRA ceased collecting Pilot data for submission to the Commission on February 13, 2015.

[8] The assessment is part of the SEC's comment file for SR–FINRA–2011–058 and also is available on FINRA's website at: *http://www.finra.org/Industry/Regulation/RuleFilings/2011/P124615* (''Pilot Assessment'').

[9] *See* Securities Exchange Act Release No. 70839 (November 8, 2013), 78 FR 68893 (November 15, 2013) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2013–049).

[10] *See* Securities Exchange Act Release No. 83129 (April 30, 2018), 83 FR 20131 (May 7, 2018) (Notice of Filing of File No. SR–FINRA–2018–015).

[11] *See* Letter from Eugene P. Torpey, Chief Compliance Officer, Vandham Securities Corp., dated May 10, 2018.

[12] 15 U.S.C. 78*o*–3(b)(6).

[13] 15 U.S.C. 78*o*–3(b)(11).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires FINRA to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. FINRA has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

designates the proposal operative upon filing.[18]

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–2018–022 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–FINRA–2018–022. 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 website (*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 website 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 will also be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2018–022 and should be submitted on or before July 5, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–12647 Filed 6–12–18; 8:45 am]

BILLING CODE 8011–01–P

[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83395; File No. SR–NASDAQ–2018–041]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Listing Standard for Paired Share Units

June 7, 2018.

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 May 30, 2018, The Nasdaq Stock Market LLC (''Nasdaq'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II 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 adopt a listing standard for Paired Share Units.

The text of the proposed rule change is set forth below. Proposed new language is italicized; deleted text is in brackets.

* * * * *

The Nasdaq Stock Market Rules

* * * * *

5225. Listing Requirements for Units *(other than Paired Share Units)*

No change.

5226. Paired Share Units

A ''Paired Share Unit'' is a security consisting of a share of the common stock of a Company (the ''Parent'') and a share of the common stock of that Company's controlled subsidiary, which: (1) are attached together; and (2) only can be traded together as a unit pursuant to a pairing agreement. Instead of the requirements in Rule 5225 (except as indicated below), a Paired Share Unit can list on the Nasdaq Global or Global Select Markets if it meets the following requirements:

(a) For initial and continued listing, the controlled subsidiary must be a real estate investment trust (the ''REIT'') and the Parent must maintain ownership control, including voting control, over the REIT.

(b) For initial listing, the Parent and the REIT must each separately satisfy the entity-level requirements of Rule 5315(f)(3) or Rule 5405(b) (e.g., the stockholders' equity, income, market capitalization, assets, revenue and operating history requirements), as applicable, and the Paired Share Unit must satisfy the security-level requirements of Rule 5315 or Rule 5405 (e.g., the price, publicly held shares, holder, market value of publicly held shares and market maker requirements), as applicable.

(c) For continued listing, the Parent and the REIT must each separately satisfy the applicable entity-level requirements of Rule 5450(b) and the Paired Share Unit must satisfy the applicable security-level requirements of Rules 5450(a) and 5450(b).

(d) For initial and continued listing, the Parent and the REIT must each separately satisfy all other requirements of the listing rules applicable to a Company listing its primary equity security, including, without limitation, the corporate governance requirements in the Rule 5600 Series.

(e) For initial and continued listing, the common stock of the Parent, the common stock of the REIT and the Paired Share Unit must each be registered pursuant to Section 12(b) of the Act.

(f) For initial and continued listing, the common stock of the Parent and the common stock of the REIT, as attached and traded together in the Paired Share Unit, must be the only securities of each of the Parent and the REIT available to public investors.

(g) The provisions of Rules 5225(a)(2) and 5225(a)(3) are applicable to Paired Share Units.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(h) In the event the common stock of the REIT becomes separately tradable from the common stock of the Parent, Nasdaq will immediately issue a Staff Delisting Determination for the Paired Share Unit pursuant to Listing Rule 5810(c)(1), and each of the Parent and the REIT must apply, and each of the Parent and the REIT, and their respective securities, must separately qualify for initial listing to remain listed on Nasdaq.

* * * * *

5810. Notification of Deficiency by the Listing Qualifications Department

When the Listing Qualifications Department determines that a Company does not meet a listing standard set forth in the Rule 5000 Series, it will immediately notify the Company of the deficiency. As explained in more detail below, deficiency notifications are of four types:

(1)–(4) No change.

Notifications of deficiencies that allow for submission of a compliance plan or an automatic cure or compliance period may result, after review of the compliance plan or expiration of the cure or compliance period, in issuance of a Staff Delisting Determination or a Public Reprimand Letter.

(a)–(b) No change.

(c) Types of Deficiencies and Notifications

The type of deficiency at issue determines whether the Company will be immediately suspended and delisted, or whether it may submit a compliance plan for review or is entitled to an automatic cure or compliance period before a Staff Delisting Determination is issued. In the case of a deficiency not specified below, Staff will issue the Company a Staff Delisting Determination or a Public Reprimand Letter.

(1) Deficiencies That Immediately Result in a Staff Delisting Determination

Staff's notice will inform the Company that its securities are immediately subject to suspension and delisting when:

- A Company fails to timely solicit proxies;
- an Equity Investment Tracking Stock fails to comply with the additional continued listing requirements in Rule 5222(c) or a Staff Delisting Determination has been issued with respect to the security such Equity Investment Tracking Stock tracks;
- *the common stock of the REIT in a Paired Share Unit listed under Rule 5226 becomes separately tradable from the common stock of the Parent;* or
- Staff has determined, under its discretionary authority in the Rule 5100 Series, that the Company's continued listing raises a public interest concern.

(2)–(4) No change.

(d) 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, 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq Listing Rule 5225 provides the requirements to list units on the Nasdaq Stock Market. Listing Rule 5225(a)(1)(C) provides that all components of a unit listed on the Nasdaq Global or Global Select Market must be issued by the same issuer.

Nasdaq notes that in limited circumstances the securities of a company and its controlled subsidiary are attached and only can be traded together as a ''Paired Share.'' Nasdaq proposes to adopt new Listing Rule 5226 to allow the listing of this specific type of unit, called a Paired Share Unit, on the Nasdaq Global or Global Select Markets [3] under limited circumstances, even though one component of the unit is issued by a controlled subsidiary of the issuer of the other security in the unit and they are, therefore, not technically issued by the same issuer.

Under the proposed rule, a Paired Share Unit, consisting of a share of the common stock of a company (the ''Parent'') and a share of the common stock of that company's controlled subsidiary, which are attached together and can only be traded together as a unit pursuant to a pairing agreement, can be listed on the Nasdaq Global or Global Select Market provided it meets the following requirements.

First, the controlled subsidiary must be a real estate investment trust (the ''REIT'') and the Parent must maintain ownership control, including voting control, over the REIT. Ownership control will be determined based on an analysis of the facts and circumstances surrounding the relationship between the Parent and the REIT, but will require that the Parent control at least a majority (*i.e.,* over 50%) of the voting power of the REIT. In addition, the common stock of the Parent and the common stock of the REIT, as attached and traded together in the Paired Share Unit, must be the only security of each of the Parent and the REIT available to public investors, and the common stock of the Parent and the REIT must not trade separately. Thus, an investment in the Paired Share Unit represents an investment in the combined company and the only way for a public shareholder to invest in either company.

For initial listing, the Parent and the REIT must each separately satisfy the entity-level requirements of Rule 5315(f)(3) or Rule 5405(b), as applicable, and the Paired Share Unit must satisfy the security-level requirements of Rule 5315 or Rule 5405, as applicable.[4] For continued listing, the Parent and the REIT must each separately satisfy the entity-level requirements of Rule 5450(b), and the Paired Share Unit must satisfy the security-level requirements of Rules 5450(a) and (b). For these purposes the entity-level requirements include the stockholders' equity, income, market capitalization, asset, revenue and operating history requirements, and the security-level requirements include the price, publicly held shares, holder, market value of publicly held shares and market maker requirements. While the Parent and the REIT may satisfy different entity-level listing standards, in such a case the Paired Share Unit must satisfy the higher security-level requirements of those different standards.[5] In addition, for both initial and continued listing, the Parent and the REIT must each separately satisfy all other requirements of the listing rules applicable to a Company listing its primary equity security, including, without limitation,

[3] A Paired Share Unit would not be eligible to list on the Nasdaq Capital Market.

[4] The provisions of Rule 5315(b), (c) and (d) would not apply because neither the Parent nor the REIT would be a closed end management investment company or a business development company.

[5] For example, if the Parent only satisfies the entity-level requirements of the income standard in Rule 5405(b)(1) and the REIT only satisfies the entity-level requirements of the market value standard in Rule 5405(b)(3), the Paired Share Unit must satisfy the higher market value of publicly held shares and market maker requirements in Rule 5405(b)(3).

the corporate governance requirements in the Rule 5600 Series.

While proposed Rule 5226 is a new rule for listing a specific type of unit on the Nasdaq Global or Global Select Markets, the provisions of Rule 5225(a)(2), which provides the minimum listing period and notice of withdrawal requirements for units, and Rule 5225(a)(3), which provides disclosure requirements for units, are applicable to Paired Share Units. The other provisions of Rule 5225(a) are either separately incorporated in the requirements for a Paired Share Unit or are not applicable. Specifically, the first sentence of Rule 5225(a)(1)(A), which requires all units to have at least one equity component, is incorporated in the definition of a Paired Share Unit because a Paired Share Unit must contain the common stock of the Parent and the REIT. Rule 5225(a)(1)(B) is not applicable because a Paired Share Unit does not contain debt components. As described above, the first sentence of Rule 5225(a)(1)(C) is not applicable because the Paired Share Unit is a special type of unit, which contains the common stock of a company and its controlled subsidiary. The remainder of the requirements in Rules 5225(a)(1)(A) and (C) are addressed by the requirements of proposed Rules 5226(b), (c) and (d) that for initial and continued listing, respectively, the Parent and the REIT must each separately satisfy the entity-level requirements and all other requirements applicable to a company listing its primary equity security, and that the Paired Share Unit must satisfy the security-level requirements for listing on the Nasdaq Global or Global Select Market.

Rule 5225(a)(4), which imposes market maker requirements for units, is incorporated in the requirement that the Paired Share Unit must satisfy the highest applicable market maker requirement under the listing standard that each the Parent and the REIT qualify. The minimum market maker requirements under any of those standards are at least as high as in Rule 5225(a)(4): Three market makers for initial listing and two market makers for continued listing.

For initial and continued listing, the common stock of the Parent, the common stock of the REIT and the Paired Share Unit must each be registered pursuant to Section 12(b) of the Act. Finally, in the event the common stock of the REIT becomes separately tradable from the common stock of the Parent, Nasdaq will immediately issue a Staff Delisting Determination for the Paired Share Unit. Nasdaq proposes to modify Rule 5810(c)(1) to include this situation in the list of deficiencies where a company's securities are immediately subject to suspension and delisting. Each of the Parent and the REIT must apply, and each of the Parent and the REIT, and their respective securities, must separately qualify for initial listing to remain listed on Nasdaq.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Section 6(b)(5) of the Act,[7] in particular, in that it is designed 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, by allowing a unit to list on the Nasdaq Global or Global Select Markets where it includes the securities of a company and a REIT that is that company's controlled subsidiary if those entities each separately satisfy the entity-level listing requirements, the combined security satisfies the security-specific listing requirements, and the securities do not trade separately.

In these situations, the security to be listed is substantially similar to a traditional unit in that one of the companies maintains ownership and voting control of the other, and the proposed rule would adopt additional protections ensuring that both entities and the combined security have achieved sufficient size and market interest for listing on Nasdaq to be appropriate. Under the proposed rule, each company with securities in the Paired Share Unit must satisfy all listing requirements applicable to a company listing its primary equity security on the Nasdaq Global or Global Select Markets and the security itself must satisfy all applicable requirements for listing as a primary equity security. In addition, the common stock of the Parent, the common stock of the REIT and the Paired Share Unit must each be registered pursuant to Section 12(b) of the Act. Accordingly, the proposed rule change continues to impose Nasdaq's existing listing requirements, which are designed protect investors and the public interest. Further, the additional requirements proposed will supplement those existing requirements with investor protections designed to ensure that one company controls the other in the combined security. In the event the common stock of the REIT becomes separately tradable from the common stock of the Parent, Nasdaq would immediately issue a Staff Delisting Determination for the Paired Share Unit, which would be subject to suspension and delisting. Each of the Parent and the REIT must apply, and each of the Parent and the REIT, and their respective securities, must separately qualify for initial listing to remain listed on Nasdaq. Thus, adopting the proposed rule to address this unique situation with appropriate investor protections will eliminate the impediment to listing such a unit on the Nasdaq Global and Global Select Markets.

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. Nasdaq believes that the New York Stock Exchange currently lists securities similar to the Paired Share Unit described in the proposed rule change. Further, other markets could adopt comparable rules to the extent they believe it appropriate.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under Rule 19b–4(f)(6)[11] normally does not become operative for 30 days after the

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A)(iii).

[9] 17 CFR 240.19b–4(f)(6).

[10] In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 240.19b–4(f)(6).

date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[12] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing with the Commission, Nasdaq has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing to allow Nasdaq to immediately list units issued by a company and its controlled subsidiary and compete with other exchanges for such listing. As noted above, Nasdaq states that the proposed rule will continue to impose all of the existing listing requirements applicable to units, supplemented by additional requirements and investor protections designed to address this specific type of unit.

The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the Paired Share Units for which Nasdaq proposes to adopt initial and continued listing requirements are substantially similar to the traditional units that may be listed pursuant to Nasdaq Rule 5225 and the additional requirements in the proposal address the specific characteristics of Paired Share Units and how Nasdaq's existing listing rules will be applied. The Commission notes that a Paired Share Unit would consist of a share of common stock of a Company and a share of the common stock of a REIT that is that Company's controlled subsidiary, which are attached and only can be traded together. The proposed listing requirements would be substantially similar to existing listing requirements for units, but with clarification about how certain aspects will apply to a Paired Share Unit and its components and additional requirements designed to address issues relating to this specific type of unit. Therefore, the Commission designates the proposed rule change operative upon filing.[13]

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change 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–NASDAQ–2018–041 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–NASDAQ–2018–041. 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 website (*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 website 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 the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2018–041, and should be submitted on or before July 5, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–12649 Filed 6–12–18; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83393; File No. SR–FINRA–2018–023]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend FINRA Rule 6730 Relating to ATS Reporting of Transactions to TRACE in U.S. Treasury Securities

June 7, 2018.

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 June 5, 2018, 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.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Rule 6730 to require alternative trading systems (''ATSs'') that report transactions in U.S. Treasury Securities to the Transaction Reporting and Compliance Engine (''TRACE'') to identify non-FINRA member subscribers on those transaction reports.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA 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, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

On October 18, 2016, the SEC approved a proposed rule change to require FINRA members to report secondary market transactions in U.S. Treasury Securities to TRACE,[3] and on July 10, 2017, FINRA members began reporting transaction information on U.S. Treasury Security transactions through TRACE.[4] As approved, TRACE transaction information in U.S. Treasury Securities is for regulatory purposes only and is not disseminated publicly.[5]

As with all TRACE reporting, transactions in U.S. Treasury Securities that occur on an ATS generally must be reported to TRACE by the counterparties, if they are FINRA members, and by the ATS itself.[6] A significant amount of trading activity in U.S. Treasury Securities on ATSs involves market participants that are not registered as broker-dealers or are not FINRA members, including, for example, hedge funds, banks and principal trading firms (''PTFs''). As the U.S. Department of the Treasury (''Treasury Department'') noted in its recent Capital Markets Report, ''[t]rading activity [in U.S. Treasury Securities] on the major electronic interdealer platforms is dominated by PTFs, ... and collectively they account for over half of all transaction volumes in the interdealer broker segment of the [cash Treasury] market.'' [7] Although the Capital Markets Report does not define a ''PTF,'' the Joint Staff Report identifies the following as typical characteristics of PTFs: (i) Principal investor; (ii) deploys proprietary automated trading strategies; (iii) low latency is typically a key element of the trading strategies; and (iv) may be registered as a broker-dealer but does not have clients as in a typical broker-dealer business model.[8]

Because each current ATS is a FINRA member, all of the trading activity in TRACE-Eligible Securities occurring on an ATS is required to be reported to TRACE by that ATS; however, the identities of non-FINRA members (including, but not limited to, hedge funds, banks and PTFs) trading on the ATSs are not reported because they are treated as customers, not FINRA members. Thus, while an ATS identifies a specific FINRA-member counterparty on its TRACE reports by that counterparty's market participant identifier (''MPID''), for transactions involving non-FINRA members, the ATS reports the trade as a generic customer trade and identifies the counterparty only with a ''C'' identifier. Because of this, as the Capital Markets Report noted, ''[i]n essence, a significant portion of PTF activity is anonymized in the TRACE data.'' [9] The Treasury Department therefore recommended ''closing the gap in the granularity of PTF data'' by requiring ATSs that facilitate transactions in U.S. Treasury Securities ''to identify customers in their reports of Treasury security transactions to TRACE.'' [10]

To assess the scope of non-FINRA member trading activity in U.S. Treasury Securities on ATSs, FINRA analyzed transaction data submitted to TRACE and found that, consistent with the views expressed in the Capital Markets Report, the majority of trades in U.S. Treasury Securities reported by ATSs do not identify the subscriber that is a counterparty to the trade. Because a significant portion of ATS trades in U.S. Treasury Securities involves unidentified counterparties, the trading data available to FINRA and the official sector is incomplete. Requiring specific subscriber information in ATS TRACE reports for transactions in U.S. Treasury Securities would enhance the information available to FINRA and the official sector and facilitate a better understanding U.S. Treasury market structure and liquidity. As the Treasury Department noted in the JSR, ''an event like October 15 highlights the need to better understand various factors that are impacting liquidity in the U.S. Treasury market, especially during stressed market conditions . . . [including] . . . changes in intermediation, automated trading, regulation, and buy and sell-side participation that may have altered trading practices as well as the sources and characteristics of liquidity provision.'' [11]

In addition, FINRA believes that the proposed rule change would result in an improvement to the effectiveness of FINRA's surveillance patterns from the standpoint of greater granularity and thus more accurate pattern detection, including the increased ability to identify potentially manipulative activity. For example, FINRA's ability to detect wash sales or prearranged trading activity would be improved if the audit trail included the identity of the non-FINRA member counterparty rather than the generic customer indicator received today. The identity of the particular ATS subscriber allows the surveillance pattern to narrow down the potential universe of matching trades and thus more accurately detect instances of potential manipulation. As such, the additional detail that would be added to transaction reports by identifying non-FINRA member counterparties would enhance FINRA's surveillance program for U.S. Treasury Securities.

Consequently, as recommended in the Capital Markets Report, FINRA is proposing to require member ATSs with a minimum threshold of trading (''covered ATS'') to identify non-FINRA member subscribers associated with their TRACE trade reports in U.S. Treasury Securities. Specifically, FINRA proposes that a ''covered ATS'' would mean an ATS, as that term is defined in Rule 300 of SEC Regulation ATS,[12] that

[3] *See* Securities Exchange Act Release No. 79116 (October 18, 2016), 81 FR 73167 (October 24, 2016) (Order Granting Accelerated Approval of File No. SR–FINRA–2016–027).

[4] *See Regulatory Notice* 16–39 (October 2016).

[5] *See* Rule 6750(c)(5).

[6] *See Regulatory Notice* 14–53 (November 2014). There are limited exemptions available where all the counterparties are FINRA members, which would not apply where a transaction on an ATS involves a non-FINRA member.

[7] *See* Treasury Department, A Financial System That Creates Economic Opportunities: Capital Markets, Report to President Donald J. Trump, Executive Order 13772 on Core Principles for Regulating the United States Financial System, at 79–80 (October 2017) (''Capital Markets Report''), *https://www.treasury.gov/press-center/press-releases/Documents/A-Financial-System-Capital-Markets-FINAL-FINAL.pdf.* The Capital Markets Report cited the July 13, 2015 Joint Staff Report (''Joint Staff Report'' or ''JSR'') issued by the U.S. Department of the Treasury, the Board of Governors of the Federal Reserve System, the Federal Reserve Bank of New York, the SEC, and the U.S. Commodity Futures Trading Commission (Inter-Agency Working Group for Treasury Market Surveillance members (IAWG) or ''official sector'') in response to unusually high levels of volatility and a very rapid round-trip in prices that occurred in the market for U.S. Treasury Securities, futures, and other related financial products on October 15, 2014, *https://www.treasury.gov/press-center/press-releases/Documents/Joint_Staff_Report_Treasury_10-15-2015.pdf.*

[8] *See* JSR, at 50.

[9] *See* Capital Markets Report, at 80.

[10] *Id.* The Capital Markets Report recommends ''closing the gap in the granularity of PTF data,'' and also recommends requiring ATSs to identify ''customers'' in their TRACE reports, which is a broader term than ''PTFs.'' FINRA staff intends to work with the staff of the Treasury Department to ensure the scope of the reporting requirement is appropriate and meets regulatory needs in light of the recommendations in the Capital Markets Report.

[11] *See* JSR, at 45.

[12] *See* 17 CFR 242.300(a). As is the case with FINRA Rule 6720(c) (Alternative rading Systems), any member that meets the definition of ''alternative trading system'' set forth in Rule 300

executed transactions in U.S. Treasury Securities with non-FINRA member subscribers of $10 billion or more in monthly par value, computed by aggregating buy and sell transactions, for any two months in the preceding calendar quarter.[13] Pursuant to proposed Supplementary Material .07, each covered ATS would be required to provide FINRA a list of its non-FINRA member subscribers, as defined in Rule 300 of SEC Regulation ATS, which would include entities such as PTFs, hedge funds and banks. Based on the lists provided by the ATSs, FINRA would then assign each non-FINRA member subscriber a unique MPID and provide that MPID to each covered ATS to which the non-FINRA member subscribes so that each non-FINRA member subscriber can be identified consistently across all ATSs.[14] Under this approach, the confidentiality of an individual ATS's subscriber list would be preserved because FINRA would provide each ATS a list of MPIDs based solely on the customer list provided to FINRA by that ATS. Each covered ATS would then use the assigned MPID in the contra-party field for purposes of identifying each non-FINRA member counterparty, as required by Rule 6730(c)(6), in place of using the current designations for contra-party ''customer'' or ''non-member affiliate'' identifiers.

If an ATS becomes a covered ATS subsequent to the compliance date of the proposed rule, it must comply with new Supplementary Material .07 within 60 calendar days of the end of the calendar quarter in which it becomes a covered ATS. FINRA believes that 60 calendar days would afford sufficient time for a newly covered ATS to provide FINRA a list of, and obtain MPIDs for, its non-FINRA member subscribers, and to perform any programming changes necessary to accurately reflect in TRACE reports non-FINRA member counterparties using the MPIDs assigned by FINRA.

Once an ATS becomes a ''covered ATS'' under the rule, it will remain within the scope of the definition. Thus, a covered ATS must continue to identify each non-FINRA member subscriber in the contra-party field using the MPID assigned by FINRA, irrespective of whether its volume of executed transactions in U.S. Treasury Securities with non-FINRA member subscribers falls below $10 billion in par value in the future. In removing the current differentiation between subscribers that are FINRA members and those that are not, and requiring the use of an MPID by the ATS when reporting transactions in U.S. Treasury Securities regardless of the subscriber's status as a FINRA member, FINRA believes that the proposal would improve the completeness of the information on transactions in U.S. Treasury Securities available to FINRA and the official sector.

Because a significant number of ATSs have minimal volume of executions with non-FINRA members in U.S. Treasury Securities, the proposed rule change would not apply to ATSs whose par value traded in U.S. Treasury Securities with non-FINRA member subscribers is below $10 billion per month for any two months in the preceding calendar quarter. FINRA believes that this approach is appropriate in that it limits the application of the proposed requirement to the member ATSs that are most active in trading U.S. Treasury Securities with non-FINRA members, and, as such, responsible for submitting most of the ATS trade reports for transactions in U.S. Treasury Securities against non-FINRA members. Limiting the proposed counterparty identification requirement in this manner balances the burdens associated with complying with the proposed rule (*i.e.,* providing FINRA a list of all non-FINRA member subscribers, obtaining an MPID from FINRA, and using the assigned MPID in TRACE reporting), with the benefits sought to be achieved by the proposed requirement (*i.e.,* additional granularity that will enhance the quality of the information available to FINRA and the official sector on transactions in U.S. Treasury Securities).

FINRA does not believe that the absence of more detailed counterparty information from those ATSs with activity levels below the proposed threshold will materially affect the completeness of the audit trail. However, if approved, FINRA intends to monitor the continued appropriateness of the $10 billion dollar threshold to ensure that this amount remains relevant in light of market changes. In addition, FINRA intends to monitor the impact of this exception on its audit trail, as well as for any potential negative impacts or changes in ATS or non-member subscriber behavior.

If the Commission approves the proposed rule change, FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date will be no later than 180 days following publication of the *Regulatory Notice* announcing Commission approval. ATSs would be required to submit a list of its non-member subscribers to FINRA at least 60 days in advance of the effective date.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[15] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and Section 15A(b)(9) of the Act,[16] which requires that FINRA rules not impose any burden on competition that is not necessary or appropriate. FINRA believes that the proposed rule change will make TRACE reporting of U.S. Treasury Securities transactions more complete and thus enable FINRA to better identify potentially abusive trading activity in the Treasury market that is already reported to TRACE but is anonymized because of the existing limitations on customer identification. Because this activity by non-FINRA members constitutes a significant portion of ATS trading activity in U.S. Treasury Securities, the proposed rule change will significantly enhance FINRA's surveillance efforts as well as the trading data available to the official sector. As the Commission has noted in the past, improved surveillance capabilities can help FINRA detect and deter fraudulent and manipulative acts and practices, and thus promote just and equitable principles of trade and the protection of investors and the public interest. In addition, this collection is the ''type of additional data reporting to the official sector necessary to continue to effectively monitor the functioning of the Treasury market and meet the IAWG mission.'' [17]

of Regulation ATS would be required to comply with the proposed rule change irrespective of whether such member is excepted from the requirements applicable to ATSs provided in Rule 301(b) of Regulation ATS (*e.g.,* such as where the member limits its securities activities to government securities). *See* 17 CFR 242.301(a)()(ii)(A).

[13] Based on a sample review period of Treasury transaction data reported to FINRA, the top six ATSs by volume would be considered ''covered ATS'' and account for over 99% of the trade reports submitted by ATSs to TRACE for U.S. Treasury Securities.

[14] Some non-members may have multiple MPIDs assigned to them, for example if they use separate aggregation units or desks to access or trade through the ATS, in which case the unit assigned the MPID is the subscriber for purposes of this rule proposal.

[15] 15 U.S.C. 78*o*–3(b)(6).

[16] 15 U.S.C. 78*o*–3(b)(9).

[17] *See* JSR, at 49.

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.

Economic Impacts

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the need for the proposed rulemaking, the regulatory objective of the proposal, the economic baseline of analysis, the anticipated economic impacts, and the alternatives considered.

(a) Purpose and Regulatory Objective

The proposed change to Rule 6730 would require ATSs that meet a minimum threshold of trading against non-FINRA member subscribers to identify such subscribers on TRACE transaction reports for U.S. Treasury Securities. FINRA proposes to require ATSs to identify such non-FINRA members on TRACE transaction reports to enhance the quality of the information available to FINRA and the official sector on transactions in U.S. Treasury Securities.

(b) Economic Baseline

As discussed above, FINRA members have been reporting transaction information on U.S. Treasury Securities to TRACE since July 10, 2017 and such information is used solely for FINRA and official sector use. Since then, a majority of the trades in this market can be attributed to non-FINRA members.

Current TRACE reporting requirements enable FINRA to identify the ATS on which a transaction occurs as well as the other members that are parties to those transactions. However, FINRA does not have similar insight into the identity of the non-FINRA members that are parties to transactions on ATSs because such participants are identified as either a customer or a non-member affiliate.

The proposed rule change would apply to ATSs that report transactions in U.S. Treasury Securities to TRACE. As mentioned in FINRA's filing that required the reporting of U.S. Treasury Securities transactions to TRACE, ''[t]he Treasury cash market has been bifurcated between the inter-dealer market, in which dealers trade with one another, and the dealer-to-customer market, where customers may include asset managers, pension funds, insurance companies, and corporations.'' [18] A number of entities that are not registered broker-dealers are currently part of the inter-dealer market but they are not identified in TRACE reports.

(c) Economic Impacts

FINRA believes that the proposed rule change to require ATSs to identify non-FINRA members in TRACE reports for U.S. Treasury Securities transactions should potentially impact a small number of ATSs (*i.e.,* those whose activity is at or above the minimum threshold discussed above).

Between July 10, 2017 and March 31, 2018, there were 17 ATSs on which U.S. Treasury Securities were traded. A significant amount of the trading volume, involved at least one market participant not registered as a broker-dealer. Six of these ATSs had transaction volume of $10 billion or more in par value in at least two months in a given calendar quarter against non-FINRA members and would have been subject to the requirement had the proposed rule been in place.[19] The total trading volume of the six ATSs against non-FINRA member subscribers accounted for more than 99.9% of trading by non-FINRA member subscribers across all ATSs.

FINRA reached out to several ATSs to inquire about the potential sources of costs. ATSs that are most active in trading of U.S. Treasury Securities with non-FINRA members, and hence may have volumes at or above the proposed volume threshold, may potentially need to update the existing systems or build new systems and develop protocols in order to provide FINRA with a list of all non-FINRA member subscribers, obtain a corresponding list of MPIDs from FINRA, and use the assigned MPIDs in TRACE reporting. FINRA understands that the proposed requirement would also entail quality assurance testing relating to identifying clients and matching the assigned MPIDs with the client list.

FINRA also considered the potential impacts of the proposed identification requirement on non-FINRA member subscribers. To the extent that such participants prefer avoiding identification in TRACE reporting, they may shift some or all of their trading activity to other ATSs that are below the threshold. Non-FINRA member subscribers may also incur search costs or may have to pay a liquidity premium in case there is lighter trading on such ATSs.

Alternatively, trading may shift to FINRA-registered broker-dealers that are not ATSs or to venues that are not under FINRA jurisdiction, such as banks, and thus have no reporting obligations to TRACE. However, based on conversations with the industry, FINRA understands that most trading in this market is electronic and member firms and non-FINRA venues do not currently have the capability to facilitate the volume of orders and trades that FINRA-member ATSs can facilitate through electronic systems. FINRA cannot predict if non-FINRA member market participants will ultimately find it more beneficial to establish an alternative venue that is not required to report to TRACE, but will monitor for such a potential outcome.

(d) Alternatives Considered

FINRA considered various approaches to identifying non-FINRA members that are parties to reported transactions in U.S. Treasury Securities and engaged in discussions with ATSs and other stakeholders. One alternative considered was to require each ATS to provide a monthly list of all of its non-FINRA member subscribers and identify each of its customers on TRACE reports for U.S. Treasury Securities. This approach, which would cover the broadest range of subscribers, would identify all of an ATS's subscribers regardless of the ATS's amount of trading activity. Another alternative considered was to require each ATS to provide FINRA with its order book information, including providing each customer's order book activity rather than identifying individual customers on TRACE trade reports. FINRA would then link the order book information to the trade reports. Like the first option, this alternative would provide FINRA with complete insight into each customer's activity on the ATS; however, FINRA would be compiling the transaction data from the order book information submitted by ATSs, rather than having the ATSs identify customers when reporting to TRACE.

However, the analysis of the transaction data and careful consideration of the trade-offs between the costs associated with collecting transaction or order book information from each ATS and the incremental value the information brings to the surveillance program, concluded that the proposed approach would cover a significant amount of non-FINRA member customer activity, and enhance the quality of the information available

[18] *See* Securities Exchange Act Release No. 78359 (July 19, 2016), 81 FR 48465 (July 25, 2016) (Notice of Filing of File No. SR–FINRA–2016–027).

[19] The six ATSs had transaction volume of more than $10 billion in par value in all of the months in our sample period, while the remaining 11 ATSs never reached the threshold in any of the months.

to FINRA and the official sector on transactions in U.S. Treasury Securities.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–2018–023 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–FINRA–2018–023. 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 website (*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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2018–023, and should be submitted on or before July 5, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–12648 Filed 6–12–18; 8:45 am]

BILLING CODE 8011–01–P

[20] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 10447]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: ''Truth and Beauty: The Pre-Raphaelites and the Old Masters'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Truth and Beauty: The Pre-Raphaelites and the Old Masters,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Fine Arts Museums of San Francisco, Legion of Honor Museum, San Francisco, California, from on or about June 30, 2018, until on or about September 30, 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: Julie Simpson, Attorney-Adviser, 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.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 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, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–12720 Filed 6–12–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10452]

Notice of Determinations; Culturally Significant Object Imported for Exhibition Determinations: Exhibition of the ''Wagner Garden Carpet''

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object, entitled the ''Wagner Garden Carpet,'' to be exhibited in the Department of Islamic Art of The Metropolitan Museum of Art and at the Museum of Fine Arts, Houston, and imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to loan agreements 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 July 10, 2018, until on or about October 7, 2018, at the Museum of Fine Arts, Houston, in Houston, Texas, from on or about November 2, 2018, until on or about March 24, 2019, 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: Julie Simpson, Attorney-Adviser, 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.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me

by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 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, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–12721 Filed 6–12–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10445]

Proposal To Extend Cultural Property Agreement Between the United States and Honduras

AGENCY: Department of State.

ACTION: Public notice.

SUMMARY: Proposal to extend the *Memorandum of Understanding between the Government of United States of America and the Government of the Republic of Honduras Concerning the Imposition of Import Restrictions on Archaeological Material from the Pre-Columbian Cultures of Honduras and Ecclesiastical Ethnological Material from the Colonial Period of Honduras.*

FOR FURTHER INFORMATION CONTACT: Allison Davis, Cultural Heritage Center, Bureau of Educational and Cultural Affairs; 202–632–6301; *culprop@state.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the authority vested in the Assistant Secretary of State for Educational and Cultural Affairs, and pursuant to 19 U.S.C. 2602(f)(1), an extension of the *Memorandum of Understanding between the Government of United States of America and the Government of the Republic of Honduras Concerning the Imposition of Import Restrictions on Archaeological Material from the Pre-Columbian Cultures of Honduras and Ecclesiastical Ethnological Material from the Colonial Period of Honduras* is hereby proposed.

A copy of the Memorandum of Understanding, the Designated List of categories of material restricted from import into the United States, and related information can be found at the Cultural Heritage Center website: *http://culturalheritage.state.gov.*

Marie Therese Porter Royce,

Assistant Secretary Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–12678 Filed 6–12–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10443]

Cultural Property Advisory Committee; Notice of Meeting

AGENCY: Department of State.

ACTION: Notice of a meeting.

SUMMARY: The Department of State is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Cultural Property Advisory Committee.

DATES: July 31 through August 2, 2018, 10:00 a.m. to 5:00 p.m. (EDT). The open session of the Cultural Property Advisory Committee will be held on July 31, 2018, at 10:30 a.m. (EDT). It will last approximately an hour and a half. Participants will participate electronically. Those who wish to participate in the open session should visit *http://culturalheritage.state.gov* where information will be provided on how to access the meeting. If needed, please request reasonable accommodation not later than July 15 by contacting the Bureau of Educational and Cultural Affairs at *culprop@state.gov.* It may not be possible to accommodate requests made after that date.

Written Comments: Must be received no later than July 15, 2018, at 11:59 p.m. (EDT).

ADDRESSES: The public will participate electronically. The members will meet at the U.S. Department of State, Annex 5, 2200 C St. NW and the Harry S. Truman Building, 2201 C St. NW, Washington, DC.

Comments: Methods of written comment submission are as follows:

- *Electronic Comments:* Use *http://www.regulations.gov,* enter the docket [DOS–2018–0022] and follow the prompts to submit comments.
- *Paper Comments:* If comments contain privileged or confidential information (within the meaning of 19 U.S.C. 2605(i)(1)), you may send comments to: U.S. Department of State, Bureau of Educational and Cultural Affairs—Cultural Heritage Center, SA–5 Floor 5, 2200 C St. NW, Washington, DC 20522–0505.

FOR FURTHER INFORMATION CONTACT: For general questions concerning the meeting, contact Andrew Cohen, Bureau of Educational and Cultural Affairs—Cultural Heritage Center by phone, (202) 632–6301, or email: *culprop@state.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 306(e)(2) of the Convention on Cultural Property Implementation Act (5 U.S.C. 2601 *et seq.*) (''the Act''), the Assistant Secretary of State for Educational and Cultural Affairs calls a meeting of the Cultural Property Advisory Committee (''the Committee''). The Committee's responsibilities are carried out in accordance with provisions of the Act. A portion of this meeting will be closed to the public pursuant to 5 U.S.C. 552b(c)(9)(B) and 19 U.S.C. 2605.

Meeting Agenda: The Committee will review the request by the Government of Algeria seeking import restrictions on archaeological and ethnological material. The Committee will also review a proposal to extend the *Memorandum of Understanding between the Government of United States of America and the Government of the Republic of Honduras Concerning the Imposition of Import Restrictions on Archaeological Material from the Pre-Columbian Cultures of Honduras and Ecclesiastical Ethnological Material from the Colonial Period of Honduras* (''the Honduras MOU''). The Committee will also review a proposal to extend the *Memorandum of Understanding between the Government of United States of America and the Government of the Republic of Bulgaria Concerning the Imposition of Import Restrictions on Categories of Archaeological and Ecclesiastical Ethnological Material of the Republic of Bulgaria* (''the Bulgaria MOU'').

Open Session Participation: An open session of the meeting to receive oral public comments on the Algeria request and the proposed extensions of the Honduras MOU and the Bulgaria MOU will be held Tuesday, July 31, 2018, from 10:30 a.m. to approximately 12:00 p.m. (EDT). Instructions on calling in to the meeting, the text of the Act, a summary of the Government of Algeria's request, and copies of the Honduras MOU and the Bulgaria MOU may be found at *http://culturalheritage.state.gov.* If you wish to make an oral presentation at the meeting, you must: (1) Request to be scheduled by July 15, 2018, via email (*culprop@state.gov*); and (2) submit a written summary of your oral presentation, ensuring that it is submitted no later than 11:59 p.m. (EDT) on July 15, 2018, on the *Regulations.gov* website listed in the ''COMMENTS'' section above. Oral

comments will be limited to five (5) minutes to allow time for questions from members of the Committee. All oral comments must relate specifically to matters referred to in 19 U.S.C. 2602(a)(1), with respect to which the Committee makes its findings and recommendations. Oral presentation to the Committee may be requested but, due to time constraints, is not guaranteed.

Written Comments: If you do not wish to make oral comments but still wish to make your views known, you may submit written comments for the Committee to consider. Written comments from outside interested parties regarding the Algeria request and the proposed extensions of the Honduras MOU and the Bulgaria MOU must be received submitted to the *Regulations.gov* website listed in the ''COMMENTS'' section above no later than July 15, 2018, at 11:59 p.m. (EDT). Your written comments should relate specifically to the matters referred to in 19 U.S.C. 2602(a)(1). The Department requests that any party soliciting or aggregating written comments received from other persons for submission to the Department inform those persons that the Department will not edit their comments to remove any identifying or contact information and that they therefore should not include any such information in their comments that they do not want publicly disclosed. Written comments submitted in electronic form are not private. The Department will post the comments at *http://www.regulations.gov.* Because written comments cannot be edited to remove any personally identifying or contact information, the U.S. Department of State cautions against including any information in an electronic submission that one does not want publicly disclosed (including trade secrets and commercial or financial information that are privileged or confidential within the meaning of 19 U.S.C. 2605(i)(1)).

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs Department of State.

[FR Doc. 2018–12676 Filed 6–12–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 10444]

Notice of Receipt of Request From the Government of the People's Democratic Republic of Algeria Under Article 9 of the 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice of receipt of request from Algeria for cultural property protection.

FOR FURTHER INFORMATION CONTACT: Catherine Foster, Cultural Heritage Center, Bureau of Educational and Cultural Affairs: 202–632–6301; *culprop@state.gov.*

SUPPLEMENTARY INFORMATION: The Government of Algeria has made a request to the Government of the United States under Article 9 of the 1970 UNESCO *Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property.* The United States Department of State received this request on February 27, 2018. Algeria's request seeks U.S. import restrictions on archaeological and ethnological material representing Algeria's cultural patrimony. Pursuant to the authority vested in the Assistant Secretary of State for Educational and Cultural Affairs, and pursuant to 19 U.S.C. 2602(f)(1), notification of the request is hereby published. A public summary of Algeria's request and information about U.S. implementation of the 1970 UNESCO Convention will be available at the Cultural Heritage Center website: *http://culturalheritage.state.gov.*

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–12677 Filed 6–12–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10446]

Proposal To Extend Cultural Property Agreement Between the United States and Bulgaria

AGENCY: Department of State.

ACTION: Public notice.

SUMMARY: Proposal to extend the *Memorandum of Understanding between the Government of United States of America and the Government of the Republic of Bulgaria Concerning the Imposition of Import Restrictions on Categories of Archaeological and Ecclesiastical Ethnological Material of the Republic of Bulgaria.*

FOR FURTHER INFORMATION CONTACT: Andrew Cohen, Cultural Heritage Center, Bureau of Educational and Cultural Affairs: 202–632–6301; *culprop@state.gov.*

SUPPLEMENTARY INFORMATION: The Government of the Republic of Bulgaria has informed the Government of the United States of America of its interest in an extension of the *Memorandum of Understanding between the Government of United States of America and the Government of the Republic of Bulgaria Concerning the Imposition of Import Restrictions on Categories of Archaeological and Ecclesiastical Ethnological Material of the Republic of Bulgaria.* Pursuant to the authority vested in the Assistant Secretary of State for Educational and Cultural Affairs, and pursuant to 19 U.S.C. 2602(f)(1), an extension of this Memorandum of Understanding is hereby proposed.

A copy of the Memorandum of Understanding, the Designated List of categories of material restricted from import into the United States, and related information can be found at the Cultural Heritage Center website: *http://culturalheritage.state.gov.*

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–12679 Filed 6–12–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

June 27, 2018 Meeting of the NextGen Advisory Committee (NAC)

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

ACTION: Notice.

SUMMARY: The FAA is issuing this notice to advise the public of the June 27, 2018 Meeting of the NextGen Advisory Committee.

DATES: The meeting will be held Wednesday, June 27, 2018, 8:30 a.m. EST to 12:00 p.m. EST.

ADDRESSES: The meeting will be held at U.S. DOT (Conference Center), 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Greg Schwab, FAA, 950 L'Enfant Plaza SW,

Washington, DC 20024, 202–267–1201, *gregory.schwab@faa.gov, https://www.faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a June 27, 2018 Meeting of the NextGen Advisory Committee (NAC). The NAC Charter **Federal Register** Notice announcing the intent to establish the Committee was published on May 31, 2018 (document number 2018–11696). Under 41 Code of Federal Regulations (CFR) 102–3.150, the agenda is planned as follows:

Wednesday, June 27, 2018, 8:30 a.m.–12:00 p.m.

1. Opening of Meeting/Introduction of NAC Members
2. Official Statement of Designated Federal Official
3. Chairman's Report
4. FAA Report
   —FAA Response to NAC Recommendations on Enhanced Surveillance
5. NAC Subcommittee Chairman's Report and NextGen Priorities 3-Year Work Plan [For Approval]
   —NextGen Priorities Report
6. Northeast Corridor Phase 2 Recommendations [For Approval]
7. Northeast Corridor Public Engagement—Guided Discussion 1
   —FAA Lessons Learned and Engagement Plans Going Forward in the Northeast Corridor
8. Break
9. Northeast Corridor Equipage Risk to Northeast Corridor Benefits—Guided Discussion 2
   —Navigation Equipage and Factors Influencing Increased Regional Equipage in the Northeast Corridor
10. Next Steps
11. Summary of Meeting and Action Item Review
12. NAC Chairman Closing Comments & Adjourn

To Attend the NAC Meeting: In order to attend the NAC meeting at DOT on June 27:

—Pre-registration is required. To pre-register, you must provide your full name, company/organization you are representing, title/position, and contact information (telephone number and email address) no later than Wednesday, June 20 to *NACRegistration@Concept-Solutions.com.*

○ *For Foreign National attendees,* please also provide your country of citizenship, date of birth, and passport or diplomatic ID# with expiration date.

—Upon arrival at the DOT Conference Center, all attendees must show photo identification that match the pre-registration name, specifically, government-issued photo identification (*e.g.,* U.S. driver's license; passport for non-U.S. citizens; federal government identification card). Refer to the information on items prohibited from Federal facilities, published by the Department of Homeland Security: *https://www.dhs.gov/sites/default/files/publications/isc-items-prohibited-federal-facilities-feb-2013-508.pdf.*

With the approval of the NAC Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on June 8, 2018.

John Wesley Raper,

Manager, Partnership Branch, ANG–A17, NextGen, Management Services, Federal Aviation Administration.

[FR Doc. 2018–12681 Filed 6–12–18; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL REGISTER

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Part II

Department of Justice

Antitrust Division

United States of America v. Bayer AG and Monsanto Company; Proposed Final Judgment and Competitive Impact Statement; Notice

DEPARTMENT OF JUSTICE

Antitrust Division

United States of America v. Bayer AG and Monsanto Company; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h), that a proposed Final Judgment, Stipulation and Order, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Bayer AG and Monsanto Company,* Civil Action No. 1:18–cv–1241. On May 29, 2018, the United States filed a Complaint alleging that Bayer AG's proposed acquisition of Monsanto Company would violate Section 7 of the Clayton Act, 15 U.S.C. § 18. The proposed Final Judgment, filed at the same time as the Complaint, requires Bayer AG to divest a substantial collection of assets relating to seeds and traits, crop protection, and digital agriculture.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be mailed to Kathleen S. O'Neill, Chief, Transportation, Energy & Agriculture Section, Antitrust Division, Department of Justice, 450 5th Street NW, Suite 8000, Washington, DC 20530.

Patricia A. Brink,

Director of Civil Enforcement.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, 450 5th Street NW, Suite 8000, Washington, DC 20530, *Plaintiff,* v. *Bayer AG,* Kaiser-Wilhelm-Allee 1, Leverkusen, Germany 51368, and *Monsanto Company,* 800 North Lindbergh Boulevard, St. Louis, MO 63167, *Defendants.*

Civil Action No.: 1:18–cv–1241
Judge James E. Boasberg

COMPLAINT

The United States of America, acting under the direction of the Attorney General of the United States, brings this civil antitrust action to prevent Bayer AG from acquiring Monsanto Company. The United States alleges as follows:

I. INTRODUCTION

1. Bayer's proposed $66 billion acquisition of its rival, Monsanto, would combine two of the largest agricultural companies in the world. Across the globe, Bayer and Monsanto compete to sell seeds and chemicals that farmers use to grow their crops. This competition has bolstered an American farming industry that contributes hundreds of billions of dollars a year to the economy, provides millions of jobs across the country, and ensures a safe and reliable food supply for consumers in the United States and around the world.

2. If allowed to proceed, the proposed acquisition would transform the agricultural industry and harm competition across a broad range of products. Most prominently, the acquisition would eliminate competition to develop and sell genetically modified seeds in cotton, canola, and soybeans—three of the largest crops grown in the United States—and the herbicides that are paired with these seeds to form the foundation of farmers' weed-control strategies.

3. These agricultural technologies emerged in the 1990s when Monsanto introduced ''Roundup Ready'' soybeans, which were genetically engineered to resist Monsanto's herbicide, Roundup. Monsanto's invention allowed farmers who planted Roundup Ready soybeans to spray Roundup over the top of their crops, thereby killing the weeds without harming the crops. It was a wildly popular invention; by 2005, almost 90% of U.S. soybean acres were planted with Roundup Ready seeds. In response, in 2009, Bayer launched its own ''LibertyLink'' genetically modified soybeans, which were engineered to withstand Bayer's Liberty herbicide. Both companies have introduced similar innovations in cotton and canola, generating competition that has resulted in higher crop yields, lower prices, and greater choice for American farmers. Today, Bayer's weed-control systems are the only competitive alternatives to Monsanto's Roundup Ready systems in cotton, canola, and soybeans.

4. Bayer and Monsanto also compete head-to-head to develop the next generation of transformative products, including cotton, canola, and soybean seeds with new genetically modified traits, as well as other innovative products that improve yields for farmers. This competition is central to their businesses. Monsanto's chief technology officer has said that innovation is ''the heart and soul of who we are.'' Similarly, Bayer's core strategy is to become the ''most innovative'' agricultural company in the world. Both companies invest significant sums of money into research and development and monitor each other's efforts, spurring each other to work faster and invest more to improve their offerings and develop new products. For instance, Monsanto recently developed a seed treatment product that protects crops from destructive worms called nematodes, directly challenging Bayer's historic dominance in that space. The proposed acquisition would eliminate this competition to develop new products that farmers will depend on for decades into the future.

5. The merger would also substantially lessen competition through the vertical integration of the two companies. Specifically, by combining Monsanto's strong position in seeds with Bayer's dominant position in certain seed treatments, the merger would give the combined company the incentive and ability to harm its seed rivals by raising the price of those seed treatments—a key input for genetically modified seeds. For example, today, Bayer sells the only seed treatment that effectively controls a destructive pest called corn rootworm. Because Bayer does not sell corn seeds itself, it has a strong incentive to sell that seed treatment to all corn seed companies, including Monsanto's rivals. But the merger would change the calculus for Bayer because it would now own Monsanto, the largest supplier of corn seeds in the United States. Armed with Monsanto's strong position in corn seeds, the merged company would likely charge its seed rivals more for the seed treatment, knowing that they rely on the product and would be less able to compete effectively without it.

6. Finally, the merger would eliminate head-to-head competition between Bayer and Monsanto to develop and sell seeds for five types of vegetables: tomatoes, carrots, cucumbers, onions, and watermelons. Although vegetable seeds are not genetically modified like cotton, canola, and soybeans, Bayer and Monsanto compete aggressively with one another to breed higher-quality and higher-yielding varieties.

7. By eliminating competition between Bayer and Monsanto and combining their businesses, the proposed acquisition would result in

higher prices, less innovation, fewer choices, and lower-quality products for farmers and consumers throughout the United States and around the world. To prevent those harms, this unlawful acquisition should be enjoined.

II. DEFENDANTS AND THE TRANSACTION

8. Bayer is a life-sciences company based in Leverkusen, Germany. The company employs nearly 100,000 people worldwide and has operations in almost 80 countries. Bayer has three main business lines: pharmaceuticals, which focuses on prescription medicines; consumer health, which focuses on over-the-counter products; and its agricultural business, Bayer Crop Science. Over the past decade, Bayer Crop Science has become one of the largest global agricultural companies. Today, its crop protection business is the second largest in the world, and its seeds and traits business is also among the world's largest. In 2016, Bayer Crop Science had about $12 billion in annual revenues.

9. Monsanto, based in St. Louis, Missouri, is also a leading producer of agricultural products. Monsanto employs more than 20,000 people in almost 70 countries. As noted, in the 1990s, Monsanto pioneered a revolutionary technology that enables certain crops to resist exposure to glyphosate, the active ingredient in Monsanto's Roundup herbicide. This technology propelled Monsanto's success: today, Monsanto is the leading global producer of seeds and traits and is among the world's largest producers of crop protection products. In 2017, Monsanto had almost $15 billion in annual revenues.

10. On September 14, 2016, Bayer agreed to acquire Monsanto for approximately $66 billion.

III. JURISDICTION AND VENUE

11. The United States brings this action, and the Court has subject-matter jurisdiction, under Section 15 of the Clayton Act, 15 U.S.C. § 25, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. § 18.

12. Defendants are engaged in, and their activities substantially affect, interstate commerce. Bayer and Monsanto sell agricultural products, including seeds and crop protection products, throughout the United States and the world.

13. Defendants have consented to venue and personal jurisdiction in this district. Venue is also proper under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391.

IV. RELEVANT MARKETS

14. As noted, Bayer and Monsanto compete across a broad range of agricultural products, including genetically modified (GM) seeds and traits for row crops; crop protection products, such as herbicides and seed treatments; and vegetable seeds. The proposed acquisition would substantially lessen competition in the following 17 products:

Bayer–Monsanto: Relevant Products

GM Seeds and Traits

Cotton:
- Herbicide-tolerant traits
- Insect-resistant traits
- GM cotton seeds

Canola:
- Herbicide-tolerant traits
- GM canola seeds

Soybeans:
- Herbicide-tolerant traits
- GM soybeans

Corn:
- GM corn seeds

Crop Protection

Foundational herbicides

Nematicidal seed treatments:
- Corn
- Soybeans
- Cotton

Vegetables
- Carrot seeds
- Cucumber seeds
- Onion seeds
- Tomato seeds
- Watermelon seeds

15. Each of these products is a relevant product and line of commerce under Section 7 of the Clayton Act, 15 U.S.C. § 18. The industry views these products as separate business lines, and they satisfy the well-accepted hypothetical monopolist test in the U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines, which asks whether a hypothetical monopolist likely would impose at least a small but significant and non-transitory increase in price. Such a price increase for these products would not be defeated by substitution to alternative products.

16. The relevant geographic markets in this case vary by product. For seeds and traits generally, the markets are regional because seeds are tailored to regional growing conditions (such as weather and soil type) and suppliers can charge different prices for seeds and traits to customers in different regions. With the exception of soybeans, however, virtually all of the regions affected by the merger have a similar market structure, so in this case it is appropriate to aggregate them to a national level for convenience. For soybeans, the market structure differs across regions; thus, the relevant geographic market is the southern United States, where Bayer has focused its soybean breeding program and been particularly successful.

17. For the relevant crop protection products (foundational herbicides and nematicidal seed treatments), the geographic markets are national. Bayer and Monsanto sell these products throughout the United States. In addition, these products require U.S. regulatory approval, which is expensive and time-consuming, so competition is limited to products that have obtained the necessary approvals. Similar products sold in other countries but not approved for use in the United States are not reasonable substitutes for American farmers.

18. For these reasons, in each of the relevant geographic markets for seeds and crop protection products, a hypothetical monopolist likely would impose at least a small but significant and non-transitory increase in price.

19. Most of the relevant markets are already highly concentrated, and in each market the merger would significantly increase concentration. The more concentrated a market and the more a transaction increases concentration in that market, the more likely it is that the transaction will reduce competition. Concentration is typically measured by market shares and by the widely-used Herfindahl-Hirschman Index (HHI). If the post-transaction HHI would be more than 2,500 and the change in HHI more than 200, the transaction is presumed to enhance market power and substantially lessen competition. *See, e.g., United States* v. *Anthem, Inc.,* 855 F.3d 345, 349 (D.C. Cir. 2017). Given the high concentration levels and increases in concentration in the relevant markets in this case, the proposed acquisition presumptively violates Section 7 of the Clayton Act.

A. Genetically Modified Seeds and Traits

20. Several markets in this case involve genetically modified seeds and traits. A genetic trait is simply an attribute of a plant, such as being tall, short, or leafy. Most traits derive from a plant's natural DNA. Over the last 30 years, however, a small set of highly sophisticated biotechnology firms—including Bayer and Monsanto—have successfully inserted DNA from other organisms into the DNA of certain crops, giving the crops a desirable trait associated with that non-native DNA. For example, scientists have developed traits that make crops resistant to certain

pests, allowing farmers to reduce their use of chemical insecticides. And scientists have developed herbicide-tolerant traits that make crops resistant to herbicides like Roundup, allowing a farmer to spray the herbicide over an entire field and kill the weeds without harming the crops. A genetically modified seed is simply a seed that contains DNA—and hence the desirable trait—of a different organism. Farmers have embraced this technology: today, more than 90% of the corn, soybeans, cotton, and canola seeds grown in the United States are genetically modified. These seeds provide farmers with considerable savings in labor and expense, increased yields, and reduced soil erosion by eliminating the need for tilling fields. Thus, a vast majority of farmers do not view conventional seeds as a reasonable substitute.

21. With the rise of genetically modified crops, it has also become harder for smaller companies, which lack the massive resources necessary to devote to research and development, to compete in these high-tech markets. It typically takes hundreds of millions of dollars and more than a decade to bring a genetically modified seed variety or a new pesticide to market. A company must also have access to an extensive library of high-quality seeds that are necessary for research and plant breeding. Today, such resources are increasingly controlled by four vertically integrated companies: Monsanto, Bayer, DowDuPont, and Syngenta, also known as the ''Big Four.'' Although smaller independent seed companies also sell genetically modified seeds to farmers, most of those companies license traits and seed varieties from Monsanto, limiting their ability to compete.

22. As described below, Bayer and Monsanto are close competitors in three important row crops: cotton, canola, and soybeans.

(1) Genetically modified cotton

23. Cotton is a major crop grown across the southern United States, particularly in states like Texas and Georgia. Cotton seeds are widely used in vegetable oil, packaged foods, and animal feed, and cotton fibers are widely used in clothing. In 2017, U.S. farmers planted about 12 million acres of cotton and sales of cotton seeds totaled over $800 million. For cotton, the proposed acquisition would harm competition in the markets for (1) genetically modified cotton seeds, (2) herbicide-tolerant traits for cotton, and (3) insect-resistant traits for cotton.

24. ***GM cotton seeds.*** Bayer and Monsanto have long been the two leading suppliers of genetically modified cotton seeds throughout the United States. In addition to owning critical traits (discussed below), they own extensive libraries of elite seed varieties, which are essential for developing and commercializing competitive cotton seeds. If the transaction is allowed to proceed, Bayer and Monsanto would have a combined 59% share of genetically modified cotton seeds in the United States. The post-transaction HHI would be approximately 4,100, with an increase of approximately 1,500 resulting from the transaction.

25. ***Herbicide-tolerant traits.*** Given the widespread adoption of genetically modified cotton seeds, herbicide-tolerant traits are now used on approximately 98% of the cotton acres in the United States. In 2017, Bayer and Monsanto accounted for virtually all of those acres, with about 19% of acres containing Bayer's traits and about 80% containing Monsanto's traits. The merger would thus give Bayer a monopoly in these markets: the post-transaction HHI would be approximately 9,600, with an increase of approximately 3,000. Bayer and Monsanto are also competing aggressively to develop the next generation of herbicide-tolerant cotton traits. Farmers need these innovations to combat the growing number of weeds, like pigweed, that have become increasingly resistant to glyphosate in recent years. Without the merger, these new traits would likely compete in the future.

26. ***Insect-resistant traits.*** Bayer and Monsanto also compete for sales of insect-resistant traits that protect cotton from destructive pests such as moth and bollworm larvae. In 2017, insect-resistant traits were used on approximately 88% of the cotton acres in the United States. Bayer and Monsanto accounted for approximately 85% of those acres, with about 10% of acres containing Bayer's traits and about 75% containing Monsanto's traits. The post-transaction HHI would be approximately 7,400, with an increase of approximately 1,400.

(2) Genetically modified canola

27. Canola is an important crop used in vegetable oil, packaged foods, biodiesel fuels, and animal feed. In the United States, canola is grown on approximately 1.7 million acres, mainly in North Dakota, but also in several other states. The proposed merger would harm competition in the markets for (1) genetically modified canola seeds and (2) herbicide-tolerant traits for canola.

28. ***GM canola seeds.*** In 2016, genetically modified canola seeds accounted for $83 million in sales in the United States, and virtually all canola seeds contain genetically modified traits. Bayer's canola innovations in recent years have allowed it to surpass Monsanto. In 2016, Bayer's share of genetically modified canola seeds in the United States was 60% and Monsanto's share was 14%. The post-transaction HHI would be approximately 5,600, with an increase of approximately 1,700.

29. ***Herbicide-tolerant traits.*** Bayer and Monsanto are even more dominant in herbicide-tolerant traits for canola, where they have a combined share of 95%. Virtually all canola seeds planted in the United States contain either Bayer's LibertyLink trait or Monsanto's Roundup Ready trait. For these traits, the post-transaction HHI would be approximately 9,200, with an increase of over 4,100.

(3) Genetically modified soybeans

30. After corn, soybeans are the largest crop grown in the United States. Soybeans are widely used in vegetable oil, packaged foods, and animal feed. In 2017, U.S. farmers planted almost 90 million acres of soybeans, accounting for $4.6 billion in seed purchases, and 94% of those acres contained herbicide-tolerant traits. The proposed acquisition would harm competition in the markets for (1) genetically modified soybeans and (2) herbicide-tolerant traits for soybeans.

31. ***GM soybeans.*** Since launching genetically modified soybeans in the 1990s, Monsanto has been the market leader. For years, Monsanto's only competitors were companies that relied on Monsanto for licenses to the Roundup Ready traits. Since 2009, however, Bayer has emerged as a serious threat: it has invested over $250 million to develop an independent source of soybean varieties and in 2014 launched its own soybean business, Credenz, which sells varieties that perform well in the southern United States. In 2017, Bayer had a 6% share of soybeans in that region and Monsanto had a 39% share. The post-transaction HHI in the southern United States would be approximately 2,800, with an increase of approximately 500.

32. ***Herbicide-tolerant traits.*** Bayer and Monsanto also have the leading herbicide-tolerant traits for soybeans. Monsanto's Roundup Ready trait has historically dominated sales, but in recent years Bayer's LibertyLink trait has made inroads. In 2017, Monsanto had a 67% share of U.S. sales and Bayer's share had risen to 14%. (The

remaining market participants use a post-patent version of the original Roundup Ready trait.) For herbicide-tolerant traits, the post-transaction HHI would be approximately 6,900 on a national basis, with an increase of approximately 1,900. Without the merger, competition between the two companies would likely increase: Bayer and Monsanto each have new traits in their research pipelines that would confer tolerance to additional herbicides and compete in the future.

B. Foundational Herbicides

33. In addition to competing to sell herbicide-tolerant seeds, Bayer and Monsanto also compete to sell the foundational herbicides—glyphosate and glufosinate—that are paired with these seeds.

34. Foundational herbicides are herbicides used on row crops that have two defining characteristics. First, they are ''non-selective,'' meaning that they kill all types of weeds, thus providing farmers with the broadest possible protection for their crops. In contrast, other types of herbicides are ''selective,'' meaning that they kill only certain types of weeds. Selective herbicides are often used to supplement non-selective herbicides but are not generally used in lieu of them. Second, foundational herbicides can be paired with seeds that are engineered to tolerate the herbicide. Other non-selective herbicides are not a substitute for farmers because no seeds are engineered to withstand them, so spraying those herbicides over a crop would damage it. For these reasons, farmers have no good substitutes for foundational herbicides. Today, glyphosate and glufosinate are the only two foundational herbicides, but, as discussed further below, new foundational herbicides are in development.

35. Bayer and Monsanto are the world's leading producers of foundational herbicides. As noted above, glyphosate was developed by Monsanto and is the active ingredient in Roundup; glufosinate was developed by Bayer and is the active ingredient in Liberty. Since the launch of genetically modified crops in the 1990s, Monsanto's Roundup has dominated the market. As some weeds have developed resistance to glyphosate, however, farmers are increasingly turning to Liberty. And while glufosinate and glyphosate are now off patent, competition from generic suppliers has not prevented Bayer and Monsanto from maintaining branded price premiums. In 2017, Bayer had a 7% share of the market for foundational herbicides in the United States, and Monsanto had a 53% share. Thus, this market is already highly concentrated and the merger would result in a post-transaction HHI of approximately 3,700, with an increase of over 650.

36. Going forward, competition between Bayer and Monsanto to develop next-generation weed-management systems is likely to increase. According to a Bayer strategy document, the company's number one ''Must Win Battle'' is to ''[e]stablish LibertyLink as a foundation trait for broadacre [row] crops and position Liberty herbicide as the superior weed management tool.'' Bayer is also developing new non-selective herbicides for soybeans and corn called N,O-Chelators (NOCs), along with traits conferring tolerance to NOCs. If successful, NOCs would form the basis of a new foundational herbicide system that would rival Monsanto's Roundup Ready-based systems.

37. Likewise, Monsanto is actively pursuing innovations in foundational herbicides. For example, Monsanto is developing an improved formulation of Roundup that is expected for release in 2019. Bayer's and Monsanto's incentives to independently pursue these future products in close competition with each other would disappear post-merger.

C. Seed Treatments

38. In addition to relying on genetically modified seeds and herbicides, farmers also protect their crops using seed treatments, which are coatings applied to seeds before they are planted. Seed treatments are a critical tool for modern farmers, and today at least one seed treatment is applied to the vast majority of genetically modified seeds grown in the United States. Multiple seed treatments can be applied to a seed to protect it from various threats; seed treatments designed for one purpose (such as killing insects) are rarely an effective substitute for seed treatments designed for a different purpose (such as controlling fungal diseases).

39. The merger would likely result in three forms of competitive harm related to seed treatments: (1) the loss of head-to-head competition between Bayer's and Monsanto's nematicidal seed treatments; (2) foreclosure effects resulting from the combination of Monsanto's strong position in corn seeds with Bayer's dominant position in insecticidal seed treatments for corn rootworm; and (3) foreclosure effects resulting from the combination of Monsanto's strong position in soybeans with Bayer's dominant position in fungicidal seed treatment for sudden death syndrome.

(1) Nematicidal seed treatments for corn, cotton, and soybeans

40. The merger would eliminate head-to-head competition for nematicidal seed treatments used on corn, cotton, and soybeans. Nematicidal seed treatments protect crops from parasitic roundworms known as nematodes. For corn, cotton, and soybean farmers, there are no cost-effective alternatives to nematicidal seed treatments. And, in part because seed treatments must be registered on a crop-by-crop basis, the treatments for each crop constitute a separate market.

41. All three nematicidal seed treatment markets are highly concentrated. For years, Bayer has had a monopoly in the market for nematicidal seed treatments for corn, with over a 95% share in 2017. Bayer dominates the market for nematicidal seed treatments for soybeans, with a share over 85%. And, in the market for nematicidal seed treatments for cotton, Bayer and Syngenta currently share a duopoly.

42. Although Monsanto does not currently sell in this market, it is poised to launch its first nematicidal seed treatment, NemaStrike. NemaStrike is expected to challenge Bayer's market position in nematicidal seed treatments in all three crops—corn, cotton, and soybeans. Both Bayer and Monsanto project that NemaStrike will capture significant market share from Bayer. By acquiring Monsanto, Bayer would thus eliminate the most significant competitive threat to its dominant position in these markets, to the detriment of farmers who rely on these important products to protect their crops.

(2) Vertical foreclosure—insecticidal seed treatments for corn rootworm and genetically modified corn seeds

43. The merger would also likely harm competition in the market for genetically modified corn by combining Monsanto's strong position in genetically modified corn seeds with Bayer's dominant position in insecticidal seed treatments for corn rootworm.

44. Corn is the largest crop grown in the United States, accounting for over $8 billion in seed sales annually. The vast majority (92%) of U.S. corn seeds are genetically modified. Monsanto is the leading supplier of those seeds, effectively controlling 50% of the market between sales of its own branded seeds and sales through its licensees. Monsanto's only significant rival for corn seed is DowDuPont (with a 34%

share); a few smaller companies also have a small share.

45. Although Bayer does not sell corn seeds, it does sell a critical seed treatment called Poncho. When Poncho is applied at a high rate (with a greater amount of the seed treatment coating per seed), it protects corn seeds from corn rootworm—a pest nicknamed ''the billion dollar bug'' for the amount of loss it costs farmers each year. Poncho is the only significant seed treatment that effectively combats corn rootworm. Thus, most of Monsanto's corn seed rivals depend on Poncho and are expected to become more dependent as the corn rootworm problem grows.

46. By placing Bayer's Poncho and Monsanto's leading GM corn seed under the control of one company, the transaction would give the merged company the incentive and ability to foreclose its corn seed rivals who lack their own seed treatment product and rely on an independent Bayer for their seed treatment supply. Specifically, the merged company would likely hinder its corn seed rivals by forcing them to pay more for Poncho or by denying them access to it entirely. This loss of competition would ultimately hit the pocketbooks of American farmers. By making it harder for Monsanto's corn rivals to compete, farmers would pay higher prices and have fewer effective choices for genetically modified corn seeds throughout the country.

(3) Vertical foreclosure—fungicidal seed treatments for sudden death syndrome and genetically modified soybeans

47. Similarly, the merger would harm competition by combining Monsanto's leading position in genetically modified soybeans with Bayer's dominant position in fungicidal seed treatments.

48. As discussed above, Monsanto leads the market for genetically modified soybeans. It is followed by DowDuPont, with Bayer emerging as a threat and investing heavily to gain share. Smaller players, such as Beck's, also serve the market.

49. Bayer also sells ILeVO, the only seed treatment that effectively protects soybeans from a fungal disease called sudden death syndrome (SDS). According to Bayer, SDS costs farmers an average of over 44 million bushels in lost yield per year, and losses from SDS damage are expected to increase, making Bayer's seed treatment a critical tool for farmers in areas where SDS is a particular risk. Bayer sells ILeVO to Monsanto's soybean rivals, including DowDuPont and Beck's. Since the launch of ILeVO in 2015, Bayer's sales of ILeVO have doubled annually and are expected to continue to grow steadily over the next decade.

50. If allowed to proceed, the merger would combine Monsanto's leading genetically modified soybeans with a key input used on those seeds (ILeVO). As a result, the merged company would likely hinder its soybean rivals by forcing them to pay more for ILeVO or by denying them access to it entirely. This loss of competition would likewise make it harder for Monsanto's rivals to compete, and it would result in higher prices and fewer choices for genetically modified soybeans.

D. Vegetable Seeds

51. Finally, the proposed acquisition would eliminate vital competition between Bayer and Monsanto for the sale of vegetable seeds. In the past 25 years, global vegetable production has doubled as breeders have developed new varieties of vegetables with better disease resistance and higher yields. Unlike with row crops, however, these improvements are due entirely to traditional plant breeding rather than genetic modification. Bayer and Monsanto are leaders in these efforts. Today, Monsanto is the largest vegetable seed company in the world and Bayer is fourth largest. If the merger is allowed to proceed, the combined company would dominate the industry, with global sales rivaling the combined sales of the second- and third-largest vegetable producers (Syngenta and Limagrain, respectively). In the United States, the merger would harm competition for five distinct vegetable species: carrots, cucumbers, onions, tomatoes, and watermelons.

(1) Carrot seeds

52. In the United States, Bayer and Monsanto are the dominant producers of carrot seeds with a combined market share of approximately 94%. The post-transaction HHI would be approximately 8,800, with an increase of approximately 4,000 resulting from the transaction.

53. While competition would be harmed in the market for carrot seeds as a whole, the effects of the acquisition would be particularly acute in the ''cut-and-peel'' carrot segment, which consists of certain carrot varieties that are processed and sold as ready-to-eat baby carrots. Bayer and Monsanto are particularly close competitors in this segment, which constitutes approximately 80% of all carrots consumed in the United States.

(2) Cucumber seeds

54. The market for cucumber seeds is also highly concentrated, with Bayer and Monsanto dominating the market with 34% and 56% market shares, respectively. The post-acquisition HHI would be approximately 7,900, with an increase of approximately 3,700.

55. The effects of the acquisition would be particularly significant in the pickling cucumber seed segment, which makes up a large majority of cucumber acres in the United States. Bayer and Monsanto are two of only three suppliers of pickling cucumber seeds in the United States, with Monsanto as the dominant competitor, followed by Bayer and a company called Rijk Zwaan, based in the Netherlands. As in other markets, Bayer has competed against Monsanto in this segment through innovation, developing seedless varieties of pickling cucumbers to compete with Monsanto's seeded varieties.

(3) Onion seeds

56. Bayer and Monsanto are the two largest onion seed producers in the United States and globally, with substantial sales across a wide variety of onion segments. The U.S. market for onion seeds is already highly concentrated—besides Bayer and Monsanto, the only other producers are Bejo Zaden B.V., based in the Netherlands, and American Takii, Inc., based in California. The merger would give the combined company a share of approximately 71%. The post-transaction HHI would be approximately 5,000, with an increase of approximately 2,500.

(4) Tomato seeds

57. Bayer and Monsanto are two of the largest producers of tomato seeds in the United States, with market shares of 21% and 34%, respectively. The market for tomato seeds is moderately concentrated, and the merger would result in a highly concentrated market. The post-transaction HHI would be approximately 3,000, with an increase of approximately 1,400.

(5) Watermelon seeds

58. Lastly, the watermelon seed market is already highly concentrated, with Bayer and Syngenta, followed by Monsanto, as the largest suppliers in the United States. Bayer has a 37% market share in watermelon seeds, and Monsanto has a 6% share. As a result, the post-acquisition HHI would be approximately 3,300, with an increase of approximately 400. Monsanto's market share in watermelon seeds understates its competitive significance; its recent introduction of competitive seedless watermelon varieties, which are in high demand and already offered

by Monsanto's competitors, would significantly improve its position going forward.

V. ANTICOMPETITIVE EFFECTS

59. The proposed acquisition would substantially lessen competition and harm consumers in each of the relevant markets, either by eliminating head-to-head competition between Bayer and Monsanto or, in the case of certain seed treatments, raising the price of a key input. In each of these markets, the merger would likely result in higher prices, lower quality, and reduced choice. The price effects in these markets would likely result in hundreds of millions of dollars per year in harm, raising costs to farmers and consumers throughout the United States.

60. But the harm does not stop there. The merger would also have a significant impact on innovation. Today, four companies dominate the industry's research and development efforts for seeds and traits. Bayer and Monsanto are the industry leaders, with Bayer emerging as a threat to Monsanto's dominance. In 2016, for example, Bayer spent more on seeds-related research and development as a percentage of sales than any of the other Big Four. As leading innovators, Bayer and Monsanto push each other to improve their current products and technologies, monitor each other's research efforts, and compete to develop new blockbuster products.

61. Without the merger, this competition would intensify as both companies pursue what the industry refers to as integrated solutions—combinations of seeds, traits, and crop protection products, supported by digital-farming technologies and other services. Although integrated solutions are still evolving, it is widely believed that only the Big Four companies—each with its own unique strengths—will be able to offer fully integrated solutions to farmers. With this merger, that competition would be lost.

VI. ABSENCE OF COUNTERVAILING FACTORS

62. Entry would not prevent the merger's likely anticompetitive effects. It takes many years and hundreds of millions of dollars to discover new crop protection chemicals and to develop and commercialize new traits. Once a new trait has been discovered, companies cannot successfully incorporate that trait and sell seeds without access to the extensive libraries of elite seed varieties that are already owned by Bayer, Monsanto, and a small number of other companies. As Bayer's and Monsanto's executives have recognized, barriers to entry in the relevant markets are extraordinarily high.

63. In addition to the difficulty of entry, the proposed acquisition is unlikely to generate verifiable, merger-specific efficiencies that would offset the proposed acquisition's likely anticompetitive effects in the relevant markets.

VII. VIOLATIONS ALLEGED

64. Bayer's proposed acquisition of Monsanto is likely to substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

65. Unless enjoined, the proposed acquisition would likely have the following anticompetitive effects in the relevant markets:

(a) eliminate present and future competition between Bayer and Monsanto;

(b) lessen innovation;

(c) raise prices for farmers and other purchasers; and

(d) reduce quality, service, and choice for farmers and other purchasers.

VIII. REQUEST FOR RELIEF

66. The United States requests that this Court do the following:

(a) adjudge Bayer's proposed acquisition of Monsanto to violate Section 7 of the Clayton Act, 15 U.S.C. § 18;

(b) permanently enjoin Bayer and Monsanto from consummating their proposed acquisition or from entering into or carrying out any other agreement, understanding, or plan by which control of the assets or businesses of Bayer and Monsanto would be combined;

(c) award the United States its costs of this action; and

(d) award the United States other relief that the Court deems just and proper.

Dated: _____

Respectfully submitted,

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Plaintiff, v. *Bayer AG, Monsanto Company*, and *BASF SE, Defendants.*

Civil Action No.: 1:18–cv–1241
Judge James E. Boasberg

PROPOSED FINAL JUDGMENT

WHEREAS, Plaintiff United States of America filed its Complaint against Bayer AG (''Bayer'') and Monsanto Company (''Monsanto'') on May 29, 2018;

AND WHEREAS, pursuant to a Stipulation and Order among Bayer, Monsanto, and BASF SE (''BASF'') (collectively, ''Defendants'') and Plaintiff, the Court has joined BASF as a defendant to this action for the purposes of settlement and for the entry of this Final Judgment;

AND WHEREAS, Plaintiff and Defendants, by their respective

attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

AND WHEREAS, Defendants agree to be bound by the provisions of this Final Judgment pending its approval by this Court;

AND WHEREAS, the essence of this Final Judgment is the prompt and certain divestiture of certain businesses, rights, and assets by Bayer and Monsanto to assure that competition is not substantially lessened;

AND WHEREAS, Plaintiff requires Bayer and Monsanto to make certain divestitures to BASF for the purpose of remedying the loss of competition alleged in the Complaint;

AND WHEREAS, Bayer and Monsanto have represented to Plaintiff that all of the divestitures required below can and will be made as required by this Final Judgment, BASF has represented to Plaintiff that it can and will acquire the Divestiture Assets pursuant to its obligations under this Final Judgment, and Defendants have represented to Plaintiff that they will later raise no claim of hardship or difficulty as grounds for failing to comply with their obligations under this Final Judgment or for asking this Court to modify any of the provisions contained below;

NOW THEREFORE, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is ORDERED, ADJUDGED, AND DECREED:

I. *JURISDICTION*

This Court has jurisdiction over the subject matter of and each of the parties hereto with respect to this action. The Complaint states a claim upon which relief may be granted against Bayer and Monsanto under Section 7 of the Clayton Act, as amended (15 U.S.C. § 18). Pursuant to the Stipulation and Order filed simultaneously with this Final Judgment joining BASF as a defendant to this action, BASF has consented to this Court's exercise of specific personal jurisdiction over BASF in this matter solely for the purposes of settlement and for the entry and enforcement of the Final Judgment.

II. *DEFINITIONS*

As used in this Final Judgment:

A. ''*Bayer*'' means Defendant Bayer AG, a German corporation with its headquarters in Leverkusen, Germany, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

B. ''*Monsanto*'' means Defendant Monsanto Company, a Delaware corporation with its headquarters in St. Louis, Missouri, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''*BASF*'' means Defendant BASF SE, a Societas Europaea with its headquarters in Ludwigshafen, Germany, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

D. ''*'839 Business*'' means Bayer's global business of researching, developing, and manufacturing the BCS–CT12839 pipeline product.

E. ''*Balance Herbicide Business*'' means Bayer's global business of researching, developing, manufacturing, and selling isoxaflutole-based herbicides for use on crops that are isoxaflutole-tolerant as a result of genetic modification.

F. ''*Balance Herbicide Divestiture Assets*'' means the following assets related to the Balance Herbicide Business:

(1) all tangible assets used primarily by or critical to the operation of the Balance Herbicide Business, including, but not limited to, all transferable licenses, permits, product registrations, regulatory submissions, and authorizations issued by or submitted to any governmental organization; all contracts, agreements, leases, commitments, certifications, and understandings, including supply agreements; and all customer lists, accounts, credit records, and transferable customer contracts;

(2) all patents used by the Balance Herbicide Business;

(3) a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license to Bayer's BALANCE trademark for marketing and selling isoxaflutole-based herbicides for use on crops that are isoxaflutole-tolerant as a result of genetic modification;

(4) a worldwide, non-exclusive, royalty-free, paid-up, irrevocable, perpetual license (sub-licensable to any tollers designated by BASF) to any intellectual property, registration data, technology, know-how, or other rights used in the manufacture or formulation of isoxaflutole-based herbicides for use on crops that are isoxaflutole-tolerant as a result of genetic modification; and

(5) all other intangible assets owned, licensed, controlled, or used primarily by or critical to the operation of the Balance Herbicide Business, including, but not limited to, all data concerning historical and current research and development efforts, including, but not limited to, designs of experiments and the results of successful and unsuccessful designs and experiments.

G. ''*Broad Acre Seeds and Traits Business*'' means Bayer's global business of researching, developing, manufacturing, and selling broad acre seeds and traits, including, but not limited to, the global cotton seed business; the global canola seed business; the global soybean seed business; the global LibertyLink trait business for all crops except rice; the global research and development programs for wheat and ''canola quality'' *Brassica juncea;* and the global trait research and development activities. The Broad Acre Seeds and Traits Business excludes those assets that relate solely to the following: hybrid rice sold in Asia, hybrid cotton sold in India, traditional *juncea* (mustard) and millet sold in India, cotton sold in South Africa, the research and development program for sugarcane in Brazil, the research and development program for sugarbeets in Europe, and the LibertyLink event in rice.

H. ''*Broad Acre Seeds and Traits Divestiture Assets*'' means the following assets related to the Broad Acre Seeds and Traits Business:

(1) all tangible assets that comprise the Broad Acre Seeds and Traits Business, including, but not limited to, research and development activities; all manufacturing plants and equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property; all transferable licenses, permits, product registrations and regulatory submissions (including supporting data), certifications, and authorizations issued by or submitted to any governmental organization; all contracts, teaming arrangements, agreements, leases, commitments, certifications, and understandings, including supply agreements; all customer lists, accounts, credit records, and transferable customer contracts; all other business and administrative records; all seed production facilities; all breeding stations; all research and development facilities; all germplasm; and all breeding data, including, but not limited to, phenotype, genotype, molecular markers, and performance data;

(2) all intangible assets owned, licensed, controlled, or used by the Broad Acre Seeds and Traits Business, including, but not limited to, all patents,

plant variety certificates, licenses and sublicenses, intellectual property, copyrights, trademarks, trade names, service marks, service names, technical information, computer software and related documentation, know-how, trade secrets, drawings, blueprints, designs, design protocols, specifications for materials, specifications for parts and devices, safety procedures for the handling of materials and substances, quality assurance and control procedures, design tools and simulation capability, manuals and technical information provided by Bayer to its own employees, customers, suppliers, agents, or licensees; and research data concerning historical and current research and development efforts, including, but not limited to, designs of experiments and the results of successful and unsuccessful designs and experiments; and

(3) the copy of Bayer's microbial strain collection (''MSC'') stored in Morrisville, North Carolina, including, but not limited to, all biological materials comprising the MSC and all documents, data, information, reference materials, and trade secrets related to the MSC, and (a) a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license to use the MSC for trait research in any crop and (b) a worldwide, non-exclusive, royalty-free, paid-up, irrevocable, perpetual license to use the MSC for any other agricultural use.

Notwithstanding Paragraphs II(H)(1) through II(H)(3) above, the Broad Acre Seeds and Traits Divestiture Assets do not include the facilities identified in Appendix A, Paragraphs 1 and 2, or trademarks, trade names, service marks, or service names containing the name ''Bayer.''

I. ''*Clothianidin Seed Treatment Business*'' means Bayer's global business of researching, developing, manufacturing, and selling seed treatments containing clothianidin, *Bacillus firmus* strain I–1582, or *Bacillus thuringiensis* strain EX 297512. The Clothianidin Seed Treatment Business excludes Bayer's business of manufacturing and selling seed treatment mixture products containing clothianidin for canola/oilseed rape, potatoes, sugarbeets, cereals, or vegetables that have been commercialized by Bayer as of the date of filing of the Complaint in this matter (except Poncho/VOTiVO, Poncho Plus, and Poncho Super). For the avoidance of doubt, these exclusions do not prevent BASF from researching, developing, manufacturing, and selling seed treatments containing clothianidin for canola/oilseed rape, potatoes, sugarbeets, cereals, or vegetables.

J. ''*Collaboration*'' means an agreement among non-affiliated firms involving some sharing of resources, management, or risk, including, but not limited to, joint ventures or research alliances. For the avoidance of doubt, Collaboration for the purpose of this Final Judgment does not include (1) stand-alone intellectual property licenses, including patent, trademark, software, know-how, variety, germplasm, and registration data license agreements; (2) stand-alone crop protection supply or tolling agreements; (3) cooperation agreements related to advocacy and public policy issues; (4) agreements related to participation in industry groups and organizations; and (5) material transfer agreements.

K. ''*Digital Agriculture Business*'' means Bayer's global business of researching, developing, manufacturing, and selling digital agriculture products.

L. ''*Digital Agriculture Divestiture Assets*'' means the following assets related to the Digital Agriculture Business:

(1) all tangible assets that comprise the Digital Agriculture Business, including, but not limited to, research and development activities; all manufacturing plants and equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property; all contracts, teaming arrangements, agreements, leases, commitments, certifications, and understandings, including supply agreements; all customer lists, accounts, credit records, and transferable customer contracts; all other business and administrative records; all research and development facilities; and

(2) all intangible assets owned, licensed, controlled, or used by the Digital Agriculture Business, including, but not limited to, all patents, licenses and sublicenses, intellectual property, copyrights, trademarks, trade names, service marks, service names, technical information, computer software and related documentation, know-how, trade secrets, drawings, blueprints, designs, design protocols, specifications for materials, specifications for parts and devices, safety procedures for the handling of materials and substances, quality assurance and control procedures, design tools and simulation capability, manuals and technical information provided by Bayer to its own employees, customers, suppliers, agents, or licensees; and research data concerning historical and current research and development efforts related to the Digital Agriculture Business, including, but not limited to, designs of experiments and the results of successful and unsuccessful designs and experiments.

Notwithstanding Paragraphs II(L)(1) and II(L)(2) above, the Digital Agriculture Divestiture Assets do not include trademarks, trade names, service marks, or service names containing the name ''Bayer.''

M. ''*Divestiture Assets*'' means:

(1) the Balance Herbicide Divestiture Assets;

(2) the Broad Acre Seeds and Traits Divestiture Assets;

(3) the Digital Agriculture Divestiture Assets;

(4) the Glufosinate Ammonium Divestiture Assets;

(5) the Midwest Soybean Germplasm Divestiture Assets;

(6) the Pipeline Herbicide Divestiture Assets;

(7) the Seed Treatment Divestiture Assets; and

(8) the Vegetable Seed Divestiture Assets.

N. ''*Divestiture Businesses*'' means the Balance Herbicide Business, the Broad Acre Seeds and Traits Business, the Digital Agriculture Business, the Glufosinate Ammonium Business, the Pipeline Herbicide Business, the Seed Treatment Business, and the Vegetable Seed Business.

O. ''*Divestiture Closing Date*'' means (1) with respect to assets, employees, and agreements related to all Divestiture Assets except the Vegetable Seed Divestiture Assets, the date on which Bayer divests those Divestiture Assets to BASF, and (2) with respect to assets, employees, and agreements related to the Vegetable Seed Divestiture Assets, the date on which Bayer divests the Vegetable Seed Divestiture Assets to BASF.

P. ''*Fluopyram Seed Treatment Business*'' means Bayer's global business of researching, developing, manufacturing, and selling seed treatments containing fluopyram. The Fluopyram Seed Treatment Business excludes Bayer's business of researching, developing, manufacturing, and selling cereals seed treatments containing fluopyram, claiming only fungicidal properties, and claiming no nematode control effect. For the avoidance of doubt, this exclusion does not prevent BASF from researching, developing, manufacturing, and selling seed treatments for cereals containing fluopyram.

Q. ''*Glufosinate Ammonium Business*'' means Bayer's global business of researching, developing, manufacturing, and selling glufosinate ammonium herbicide products.

R. ''*Glufosinate Ammonium Divestiture Assets*'' means the following assets related to the Glufosinate Ammonium Business:

(1) Bayer's glufosinate ammonium manufacturing facilities located in Hurth/Knapsack, Germany; Muskegon, Michigan; Mobile, Alabama; and Frankfurt, Germany; Bayer's glufosinate formulation facilities located in Regina, Canada and Muskegon, Michigan; and these facilities' associated manufacturing equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property;

(2) all other tangible assets used primarily by or critical to the operation of the Glufosinate Ammonium Business, including all contracts, teaming arrangements, agreements, leases, commitments, certifications, and understandings, including supply agreements; all transferable licenses, permits, and authorizations issued by or submitted to any governmental organization; all customer lists, accounts, credit records, and transferable customer contracts; and all other business and administrative records;

(3) all patents used in the Glufosinate Ammonium Business, except for (a) patents related to the mixture or combined or sequential use of glufosinate ammonium with other active ingredients (''Glufosinate Mixture and Use Patents'') and (b) patents related to the use of glufosinate ammonium, alone or in mixtures, on plants containing genetically modified events developed or to be developed by Bayer or Monsanto (''Glufosinate Over-The-Top Patents'');

(4) a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license for all Glufosinate Mixture and Use Patents owned, controlled, licensed, or used by Bayer or Monsanto with one or more claims covering a BASF proprietary active ingredient;

(5) a worldwide, non-exclusive, irrevocable, perpetual covenant not to assert against BASF or its direct or indirect customers all other Glufosinate Mixture and Use Patents owned, controlled, licensed, or used by Bayer or Monsanto with one or more claims covering any other active ingredient, except for any active ingredient itself covered by a Bayer or Monsanto patent, during the life of that patent;

(6) a worldwide, non-exclusive, irrevocable, perpetual covenant not to assert against BASF or its direct or indirect customers all current or future Glufosinate Over-The-Top Patents owned, controlled, licensed, or used by Bayer or Monsanto;

(7) all other intangible assets owned, licensed, controlled, or used primarily by or critical to the operation of the Glufosinate Ammonium Business, including, but not limited to, all licenses and sublicenses, intellectual property, copyrights, trademarks, trade names, service marks, service names, technical information, computer software and related documentation, know-how, trade secrets, drawings, blueprints, designs, design protocols, specifications for materials, specifications for parts and devices, safety procedures for the handling of materials and substances, quality assurance and control procedures, design tools and simulation capability, manuals and technical information provided by Bayer to its own employees, customers, suppliers, agents, or licensees; and research data concerning historical and current research and development efforts, including, but not limited to, designs of experiments and the results of successful and unsuccessful designs and experiments; and

(8) a worldwide, non-exclusive, royalty-free, paid-up, irrevocable, perpetual license to all other intellectual property (owned by Bayer or that Bayer has the right to license) that is used by the Glufosinate Ammonium Business and not addressed earlier in Paragraph II.R, including, but not limited to, all copyrights, trademarks, trade names, service marks, service names, and trade secrets. Such license shall grant BASF the right to make, have made, use, sell or offer for sale, copy, create derivative works of, modify, improve, display, perform, and enhance the licensed intangible assets. Any improvements or modifications to these intangible assets developed by BASF shall be owned solely by BASF.

Notwithstanding Paragraphs II(R)(1) through II(R)(8) above, the Glufosinate Ammonium Divestiture Assets do not include the thirty (30) general office facilities identified in Appendix A, Paragraph 1; the fourteen (14) formulation and filling sites identified in Appendix A, Paragraph 3; or trademarks, trade names, service marks, or service names containing the name ''Bayer.''

S. ''*Midwest Soybean Germplasm Divestiture Assets*'' means the following Monsanto assets:

(1) the four hundred and nineteen (419) soybean populations identified in Appendix B;

(2) a worldwide, non-exclusive, royalty-free, paid-up, irrevocable, perpetual license for breeding purposes (subject to the limitations in Paragraph II(S)(4)) to twenty (20) soybean varieties developed by Monsanto that BASF subsequently will choose pursuant to the following process: Bayer will expeditiously provide BASF with access (including to all supporting data) to all of the Monsanto Corn States lines (for which Monsanto has the ability to offer breeding rights) developed by Monsanto for each of the years 2019 and 2020. BASF may choose two varieties for each of maturity zones zero through four, resulting in a license for twenty (20) lines over the two (2) years;

(3) all data (including, but not limited to, phenotype, genotype, molecular markers, and performance data) related to the transferred populations or licensed breeding varieties in Paragraph II(S)(1) above for the purpose of developing commercial soybean varieties; and a copy of all data (including, but not limited to, phenotype, genotype, molecular markers, and performance data) related to the transferred populations or licensed breeding varieties in Paragraph II(S)(2) above for the purpose of developing commercial soybean varieties; and

(4) all rights to develop commercial soybean varieties using the transferred populations or licensed breeding varieties in Paragraphs II(S)(1) and II(S)(2) above, which rights shall not be limited other than requiring compliance with trait license agreements for any Monsanto traits remaining in any developed line.

T. ''*Pipeline Herbicide Business*'' means Bayer's global business of researching, developing, and manufacturing ketoenole and N,O-Chelator (''NOC'') herbicides for non-selective uses.

U. ''*Pipeline Herbicide Divestiture Assets*'' means the following assets related to the Pipeline Herbicide Business:

(1) a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license in the field of non-selective uses for all Bayer intellectual property rights and know-how related to Bayer's ketoenole and to Bayer's NOC herbicide candidates;

(2) a worldwide, non-exclusive, royalty-free, paid-up, irrevocable, perpetual license (sub-licensable to any tollers designated by BASF) to any intellectual property, registration data, technology, know-how, or other rights used in the manufacture or formulation of ketoenole and of NOC herbicides for non-selective uses;

(3) all data, documents, and know-how from in vitro assays related to the use of Bayer's ketoenole and Bayer's NOC herbicide candidates with Bayer's relevant herbicide-tolerance traits;

(4) all field trials conducted on Bayer's ketoenole and Bayer's NOC herbicide candidates for non-selective uses;

(5) samples of all ketoenole and all NOC herbicide molecules; and

(6) all data and information on the molecular structure and other characteristics of Bayer's ketoenole and Bayer's NOC herbicide candidates.

V. ''*Relevant Personnel*'' means all Bayer employees who have supported or whose job related to the Divestiture Businesses at any time between January 1, 2015 and the Divestiture Closing Date.

W. ''*Seed Treatment Business*'' means the Clothianidin Seed Treatment Business, the Fluopyram Seed Treatment Business, and the '839 Business.

X. ''*Seed Treatment Divestiture Assets*'' means the following assets related to the Seed Treatment Business:

(1) Bayer's Seed Growth Center located in Research Triangle Park, North Carolina, including all equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property at this facility;

(2) all other tangible assets used primarily by or critical to the operation of the Seed Treatment Business, including, but not limited to, all transferable licenses, permits, certifications, product registrations, regulatory submissions, and authorizations issued by or submitted to any governmental organization; all contracts, teaming arrangements, agreements, commitments, certifications, and understandings, including supply agreements; all customer lists, accounts, credit records, and transferable customer contracts; all sales and marketing assets, including, but not limited to, distribution plans and any market research conducted; all other business and administrative records; samples of all molecules; all information on the molecular structure and other characteristics of the products; and all internal and available external studies;

(3) all patents used in Bayer's current and pipeline Poncho, Poncho Plus, Poncho Super, Poncho/VOTiVO, Poncho/VOTiVO 2.0, VOTiVO, VOTiVO 2.0, and TWO.0 seed treatments;

(4) a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license to any other patent with one or more claims covering the combination of clothianidin, *Bacillus firmus* strain I–1582, or *Bacillus thuringiensis* strain EX 297512 with another active ingredient, for BASF to combine clothianidin, *Bacillus firmus* strain I–1582, or *Bacillus thuringiensis* strain EX 297512 with any such other active ingredient(s) for seed treatment uses; provided, however, that this license does not include any right to make, sell, use, or otherwise commercialize any active ingredient itself covered by a Bayer or Monsanto patent, during the life of that patent;

(5) a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license for seed treatment uses to all patents used in Bayer's current and pipeline ILeVO and COPeO seed treatments; provided, however, that this license will be non-exclusive for cereals seed treatments containing fluopyram, claiming only fungicidal properties, and claiming no nematode control effect;

(6) a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license to any other patent with one or more claims covering the combination of fluopyram with another active ingredient, for BASF to combine fluopyram with any such other active ingredient(s) for seed treatment uses; provided, however, that (a) this license will be non-exclusive for cereals seed treatments containing fluopyram, claiming only fungicidal properties, and claiming no nematode control effect; and (b) this license does not include any right to make, sell, use, or otherwise commercialize any active ingredient itself covered by a Bayer or Monsanto patent, during the life of that patent;

(7) all patents used exclusively in the '839 Business, and a worldwide, exclusive, royalty-free, paid-up, irrevocable, perpetual license to all other patents with one or more claims used in the '839 Business;

(8) a worldwide, non-exclusive, irrevocable, perpetual covenant not to assert against BASF and its direct or indirect customers all other patents owned, controlled, licensed, or used by Bayer or Monsanto with claims covering the mixture or combined or sequential use of clothianidin, *Bacillus firmus* strain I–1582, *Bacillus thuringiensis* strain EX 297512, fluopyram, or BCS–CT12839 with any active ingredient or combination of active ingredients, except for any active ingredient itself covered by a Bayer or Monsanto patent, during the life of that patent;

(9) a worldwide, non-exclusive, royalty-free, paid-up, irrevocable, perpetual license (sub-licensable to any tollers designated by BASF) to any other intellectual property, registration data, technology, know-how, or other rights used in the manufacture or formulation of any current or pipeline product divested as part of the Seed Treatment Business; and

(10) all other intangible assets owned, licensed, controlled, or used by the Seed Treatment Business, including, but not limited to, all licenses and sublicenses, intellectual property, copyrights, trademarks, trade names, service marks, service names, technical information, know-how, trade secrets, drawings, designs, design protocols, specifications for materials, safety procedures for the handling of materials and substances, quality assurance and control procedures, design tools and simulation capability, manuals and technical information provided by Bayer to its own employees, customers, suppliers, agents, or licensees, and data concerning historical and current research and development efforts, including, but not limited to, designs of experiments and the results of successful and unsuccessful designs and experiments.

Notwithstanding Paragraphs II(X)(1) through II(X)(10) above, the Seed Treatment Divestiture Assets do not include (a) active ingredient production facilities in Dormagen, Germany; Bergkamen, Germany; or Tlaxcala, Mexico; (b) formulation, filling, or packaging sites in Amatitlan, Guatemala; Belford Roxo, Brazil; Frankfurt, Germany; Kansas City, Missouri; Pinkenba, Australia; or Zarate, Argentina; or (c) trademarks, trade names, service marks, or service names containing the name ''Bayer.''

Y. ''*Shared Confidential Information*'' means confidential business information relayed from Bayer to BASF, or vice versa, as a result of any agreements entered into pursuant to Paragraph IV(G) or Paragraph IV(H) of this Final Judgment, including quantities, units, and prices of items ordered or purchased, and any other competitively sensitive information regarding Bayer's or BASF's performance under these agreements.

Z. ''*Vegetable Seed Business*'' means Bayer's global business of researching, developing, manufacturing, and selling vegetable seeds.

AA. ''*Vegetable Seed Divestiture Assets*'' means the following assets related to the Vegetable Seed Business:

(1) all tangible assets that comprise the Vegetable Seed Business including, but not limited to, research and development activities; all manufacturing plants and equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property; all transferable licenses, permits, product registrations and regulatory submissions (including supporting data), certifications, and authorizations issued by or submitted to

any governmental organization; all contracts, teaming arrangements, agreements, leases, commitments, certifications, and understandings, including supply agreements; all customer lists, accounts, credit records, and transferable customer contracts; all other business and administrative records; seed production facilities; breeding stations; all research and development facilities; all germplasm; and all breeding data, including, but not limited to, phenotype, genotype, molecular markers, and performance data; and

(2) all intangible assets owned, licensed, controlled, or used by the Vegetable Seed Business, including, but not limited to, all patents, plant variety certificates, licenses and sublicenses, intellectual property, copyrights, trademarks, trade names, service marks, service names, technical information, computer software and related documentation, know-how, trade secrets, drawings, blueprints, designs, design protocols, specifications for materials, specifications for parts and devices, safety procedures for the handling of materials and substances, quality assurance and control procedures, design tools and simulation capability, manuals and technical information provided by Bayer to its own employees, customers, suppliers, agents, or licensees; and research data concerning historical and current research and development efforts, including, but not limited to, designs of experiments and the results of successful and unsuccessful designs and experiments.

Notwithstanding Paragraphs II(AA)(1) and II(AA)(2) above, the Vegetable Seed Divestiture Assets do not include the thirty-four (34) office facilities identified in Appendix A, Paragraph 4, or trademarks, trade names, service marks, or service names containing the name ''Bayer.''

BB. ''*Yield and Stress Collaboration*'' means any agreement between Monsanto and BASF existing as of the date of filing of the Complaint in this matter related to a collaboration to develop yield and stress traits for row crops.

III. *APPLICABILITY*

This Final Judgment applies to Defendants and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

IV. *DIVESTITURES*

A. By the later of ninety (90) calendar days after the filing of the Complaint in this matter or ninety (90) calendar days after receiving all international antitrust approvals required for the transfer of the Divestiture Assets, Bayer and Monsanto are ordered and directed to divest the Divestiture Assets to BASF in a manner consistent with this Final Judgment. The United States, in its sole discretion, may agree to one or more extensions of this period not to exceed sixty (60) calendar days in total and shall notify this Court in such circumstances. Defendants agree to use their best efforts to divest the Divestiture Assets as expeditiously as possible.

B. Bayer shall permit BASF to have reasonable access to personnel and to make inspections of the facilities to be acquired by BASF; access to any and all environmental, zoning, and other permit documents and information; and access to any and all financial, operational, or other documents and information customarily provided as part of a due diligence process.

C. Bayer and Monsanto shall not take any action that will impede in any way the permitting, operation, or divestiture of the Divestiture Assets.

D. Unless the United States otherwise consents in writing, the divestitures pursuant to Section IV of this Final Judgment shall include the entire Divestiture Assets and shall be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by BASF as part of the viable, ongoing operation of the Divestiture Businesses. The divestitures shall be accomplished so as to satisfy the United States, in its sole discretion, that none of the terms of any agreement between BASF and Bayer and Monsanto give Bayer and Monsanto the ability unreasonably to raise BASF's costs, to lower BASF's efficiency, or otherwise to interfere in the ability of BASF to compete effectively.

E. **Employees**

(1) Within ten (10) business days following the filing of the Complaint in this matter, Bayer shall provide to BASF, the United States, and the Monitoring Trustee, organization charts covering every person providing any support for the Divestiture Businesses for each year since January 1, 2015. Within ten (10) business days of receiving a request from BASF, Bayer shall provide to BASF, the United States, and the Monitoring Trustee, additional information related to identified Relevant Personnel, including name, job title, reporting relationships, Hay points, past experience, responsibilities from January 1, 2015 through the Divestiture Closing Date, training and educational history, relevant certifications, job performance evaluations, and current salary and benefits information to enable BASF to make offers of employment. If Bayer is barred by any applicable laws from providing any of this information to BASF, within ten (10) business days of receiving BASF's request, Bayer shall provide the requested information to the greatest extent possible under applicable laws and also provide a written explanation of its inability to comply fully with BASF's request for information regarding Relevant Personnel.

(2) Upon request, Bayer shall make Relevant Personnel available for interviews with BASF during normal business hours at a mutually agreeable location. Bayer will not interfere with any negotiations by BASF to employ any Relevant Personnel. Interference includes but is not limited to offering to increase the salary or benefits of Relevant Personnel other than as part of a company-wide increase in salary or benefits granted in the ordinary course of business.

(3) For any Relevant Personnel who elect employment with BASF, Bayer shall waive all non-compete and non-disclosure agreements (except as noted in Paragraph IV(E)(5)), vest all unvested pension and other equity rights, and provide all benefits which Relevant Personnel would be provided if transferred to a buyer of an ongoing business.

(4) For a period of two (2) years from the date of filing of the Complaint in this matter, Bayer may not solicit to hire, or hire, any such person who was hired by BASF, unless (a) such individual is terminated or laid off by BASF or (b) BASF agrees in writing that Bayer may solicit or hire that individual.

(5) Nothing in Paragraph IV(E) shall prohibit Bayer from maintaining any reasonable restrictions on the disclosure by any employee who accepts an offer of employment with BASF of Bayer's proprietary non-public information that is (a) not otherwise required to be disclosed by this Final Judgment, (b) related solely to Bayer's businesses and clients, and (c) unrelated to the Divestiture Assets.

(6) BASF's right to hire Relevant Personnel pursuant to Section IV(E) and Bayer's obligations under Paragraph IV(E)(1), Paragraph IV(E)(2), and Paragraph IV(E)(3) shall last for a period of one (1) year after the Divestiture Closing Date.

F. **Asset Warranties**

(1) In addition to any other warranties in the divestiture-related agreements entered into by Defendants, Bayer and

Monsanto shall warrant to BASF (a) that each asset will be operational as of the Divestiture Closing Date; (b) that, for each of the Divestiture Assets, there are no material defects in the environmental, zoning, or other permits pertaining to the operation of each asset; (c) that following the sale of each of the Divestiture Assets, Bayer will not undertake, directly or indirectly, any challenges to the environmental, zoning, or other permits related to the operation of each of the Divestiture Assets; and (d) the Divestiture Assets are sufficient in all material respects for BASF, taking into account BASF's assets and business, to maintain the viability and competitiveness of the Divestiture Businesses.

(2) In addition to any other remedial provisions in the divestiture-related agreements entered into by Defendants, for a period of up to one (1) year following the Divestiture Closing Date, if BASF determines that any assets not included in the Divestiture Assets were previously used by the Divestiture Businesses and are reasonably necessary for the continued competitiveness of the Divestiture Businesses, it shall notify the United States, the Monitoring Trustee, and Bayer in writing that it requires such assets. The United States, in its sole discretion, taking into account BASF's assets and business, shall determine whether any of the assets identified should be divested to BASF. If the United States determines that such assets should be divested, Bayer and BASF will negotiate an agreement within thirty (30) calendar days providing for the divestiture of such assets in a period to be determined by the United States in consultation with Bayer and BASF. The terms of any such divestiture agreement shall be commercially reasonable and must be acceptable to the United States, in its sole discretion.

G. **Supply and Tolling Agreements**

(1) *Seed Treatment Supply Agreements for Broad Acre Seeds and Traits Business:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into one or more agreements with BASF for the supply of the Bayer seed treatments (except the seed treatments divested as part of the Clothianidin Seed Treatment Business or Fluopyram Seed Treatment Business) used by Bayer in the Broad Acre Seeds and Traits Business for an initial period of up to two (2) years. Bayer will supply BASF with these seed treatments at variable cost, in priority over other purchasers, and in the quantities demanded by BASF under any such agreement until the expiration of that agreement. All other terms and conditions of any such agreement must be reasonably related to market conditions for the supply of seed treatments. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of any such agreement for a total of up to an additional two (2) years. The United States, in its sole discretion, shall determine whether supply pursuant to any such extension must be at variable cost.

(2) *Isoxaflutole Supply Agreement:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into one or more agreements with BASF for the supply of isoxaflutole to be used on crops that are isoxaflutole-tolerant as a result of genetic modification for an initial period of two (2) years. Bayer will supply BASF with formulated isoxaflutole and the isoxaflutole active ingredient at variable cost, in priority over other purchasers, and in the quantities demanded by BASF under any such agreement until the expiration of that agreement. All other terms and conditions of any such agreement must be reasonably related to market conditions for the supply of herbicides and the active ingredients in herbicides. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of any such agreement for a total of up to an additional four (4) years. The United States, in its sole discretion, shall determine whether supply pursuant to any such extension must be at variable cost.

(3) *Tolling Agreement for Glufosinate Ammonium:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into one or more tolling agreements with BASF for the formulation, filling, and packaging of glufosinate ammonium products for an initial period of up to two (2) years. Bayer will formulate, fill, and package glufosinate ammonium products for BASF at variable cost, in priority over other purchasers, and in the quantities demanded by BASF under any such agreement until the expiration of that agreement. All other terms and conditions of any such agreement must be reasonably related to market conditions for the formulation, filling, and packaging of herbicides. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of any such agreement for a total of up to an additional one (1) year. The United States, in its sole discretion, shall determine whether tolling pursuant to any such extension must be at variable cost.

(4) *Tolling Agreement for Divested Seed Treatment Formulations:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into one or more tolling agreements with BASF for the formulation, filling, and packaging of the seed treatments divested as part of the Clothianidin Seed Treatment Business and the Fluopyram Seed Treatment Business for an initial period of up to two (2) years. Bayer will toll these products for BASF at variable cost, in priority over other purchasers, and in the quantities demanded by BASF under any such agreement until the expiration of that agreement. All other terms and conditions of any such agreement must be reasonably related to market conditions for the formulation, filling, and packaging of seed treatments. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of any such agreement for a total of up to an additional two (2) years. The United States, in its sole discretion, shall determine whether tolling pursuant to any such extension must be at variable cost.

(5) *Clothianidin Active Ingredient Tolling Agreement:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into one or more tolling agreements with BASF for the supply of the active ingredients used in the seed treatments divested as part of the Clothianidin Seed Treatment Business for an initial period of up to two (2) years. Bayer will toll these active ingredients for BASF at variable cost, in priority over other purchasers, and in the quantities demanded by BASF under any such agreement until the expiration of that agreement. All other terms and conditions of any such agreement must be reasonably related to market conditions for the tolling of active ingredients used in seed treatments. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of any such agreement for a total of up to an additional four (4) years. The United States, in its sole discretion, shall determine whether tolling pursuant to any such extension must be at variable cost.

(6) *Fluopyram Active Ingredient Tolling Agreement:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into a tolling agreement with BASF for the supply of the fluopyram active ingredient for an initial period of up to two (2) years. Bayer will toll this active ingredient for BASF at variable cost, in priority over other purchasers, and in the quantities demanded by BASF under any such agreement until the expiration of that agreement. All other

terms and conditions of any such agreement must be reasonably related to market conditions for the tolling of active ingredients used in seed treatments. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of any such agreement for a total of up to an additional four (4) years. The United States, in its sole discretion, shall determine whether tolling pursuant to any such extension must be at variable cost.

(7) *Reverse-Tolling Agreement for Bayer Products:* At the option of Bayer, on or before the Divestiture Closing Date, BASF shall enter into a reverse-tolling agreement with Bayer for the formulation, filling, and packaging of the Bayer products manufactured at the Regina, Canada formulation facility that is part of the Glufosinate Ammonium Divestiture Assets for an initial period of up to two (2) years. All terms and conditions of any such agreement must be reasonably related to market conditions for the formulation, filling, and packaging of these crop protection products. Upon Bayer's request, the United States, in its sole discretion, may approve one or more extensions of such agreement for a total of up to an additional six (6) months.

(8) *Other Supply and Tolling Agreements:* At the option of BASF, on or before the Divestiture Closing Date, Bayer and BASF shall enter into any other supply, reverse-supply, tolling, or reverse-tolling agreements reasonably necessary to allow BASF to operate any Divestiture Assets or to facilitate the transfer of Bayer facilities to BASF.

(9) The terms and conditions of all agreements reached between Bayer and BASF under Paragraph IV(G) must be acceptable to the United States, in its sole discretion. Any amendment or modification of such agreements may be entered into only with the approval of the United States, in its sole discretion. Bayer shall perform all duties and provide all services required of Bayer under the agreements reached between Bayer and BASF under Paragraph IV(G).

(10) BASF will use best efforts to develop or procure alternative sources of supply by the end of the initial periods identified in Paragraph IV(G) for supply and tolling agreements and will continue to use best efforts during any extension period.

(11) Bayer will use best efforts to develop or procure alternative sources of supply by the end of the initial periods identified in Paragraph IV(G) for reverse-supply and reverse-tolling agreements and will continue to use best efforts during any extension period.

H. **Transition Services**

(1) *Transition Services Agreements for Information Technology Support:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into one or more transition services agreements to provide information technology services and support for the Divestiture Assets for an initial period of up to one (1) year. Bayer will provide the transition services under any such agreement at no cost to BASF until the expiration of the agreement. All other terms and conditions of any such agreement must be reasonably related to market conditions for the provision of the relevant services. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of this agreement for a total of up to an additional one (1) year.

(2) *Bayer Warranty of Transition Services Provided by Tata Consultancy Services:* Bayer has contracted with a third-party vendor, Tata Consultancy Services, to create interim, stand-alone information and business support systems for some components of the Divestiture Assets. Bayer shall warrant to BASF that the systems developed by Tata Consultancy Services will be operational on the Divestiture Closing Date and support operations of the relevant components of the Divestiture Assets in a manner that is substantially consistent with prior operations of these businesses. Except for *de minimis* deficiencies, Bayer shall use best efforts to take all necessary actions to correct expeditiously any deficiencies inconsistent with this warranty and shall be solely responsible for all costs incurred in resolving the deficiencies, including by paying Tata Consultancy Services's fees.

(3) *Distribution Agreements for Glufosinate Ammonium and Divested Seed Treatment Products:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into one or more agreements to distribute on BASF's behalf products containing glufosinate ammonium, clothianidin, *Bacillus firmus* strain I–1582, or fluopyram outside the United States. BASF shall terminate any such agreement within one (1) year. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of the period for BASF to terminate any such agreement for a total of up to an additional one (1) year.

(4) *Other Transition Services Agreements:* At the option of BASF, on or before the Divestiture Closing Date, Bayer shall enter into other transition services or reverse transition services agreements to provide any other transition services reasonably necessary to allow BASF to operate any Divestiture Assets or to facilitate the transfer of Bayer facilities to BASF. Unless specifically excepted elsewhere in this Final Judgment, Bayer will provide transition services under any such agreement for an initial period of up to two (2) years and on price terms no worse than at variable cost until the expiration of the agreement. All other terms and conditions of any such agreement must be reasonably related to market conditions for the provision of the relevant services. Upon BASF's request, the United States, in its sole discretion, may approve one or more extensions of any such agreement for a total of up to an additional one (1) year.

(5) The terms and conditions of all agreements reached between Bayer and BASF under Paragraph IV(H) must be acceptable to the United States, in its sole discretion. Any amendments or modifications of the agreements may be entered into only with the approval of the United States, in its sole discretion. Bayer shall perform all duties and provide all services required of Bayer under the agreements reached between Bayer and BASF under Paragraph IV(H).

(6) BASF will use best efforts to develop alternative solutions by the end of the initial periods identified in Paragraph IV(H) for transition services agreements and will continue to use best efforts during any extension period.

(7) Bayer will use best efforts to develop alternative solutions by the end of the initial periods identified in Paragraph IV(H) for reverse-transition services agreements and will continue to use best efforts during any extension period.

I. **Clothianidin Licenses Back:** At the option of Bayer, BASF shall enter into an agreement to provide Bayer the following licenses:

(1) a worldwide, exclusive, royalty-free, paid-up license to the rights transferred to BASF in Paragraph II(X)(3) for (a) all non-seed treatment uses of clothianidin, (b) all uses of active ingredients other than clothianidin, *Bacillus firmus* strain I–1582, or *Bacillus thuringiensis* strain EX 297512, and (c) combinations of active ingredients that do not include clothianidin, *Bacillus firmus* strain I–1582, or *Bacillus thuringiensis* strain EX 297512; and

(2) a worldwide, non-exclusive, royalty-free, paid-up license to the rights transferred to BASF in Paragraphs II(X)(3) and II(X)(4) for the use of clothianidin in any Bayer seed treatment mixture product for canola/oilseed rape, potatoes, sugarbeets, cereals, and vegetables that has been commercialized by Bayer as of the date

of the filing of the Complaint in this matter (except Poncho/VOTiVO, Poncho Plus, and Poncho Super).

J. **Digital Agriculture License Back:** At the option of Bayer, BASF shall enter into an agreement to provide Bayer a non-exclusive, royalty-free, paid-up license to the Digital Agriculture Divestiture Assets for the limited purpose of allowing Bayer to sell outside North America the following digital agriculture products: Expert.com web application; Weedscout mobile application; Xarvio FieldManager web application; Xarvio FieldManager mobile application; and Xarvio Scouting mobile application. This license shall not give Bayer (1) any rights to any improvements made by BASF to the Digital Agriculture Divestiture Assets or (2) any rights to use any trademarks or brand names divested as part of the Digital Agriculture Divestiture Assets, including, but not limited to, Expert.com, Weedscout, or Xarvio.

K. Third-Party Agreements: At BASF's option, on or before the Divestiture Closing Date, Bayer shall assign or otherwise transfer to BASF all transferable or assignable agreements, or any assignable portions thereof, related to the Divestiture Assets, including, but not limited to, all customer contracts, licenses, and collaborations. Bayer shall use best efforts to expeditiously obtain from any third parties any consent necessary to transfer or assign to BASF all agreements related to the Divestiture Assets. To the extent consent cannot be obtained and the agreement is not otherwise assignable, in addition to the existing mitigation rules agreed upon between Bayer and BASF, Bayer shall use best efforts to obtain for BASF, as expeditiously as possible, the full benefit of any such agreement as it relates to the Divestiture Businesses by assisting BASF to secure a new agreement and by taking any other steps necessary to ensure that BASF obtains the full benefit of the agreement as it relates to the Divestiture Businesses. Bayer will not assert, directly or indirectly, any legal claim that would interfere with BASF's ability to obtain the full benefit from any transferred third-party agreement to the same extent enjoyed by Bayer prior to the transfer.

L. **Licenses, Registrations, and Permits**

(1) Where necessary, BASF will apply for licenses, registrations, and permits that support the Divestiture Businesses to replace those held by Bayer as expeditiously as possible and, in any event, no later than six (6) months from the Divestiture Closing Date. The United States, in its sole discretion, may approve one or more extensions of this period, for a total of up to an additional six (6) months, for BASF to satisfy this requirement. BASF will make best efforts to obtain such licenses, registrations, and permits as expeditiously as possible.

(2) Bayer will make best efforts to assist BASF with acquiring new licenses, registrations, and permits to support the Divestiture Businesses and, until BASF has the necessary licenses, registrations, and permits, Bayer will provide BASF with the benefit of Bayer's licenses, registrations, and permits in BASF's operation of the Divestiture Assets.

(3) Bayer will globally maintain all product registrations for isoxaflutole, fluopyram, and any other retained product registrations related to the Divestiture Businesses, and Bayer will make best efforts to obtain regulatory approvals for isoxaflutole formulations used on isoxaflutole-tolerant cotton and soybeans.

M. **Modification of Monsanto-BASF Yield and Stress Collaboration:** The Yield and Stress Collaboration will be modified consistent with the following: (1) Defendants shall not contribute any more genes to the Yield and Stress Collaboration; (2) the Yield and Stress Collaboration will continue as before with respect to genes or events in the three active research and development projects, except that BASF will receive a license with stacking rights to use in its own seeds any Yield and Stress Collaboration trait commercialized by Monsanto, on terms acceptable to the United States, in its sole discretion; (3) both Bayer and BASF shall receive (a) copies of all other genes and related research records in the Yield and Stress Collaboration regardless of crop, and (b) non-exclusive research, development, breeding, and commercialization rights to these genes in any crop with no cost, revenue, or profit sharing; and (4) the terms related to DroughtGard shall be unchanged.

N. **Monsanto Midwest Soybean Germplasm:** At the option of BASF, on or before the Divestiture Closing Date, Bayer and Monsanto shall enter into one or more agreements facilitating the transfer and licensing of the Midwest Soybean Germplasm Divestiture Assets. The terms and conditions of any such agreement reached between Bayer and Monsanto and BASF must be acceptable to the United States, in its sole discretion. Any amendment or modification of any such agreement may be entered into only with the approval of the United States, in its sole discretion. Bayer and Monsanto shall perform all duties and provide all services required of them under any such agreement reached between Bayer and BASF.

V. *FINANCING*

Neither Bayer nor Monsanto shall finance all or any part of any purchase made pursuant to Section IV of this Final Judgment.

VI. *HOLD SEPARATE AND ASSET PRESERVATION*

Until all the divestitures required by this Final Judgment have been fully accomplished, Defendants shall take all steps necessary to comply with the Stipulation and Order entered by this Court. Defendants shall take no action that would jeopardize any divestiture ordered by this Court.

VII. *AFFIDAVITS*

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestitures have been accomplished under Section IV, Bayer and Monsanto shall deliver to the United States and the Monitoring Trustee an affidavit, signed by each of Bayer's and Monsanto's Chief Financial Officer and General Counsel, which shall describe the fact and manner of Bayer's and Monsanto's compliance with Section IV. Assuming the information set forth in the affidavit is true and complete, any objection by the United States to information provided by Bayer and Monsanto, including limitation on information, shall be made within fourteen (14) calendar days of receipt of such affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, each of the Defendants shall deliver to the United States and the Monitoring Trustee an affidavit that describes in reasonable detail all actions it has taken and all steps it has implemented on an ongoing basis to comply with this Final Judgment and the Stipulation and Order. Each of the Defendants shall deliver to the United States and the Monitoring Trustee an affidavit describing any changes to the efforts and actions outlined in its earlier affidavits filed pursuant to this Final Judgment within fifteen (15) calendar days after the change is implemented.

C. In addition to providing affidavits to the United States and the Monitoring Trustee as required under Paragraph VII(A) and Paragraph VII(B), Defendants shall immediately notify the United States and the Monitoring Trustee verbally and in writing of any potential problems or delays in meeting any of the obligations set forth in this Final Judgment and the Stipulation and Order.

D. Bayer and Monsanto shall keep all records of all efforts made to preserve and divest each of the Divestiture Assets until one year after such divestitures have been completed. BASF shall keep all records of all efforts made to acquire each of the Divestiture Assets until one year after such divestitures have been completed.

VIII. *APPOINTMENT OF MONITORING TRUSTEE*

A. Upon filing of this Final Judgment, the United States may, in its sole discretion, appoint a Monitoring Trustee, subject to approval by this Court.

B. The Monitoring Trustee shall have the power and authority to monitor Defendants' compliance with the terms of this Final Judgment and the Stipulation and Order entered by this Court, and shall have such other powers as this Court deems appropriate. The Monitoring Trustee shall investigate and report on Defendants' compliance with their respective obligations under, and efforts to effectuate the purposes of, this Final Judgment and the Stipulation and Order, including, but not limited to, reviewing (1) the implementation and execution of the compliance plan required by Section IX, and (2) any claimed breach by Bayer of any agreement entered into pursuant to Paragraph IV(G) or Paragraph IV(H). If the Monitoring Trustee determines that any violation of the Final Judgment or the Stipulation and Order or breach of any related agreement has occurred, the Monitoring Trustee shall recommend an appropriate remedy to the United States, which, in its sole discretion, can accept, modify, or reject a recommendation to pursue a remedy.

C. Subject to Paragraph VIII(E), the Monitoring Trustee may hire at Bayer's cost and expense any consultants, accountants, attorneys, or other agents reasonably necessary in the Monitoring Trustee's judgment and who shall be solely accountable to the Monitoring Trustee. Any such consultants, accountants, attorneys, or other agents shall serve on such terms and conditions as the United States approves, in its sole discretion, including confidentiality requirements and conflict of interest certifications.

D. Defendants shall not object to actions taken by the Monitoring Trustee in fulfillment of the Monitoring Trustee's responsibilities under any order of this Court on any ground other than the Monitoring Trustee's malfeasance. Any such objections by Defendants must be conveyed in writing to the United States and the Monitoring Trustee within ten (10) calendar days after the action taken by the Monitoring Trustee giving rise to the Defendants' objection.

E. The Monitoring Trustee shall serve at Bayer's cost and expense pursuant to a written agreement with Bayer and on such terms and conditions as the United States approves, in its sole discretion, including confidentiality requirements and conflict of interest certifications. The compensation of the Monitoring Trustee and any consultants, accountants, attorneys, and other agents retained by the Monitoring Trustee shall be on reasonable and customary terms commensurate with the individuals' experience and responsibilities. If the Monitoring Trustee and Bayer are unable to reach agreement on the Monitoring Trustee's or any agents' or consultants' compensation or other terms and conditions of engagement within fourteen (14) calendar days of appointment of the Monitoring Trustee, the United States may, in its sole discretion, take appropriate action, including making a recommendation to this Court. The Monitoring Trustee shall, within three (3) business days of hiring any consultants, accountants, attorneys, or other agents, provide written notice of such hiring and the rate of compensation to Bayer and the United States.

F. The Monitoring Trustee shall have no responsibility or obligation for the operation of Defendants' businesses.

G. Defendants shall use their best efforts to assist the Monitoring Trustee in monitoring Defendants' compliance with their individual obligations under this Final Judgment and the Stipulation and Order. The Monitoring Trustee and any consultants, accountants, attorneys, and other agents retained by the Monitoring Trustee shall have full and complete access to the personnel, books, records, and facilities related to compliance with this Final Judgment and the Stipulation and Order, subject to reasonable protection for trade secret or other confidential research, development, or commercial information or any applicable privileges. Defendants shall take no action to interfere with or to impede the Monitoring Trustee's accomplishment of its responsibilities.

H. After its appointment, the Monitoring Trustee shall file reports monthly until all the Divestiture Assets have been divested and thereafter as frequently as the United States determines, in its sole discretion, setting forth Defendants' compliance with their obligations under this Final Judgment and under the Stipulation and Order. The Monitoring Trustee shall file such reports with the United States and, as appropriate, this Court. To the extent that any such report contains information that the Monitoring Trustee deems confidential, that report shall not be filed in the public docket of this Court.

I. The Monitoring Trustee shall audit Defendants' compliance with Section IX every six (6) months. Defendants will provide full access to any documents and make employees available for interviews requested by the Monitoring Trustee pursuant to performing the semi-annual audit. The Monitoring Trustee shall file a report of the audit with the United States and, as appropriate, this Court. To the extent that any such report contains information that the Monitoring Trustee deems confidential, that report shall not be filed in the public docket of this Court.

J. The Monitoring Trustee shall serve until the sale of the Divestiture Assets is finalized pursuant to Section IV and the expiration of any agreement entered into pursuant to Paragraph IV(G) or Paragraph IV(H) or other agreements between Bayer and BASF that may affect the accomplishment of the purposes of this Final Judgment, unless the United States, in its sole discretion, terminates earlier or extends this period.

K. If the United States determines that the Monitoring Trustee has ceased to act or failed to act diligently or in a reasonably cost-effective manner, it may recommend this Court appoint a substitute Monitoring Trustee.

IX. *FIREWALL*

A. During the term of any agreement entered into pursuant to Paragraph IV(G) or Paragraph IV(H), Bayer and BASF shall implement and maintain reasonable procedures to prevent Shared Confidential Information from being disclosed by or through implementation and execution of these agreements to components or individuals within the respective companies involved in the marketing, distribution, or sale of competing products.

B. Bayer and BASF each shall, within twenty (20) business days of the entry of the Stipulation and Order, submit to the United States and the Monitoring Trustee a document setting forth in detail the procedures implemented to effect compliance with Section IX. Upon receipt of the document, the United States shall notify Bayer and BASF within twenty (20) business days whether, in its sole discretion, it approves of or rejects each party's compliance plan. In the event that Bayer's or BASF's compliance plan is rejected, the United States shall provide

Bayer or BASF, as applicable, the reasons for the rejection. Bayer or BASF, as applicable, shall be given the opportunity to submit, within ten (10) business days of receiving a notice of rejection, a revised compliance plan. If Bayer or BASF cannot agree with the United States on a compliance plan, the United States shall have the right to request that this Court rule on whether Bayer's and BASF's proposed compliance plan fulfills the requirements of Section IX.

C. Bayer and BASF shall:

(1) furnish a copy of this Final Judgment and related Competitive Impact Statement within sixty (60) calendar days of entry of the Final Judgment to (a) each officer, director, and any other employee that will receive Shared Confidential Information; and (b) each officer, director, and any other employee that is involved in (i) any contacts with the other companies that are parties to any agreement entered into pursuant to Paragraph IV(G) or Paragraph IV(H), or (ii) making decisions under any agreement entered into pursuant to Paragraph IV(G) or Paragraph IV(H);

(2) furnish a copy of this Final Judgment and related Competitive Impact Statement to any successor to a person designated in Paragraph IX(C)(1) upon assuming that position;

(3) annually brief each person designated in Paragraph IX(C)(1) and Paragraph IX(C)(2) on the meaning and requirements of this Final Judgment and the antitrust laws; and

(4) obtain from each person designated in Paragraph IX(C)(1) and Paragraph IX(C)(2), within thirty (30) calendar days of that person's receipt of the Final Judgment, a certification that he or she (a) has read and, to the best of his or her ability, understands and agrees to abide by the terms of this Final Judgment; (b) is not aware of any violation of the Final Judgment that has not been reported to the company; and (c) understands that any person's failure to comply with this Final Judgment may result in an enforcement action for civil or criminal contempt of court against each Defendant or any person who violates this Final Judgment.

X. *COMPLIANCE INSPECTION*

A. For the purposes of determining or securing compliance with this Final Judgment, or of any related orders such as any Stipulation and Order, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time authorized representatives of the United States Department of Justice, including consultants and other persons retained by the United States, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to Defendants, be permitted:

(1) access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide hard copy or electronic copies of, all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants, related to any matters contained in this Final Judgment; and

(2) to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants shall submit written reports or responses to written interrogatories, under oath if requested, related to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in Section X shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by Defendants to the United States, Defendants shall represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(l)(G) of the Federal Rules of Civil Procedure and mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(l)(G) of the Federal Rules of Civil Procedure,'' then the United States shall give Defendants ten (10) calendar days' notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

XI. *NO REACQUISITION OR RECOMBINATION OF DIVESTITURE ASSETS*

Bayer may not reacquire any part of the Divestiture Assets during the term of this Final Judgment. Except for an acquisition pursuant to Paragraph IV(F)(2), BASF may not acquire from Bayer during the term of this Final Judgment any assets or businesses that compete with the Divestiture Assets. In addition, Bayer and BASF shall not, without the prior written consent of the United States, enter into any new Collaboration involving any of the Divestiture Assets or expand the scope of any existing Collaboration involving any of the Divestiture Assets during the term of this Final Judgment. The United States will notify Bayer and BASF of its decision within sixty (60) calendar days of receiving written notification from Bayer and BASF of the proposed new or expanded Collaboration. The decision whether or not to consent to a Collaboration shall be within the sole discretion of the United States.

XII. *NOTIFICATION OF FUTURE TRANSACTIONS*

A. For transactions that are not subject to the reporting and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, 15 U.S.C. § 18a (the ''HSR Act''), Bayer and Monsanto shall not, without providing advanced notification to the United States, directly or indirectly acquire a financial interest, including through securities, loan, equity, or management interest, in any company that researches, develops, manufactures, or sells digital agriculture products or soybean, cotton, canola, or corn seeds or traits. In addition, Bayer and Monsanto shall not acquire any digital agriculture assets, any trait assets, or all or substantially all of the germplasm assets from any such company without providing advanced notification to the United States.

B. Such notification shall be provided to the United States in the same format as, and per the instructions relating to, the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended, except that the information requested in Items 5 through 8 of the instructions must be provided only about digital agriculture products or soybean, cotton, canola, or corn seeds or traits. Notification shall be provided at least thirty (30) calendar days prior to acquiring any such interest, and shall include, beyond what may be required by the applicable instructions, the names of the principal representatives of the parties to the agreement who negotiated the agreement, and any management or strategic plans discussing the proposed transaction. If within thirty (30) calendar days after notification, the United States makes a written request for additional information, Bayer and

Monsanto shall not consummate the proposed transaction or agreement until thirty (30) calendar days after submitting and certifying, in the manner described in Part 803 of Title 16 of the Code of Federal Regulations as amended, the truth, correctness, and completeness of all such additional information. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted in the same manner as is applicable under the requirements and provisions of the HSR Act and rules promulgated thereunder. Section XII shall be broadly construed and any ambiguity or uncertainty regarding the filing of notice under Section XII shall be resolved in favor of filing notice.

XIII. *RETENTION OF JURISDICTION*

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIV. *ENFORCEMENT OF FINAL JUDGMENT*

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including its right to seek an order of contempt from this Court. Defendants agree that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of any remedy therefor by a preponderance of the evidence, and they waive any argument that a different standard of proof should apply.

B. The Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore all competition harmed by the challenged conduct. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of the Final Judgment should not be construed against either party as the drafter.

C. In any enforcement proceeding in which the Court finds that the Defendants have violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with such other relief as may be appropriate. In connection with any successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved prior to litigation, that Defendant agrees to reimburse the United States for any attorneys' fees, experts' fees, and costs incurred in connection with that enforcement effort, including the investigation of the potential violation.

XV. *EXPIRATION OF FINAL JUDGMENT*

Unless this Court grants an extension, this Final Judgment shall expire ten (10) years from the date of its entry, except that after six (6) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestitures have been completed and that the continuation of the Final Judgment no longer is necessary or in the public interest.

XVI. *PUBLIC INTEREST DETERMINATION*

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before this Court, which includes the Competitive Impact Statement and any comments and responses to comments filed with this Court, entry of this Final Judgment is in the public interest.

Date:

[Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. § 16]

United States District Judge

Appendix A

1. Bayer will retain thirty (30) office facilities largely dedicated to non-divested Bayer businesses in Argentina (Buenos Aires and Chacabuco), Brazil (Paulinia), Canada (Calgary, Ottawa, Rosthern, Saskatoon, and Winnipeg), Czech Republic (Prague), France (two sites in Lyon), Germany (Langenfeld and Monheim), Great Britain (Cambridge), Greece (Athens and Thessaloniki), Hungary (Budapest), Latvia (Riga), Poland (Warsaw), Romania (Bucharest), Russia (Moscow), Turkey (Adana, Gebze, Istanbul, Izmir, and Sanliurfa), Ukraine (Kiev), and the United States (Champaign, Clayton, and Inaha).

2. Bayer will retain one seed cleaning and bagging facility that is part of Bayer Crop Science headquarters in Monheim, Germany (known as ''EOPC'').

3. Bayer will retain fourteen (14) formulation and filling sites largely dedicated to non-divested Bayer products in Argentina (Zarate), Australia (Kwinana and Pinkenba), Brazil (Belford Roxo), China (Hangzhou), Colombia (Barranquilla), Germany (Frankfurt), Guatemala (Amatitlán), Japan (Hofu), Korea (Daejeon), South Africa (Nigel), Spain (Quart de Poblet), Thailand (Bangpoo), and the United States (Kansas City).

4. Bayer will retain thirty-four (34) general office facilities largely dedicated to non-divested businesses in Algeria (Algiers), Argentina (Munro), Australia (Pinkenba), Belgium (Diegem), Canada (Guelph), Chile (Santiago de Chile), Colombia (Bogotá), Costa Rica (San José), Denmark (Copenhagen), Egypt (Cairo), Germany (Monheim), Great Britain (Saffron Walden), Guatemala (Mixco), Hungary (Budapest), Iran (Tehran), Japan (Fukuoka), Kazakhstan (Astana), Kenya (Nairobi), Morocco (Casablanca and El Jadida), Panama (David), Peru (Ica and Lima), Poland (Warsaw), Portugal (Carnaxide), Romania (Bucharest), Russia (Krasnodar), Singapore (Singapore), South Korea (Anseong-si), Spain (Paterna), Ukraine (Kiev), the United States (two sites in West Sacramento), and Vietnam (Hanoi).

Appendix B: Monsanto Population Numbers

(1) JVK13764
(2) JVK13662
(3) JVK13647
(4) JVK13604
(5) JVK13363
(6) JVK13294
(7) JVK13624
(8) JVK13564
(9) JVK13301
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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

United States of America, Plaintiff, v. *BAYER AG, MONSANTO COMPANY,* and *BASF SE,* Defendants.

Civil Action No.: 1:18–cv–1241
Judge James E. Boasberg

COMPETITIVE IMPACT STATEMENT

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. § 16(b), Plaintiff United States of America files this Competitive Impact Statement relating to the proposed Final Judgment submitted on May 29, 2018, for entry in this civil antitrust proceeding.

I. NATURE AND PURPOSE OF THE PROCEEDING

On September 14, 2016, Defendant Bayer AG (''Bayer'') agreed to acquire Defendant Monsanto Company (''Monsanto'') in a merger valued at approximately $66 billion. The United States filed a civil antitrust Complaint against Bayer and Monsanto on May 29, 2018, seeking to enjoin the proposed merger. The Complaint alleges that the proposed merger would lessen competition substantially across various markets in the agricultural industry, resulting in higher prices, less innovation, fewer choices, and lower-quality products for American farmers and consumers, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

Simultaneously with the filing of the Complaint, the United States has filed a proposed Final Judgment and a Stipulation and Order designed to prevent the merger's likely anticompetitive effects. As detailed below, the proposed Final Judgment requires Bayer to divest its businesses that compete with Monsanto, the seed treatment businesses that the merged firm would use to harm competition in certain seed markets, and assets supporting those businesses (collectively, the ''Divestiture Assets''). Bayer has agreed to divest the Divestiture Assets to BASF SE (''BASF''), a global chemical company with a multi-billion-dollar crop protection business.[1] The required divestitures will ensure that BASF replaces Bayer as an independent and vigorous competitor in each of the

[1] Bayer, Monsanto, and BASF are referred to collectively as ''Defendants.''

markets in which the proposed merger would otherwise lessen competition.

The terms of the Stipulation and Order require Defendants to take certain steps to ensure that, pending the required divestitures, all of the Divestiture Assets will be preserved and that Monsanto will continue to be operated independently as a separate business concern.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, although the Court would continue to retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. DESCRIPTION OF THE EVENTS GIVING RISE TO ALLEGED VIOLATION

A. The Defendants and the Merger

Bayer is a life-sciences company based in Leverkusen, Germany. The company employs nearly 100,000 people worldwide and has operations in nearly 80 countries. Bayer has three main business lines: (1) pharmaceuticals, (2) consumer health, and (3) agriculture, the last of which is the Bayer Crop Science division. Over the past decade, Bayer Crop Science has become one of the largest global agricultural firms. Today, its crop protection business is the second largest in the world, and its seeds and traits business is also among the world's largest. Bayer Crop Science generated almost $12 billion in annual revenues in 2017.

Monsanto is a leading producer of agricultural products based in St. Louis, Missouri. Over 20,000 people work for the company in almost 70 countries. Monsanto's innovative technologies have established it as a global leader in agriculture; today, it is the leading global producer of seeds and traits and is among the world's largest producers of crop protection products. In 2017, Monsanto had almost $15 billion in annual revenues.

On September 14, 2016, Bayer agreed to acquire Monsanto for approximately $66 billion. In recognition of the significant competitive concerns raised by the proposed merger, Bayer has agreed to divest agricultural assets valued at approximately $9 billion to BASF. As discussed in Section III.K, *infra,* BASF has agreed to be bound by the terms of the proposed Final Judgment.

B. The Competitive Effects of the Proposed Merger across Agricultural Markets in the United States

The Complaint alleges that the proposed merger would reduce competition in the United States in 17 distinct agricultural product markets. These markets fit into four broad categories: (1) genetically modified (''GM'') seeds and traits, (2) foundational herbicides, (3) seed treatments, and (4) vegetable seeds. In addition to anticompetitive effects in each of the product markets resulting from the loss of head-to-head competition or vertical foreclosure, the Complaint also alleges that the merger would have a significant impact on innovation. Without the merger, competition between Bayer and Monsanto would intensify as both companies pursue what the industry refers to as ''integrated solutions''—combinations of seeds, traits, and crop protection products, supported by digital farming technologies and other services. Without the proposed Final Judgment, that competition would be lost.

1. GM Seeds and Traits

Bayer and Monsanto are close competitors in the GM seeds and traits markets for three important U.S. row crops: cotton, canola, and soybeans. As described in the Complaint, the proposed merger would likely lead to a substantial lessening of competition in each of these markets, resulting in hundreds of millions of dollars in harm each year to American farmers and consumers.

Cotton is a major crop grown across the southern United States. Cotton seeds are widely used in vegetable oil, packaged foods, and animal feed, and cotton fibers are widely used in clothing. In 2017, U.S. farmers planted about 12 million acres of cotton accounting for over $800 million in seed purchases.

Canola is an important crop used in vegetable oil, packaged foods, biodiesel fuels, and animal feed. In the United States, canola is grown on approximately 1.7 million acres, mainly in North Dakota but also in several other states. GM canola seeds accounted for $83 million in domestic sales in 2016.

Soy is the second-largest crop grown in the United States. Soybeans are widely used in vegetable oil, packaged foods, and animal feed. In 2017, U.S. farmers planted almost 90 million acres of soybeans accounting for $4.64 billion in seed purchases.

A genetic trait is simply an attribute of a plant, such as being tall, short, or leafy. In most cases, plant traits derive from the plant's natural DNA; however, a small number of highly sophisticated biotechnology firms can insert DNA from other organisms into the DNA of a plant, giving the plant a desirable trait associated with that non-native DNA. A GM seed is a seed that contains DNA, and hence a desirable trait, of a different organism. Scientists have developed herbicide-tolerant traits that give crops the ability to withstand exposure to herbicides that would normally damage or kill them, allowing a farmer to spray the herbicide over an entire field and efficiently kill weeds without harming the crop. Scientists also have developed traits that make crops resistant to certain insect pests, allowing farmers to prevent these pests from damaging their crops while also reducing farmers' use of chemical insecticides. Today, more than 90% of the soybeans, cotton, and canola grown in the United States is grown from GM seeds.

a) Relevant Markets

As alleged in the Complaint, GM cotton seeds, GM canola seeds, and GM soybeans are each relevant product markets under Section 7 of the Clayton Act. In canola and soy, nearly all GM seeds contain herbicide-tolerant traits, but no seeds contain insect-resistant traits. In cotton, most GM seeds contain both herbicide-tolerant traits and insect-resistant traits (found on 98% and 88% of all cotton acres, respectively). The vast majority of farmers do not view conventional (*i.e.,* non-GM) seeds as a substitute for GM cotton, GM canola, or GM soybeans because GM seeds eliminate much of the labor and expense associated with more traditional means of weed and pest management, offer higher yields, and reduce soil erosion by decreasing tillage requirements. Accordingly, a hypothetical monopolist of any of these GM seeds markets could profitably raise prices.

The Complaint also alleges that insect-resistant traits for cotton and herbicide-tolerant traits for cotton, canola, and soybeans are relevant product markets under Section 7 of the Clayton Act. Again, the vast majority of farmers growing cotton, canola, and soybeans in the United States choose to purchase GM seeds and do not consider conventional seeds an acceptable alternative. Consequently, GM traits are necessary inputs for most seed companies, and a hypothetical monopolist of any of the trait markets listed above could profitably raise prices.

The Complaint alleges that the relevant geographic markets for these

GM seeds and traits markets are regional because seeds are tailored to local growing conditions (such as weather and soil type), and suppliers can charge different prices to customers in different regions. In cotton and canola, however, virtually all of the regions affected by the merger have similar market conditions, so the regions can reasonably be aggregated to a national level for purposes of analysis. For soybeans, the market structure differs across regions, and the relevant geographic market in which the merger will lead to harm is the southern United States, where Bayer has focused its soybean breeding program and been particularly successful.

b) Competitive Effects—GM Seeds

The market for GM cotton seeds in the United States is highly concentrated and would become significantly more so if Bayer were allowed to acquire Monsanto. Bayer and Monsanto have long been the two leading suppliers of GM cotton seeds throughout the United States. In addition to owning critical herbicide-tolerant and insect-resistant traits, discussed in more detail below, the companies each own extensive libraries of elite seed varieties, which are essential for breeding and commercializing competitive cotton seeds. If the proposed merger were allowed to proceed, Bayer and Monsanto would have a combined 59% share of GM cotton seeds in the United States.

In the market for GM canola seeds in the United States, Bayer and Monsanto are by far the two largest competitors, with a combined share of approximately 74%. Bayer and Monsanto compete aggressively, and Bayer's canola innovations in recent years have allowed it to surpass Monsanto, previously the largest firm in this market.

In the market for GM soybeans, the proposed merger would eliminate Bayer as a uniquely positioned challenger to Monsanto, which has dominated the market since traits were first commercialized in soybeans in the 1990s. For years, Monsanto's competitors relied on Monsanto for licenses to GM traits and, in most cases, for licenses to seed varieties as well. Bayer, however, invested over $250 million to develop an independent source of soybean varieties and launched its own branded soybean business, Credenz, which sells varieties that perform well in the southern United States. In 2017, Monsanto had a 39% market share in that region, with Bayer holding a 6% share that it planned to grow in the future.

Even these figures significantly understate the level of dominance the merged company would have in each of these markets. Monsanto licenses seeds with traits to certain smaller seed companies (referred to in the industry as ''independent seed companies''), leaving these smaller rivals with limited ability to exert competitive pressure on the merged firm.

c) Competitive Effects—GM Traits

In addition to effects in each GM seed market, the proposed merger would harm American farmers by eliminating head-to-head competition between Bayer and Monsanto to develop and sell GM traits. These trait markets are even more highly concentrated than the GM seed markets. Bayer and Monsanto effectively have a duopoly in cotton herbicide-tolerant traits, and the proposed merger would lead to a monopoly. In 2017, Bayer's herbicide-tolerant cotton traits accounted for 19% of the market, and Monsanto's accounted for 80%. The proposed merger would also lead to a substantial increase in concentration in the market for canola herbicide-tolerant traits; virtually all canola seeds planted in the United States contain either a Bayer or a Monsanto trait. In the soybean herbicide-tolerant trait market, Bayer has chipped away at Monsanto's position, and the merger threatens to eliminate Monsanto's only serious challenger. In 2017, Bayer and Monsanto represented 14% and 67% of the market, respectively, with the remainder attributable to market participants using an off-patent version of Monsanto's original Roundup Ready trait. Finally, the merger would also significantly increase concentration in the already highly concentrated market for insect-resistant traits for cotton; Bayer and Monsanto accounted for 10% and 75% of that market, respectively, in 2017.

Without the merger, competition between the two companies across the GM trait markets would likely increase over time. Bayer and Monsanto each have new traits in their research pipelines that would confer tolerance to additional herbicides, and farmers would benefit as Bayer and Monsanto continued to develop these new innovations.

d) Entry and Expansion in GM Seeds and Traits Markets

Entry is unlikely to counteract the anticompetitive effects of the proposed merger in any of the GM seed or GM trait markets. To compete in a GM seed market, a company must have high-quality varieties for the current growing season and access to a deep and diverse collection of high-quality seeds for breeding future varieties. The varieties must also be suitable for the particular geographic region. Elite seed varieties suitable for regions in the United States are increasingly difficult to procure and are controlled largely by a handful of vertically integrated companies, including Monsanto, Bayer, DowDuPont, and Syngenta. In addition, the time, expense, and expertise required to commercialize a GM trait is prohibitive for all but these four companies. Although certain smaller companies may participate in some limited aspect of initially discovering a trait, they do not have the ability to commercialize these traits.

2. Foundational Herbicides

In addition to competing to sell herbicide-tolerant seeds, Bayer and Monsanto also compete to sell the herbicides that are paired with them. Monsanto's Roundup Ready seeds are engineered to tolerate the herbicide glyphosate, which Monsanto sells under its Roundup brands, while Bayer's LibertyLink seeds are engineered to tolerate glufosinate ammonium, the herbicide that Bayer sells under the Liberty brand. These ''foundational'' herbicides, glyphosate and glufosinate, have unique characteristics that make them important competitive alternatives for farmers.

a) Relevant Market

The Complaint alleges that foundational herbicides constitute a relevant product market under Section 7 of the Clayton Act. Foundational herbicides are herbicides used on row crops that have two defining characteristics. First, they are ''non-selective,'' meaning that they kill all types of weeds, thus providing farmers with the broadest possible protection for their crops. In contrast, other types of herbicides are ''selective,'' meaning that they kill only certain types of weeds. Selective herbicides are often used to supplement non-selective herbicides but are not generally used in lieu of them. Second, foundational herbicides can be paired with seeds that are engineered to tolerate the herbicide. Other non-selective herbicides are not a substitute for farmers because no seeds are engineered to withstand them, so spraying those herbicides over a crop would damage it. For these reasons, farmers have no good substitutes for foundational herbicides, and a hypothetical monopolist would find it profitable to increase the price of some foundational herbicides by a small but significant amount. Today, glyphosate

and glufosinate are the only two foundational herbicides, but, as discussed further below, new foundational herbicides are in development.

b) Competitive Effects

The proposed merger would combine the world's leading producers of foundational herbicides and would lead to a presumptively anticompetitive increase in market concentration. Since the launch of herbicide-tolerant crops in the 1990s, Monsanto's Roundup has dominated the market. As some weeds have developed resistance to glyphosate, however, farmers are increasingly turning to Liberty. While glufosinate and glyphosate are now off patent, competition from generic suppliers has not prevented Bayer and Monsanto from maintaining branded price premiums. In 2017, Bayer held a 7% share and Monsanto held a 53% share, with generic manufacturers holding the remaining share.

The proposed merger is also likely to eliminate competition between Bayer and Monsanto to develop next-generation weed management systems. The Complaint explains that Bayer is developing new foundational herbicides and related herbicide-tolerant traits that would rival Monsanto's Roundup Ready-based systems. Likewise, Monsanto is actively pursuing innovations in foundational herbicides, including improvements to its Roundup formulations. Absent the merger, Bayer and Monsanto would each have incentives to pursue these competing pipeline products because any new innovations developed would help win market share from the other. In contrast, the merged firm will have different incentives due to heightened concerns that new innovations would simply cannibalize sales.

c) Entry and Expansion

As alleged in the Complaint, the anticompetitive effects of the proposed merger would not be remedied by entry or expansion in the foundational herbicide market. The manufacture of foundational herbicides is complex and hazardous, requiring regulatory and safety approvals, which are expensive and time-consuming to secure. Reputation, brand loyalty, and economies of scale also present barriers to entry and expansion.

3. Seed Treatments

Seed treatments are coatings applied to seeds that can protect the seed and the young plant from various insects or diseases. Seed treatments are a critical tool for farmers, and one or more seed treatments are applied to the majority of GM seeds sold in the United States today. Multiple seed treatments can be applied to a seed to protect it from various threats; seed treatments designed for one purpose (*e.g.,* killing insects) are rarely an effective substitute for seed treatments designed for a different purpose (*e.g.,* controlling fungal plant diseases).

The Complaint alleges that the proposed merger would likely result in three forms of competitive harm related to seed treatments: (1) the loss of head-to-head competition between Bayer's and Monsanto's seed treatments for nematodes, (2) vertical foreclosure effects resulting from the combination of Monsanto's strong position in corn seeds with Bayer's substantial position in insecticidal seed treatments for corn rootworm, and (3) vertical foreclosure effects resulting from the combination of Monsanto's strong position in soybeans with Bayer's substantial position in fungicidal seed treatments for soybean sudden death syndrome.

a) Nematicidal Seed Treatments for Corn, Cotton, and Soybeans

Nematicidal seed treatments protect crops from parasitic roundworms known as nematodes. Farmers have no cost-effective alternatives to nematicidal seed treatments. Seed treatments are approved for use by the government on a crop-by-crop basis, so a soybean farmer, for example, chooses between a different set of competitive alternatives than a cotton farmer. Accordingly, the Complaint alleges that nematicidal seed treatments for corn, cotton, and soybean seeds are each relevant markets under Section 7 of the Clayton Act and that a hypothetical monopolist in each market could profitably raise prices.

All three nematicidal seed treatment markets are highly concentrated. For years, Bayer has had a monopoly in the market for nematicidal seed treatments for corn; in 2017, its market share was over 95%. Bayer also dominates the market for nematicidal seed treatments for soybeans, with a share over 85%. And in the market for nematicidal seed treatments for cotton, Bayer and Syngenta currently split the market roughly evenly.

Although Monsanto does not currently sell any nematicidal seed treatments, it is about to launch its first product, NemaStrike. Without the merger, both Bayer and Monsanto expected NemaStrike to capture significant share from Bayer in all three seed treatment markets. The Complaint alleges that the proposed merger would harm competition in the nematicidal seed treatment market by removing the most significant threat to Bayer's dominance.

b) Vertical Foreclosure—Seed Treatments for Corn Rootworm and GM Corn Seeds

Corn is the largest crop grown in the United States, accounting for over $8 billion in seed sales annually. Over 90% of U.S. corn seeds are genetically modified, and, like the other GM seeds discussed above, GM corn seeds are a relevant product market under Section 7 of the Clayton Act. Although Bayer does not sell corn seeds, Monsanto effectively controls 50% of the market and faces only one major rival.

Corn rootworm is a destructive pest that can devastate a farmer's fields. To deal with this threat, some farmers rely on Bayer's Poncho insecticidal seed treatment. For many farmers, there are no cost-effective alternatives to insecticidal seed treatments. Because Poncho is the only seed treatment that offers meaningful protection against corn rootworm, corn seed companies purchase Bayer's insecticidal seed treatment to apply to their seeds so they can offer a competitive product.

The merger would likely harm competition in the market for GM corn seeds by combining Monsanto's strong position in GM corn seeds with Bayer's dominant position in insecticidal seed treatments for corn rootworm. The merged firm would have the incentive and ability to make its corn seed rivals less competitive by forcing them to pay more for Poncho or cutting off their supply of the product. This would limit farmers' choices, reduce competition, and ultimately allow the merged firm to increase the price for GM corn seeds.

c) Vertical Foreclosure—Fungicidal Seed Treatments for Sudden Death Syndrome and GM Soybeans

The merger is likely to have similar effects in soy. Sudden death syndrome (''SDS'') is a fungal disease afflicting millions of soybean acres across the United States. In 2015, Bayer began selling ILeVO, the only effective fungicidal seed treatment combatting SDS, and ILeVO's sales have doubled annually since its introduction. The merger is likely to reduce competition by combining Monsanto's leading GM soybean business with Bayer's dominant position in fungicidal seed treatments for SDS. The merged firm would have the incentive and ability to make its soybean rivals less competitive by charging them more for ILeVO or cutting off their supply, diminishing competition in the market for GM soybeans and reducing choices available to farmers.

d) Entry and Expansion

As alleged in the Complaint, the anticompetitive effects of the proposed merger would not be remedied by entry or expansion in the relevant seed treatment markets. Developing a new, effective seed treatment is a slow, costly, and difficult process, and new seed treatments require extensive regulatory approvals before farmers can use them. Generic versions of the Bayer seed treatments discussed above will not be available for at least the next several years due to various intellectual property protections. Neither expansion by existing seed treatments nor new seed treatments expected to launch in the next several years would prevent the anticompetitive effects of the proposed merger.

4. Vegetables

Finally, the Complaint alleges that the proposed merger is likely to substantially lessen competition in the markets for five types of vegetable seeds: carrots, cucumbers, onions, tomatoes, and watermelons. Overall, Monsanto is the largest global vegetable seed company, while Bayer is the fourth largest, and the two companies are strong competitors in all five of these markets.

a) Relevant Markets

The Complaint alleges that the seeds markets for carrots, cucumbers, onions, tomatoes, and watermelons each constitute a relevant market under Section 7 of the Clayton Act. Each vegetable species has unique characteristics, and other crops are not viable substitutes. Many vegetable seed customers rely on access to particular types of vegetables to operate their businesses. For example, in the United States, companies that sell pre-cut baby carrots and other carrot products, such as juice, purchase carrot seeds to grow their carrots. These companies are unlikely to begin growing a different crop in large quantities in response to a price increase. Nor are other farmers likely to switch crops in response to a price increase because they have invested in crop-specific facilities and equipment, possess specialized crop-specific knowledge, or live in an area best suited to growing that particular type of vegetable. A hypothetical monopolist of any of the five vegetable seed species would find it profitable to increase prices by at least a small but significant amount because the bulk of farmers would not switch away from their preferred vegetable crops in response. As vegetable seeds are bred to thrive in particular regions of the country, geographic markets are regional, but, similar to row crops, virtually all regions affected by the merger have similar market structure, so in this case it is appropriate to aggregate these regions to the national level for convenience.

b) Competitive Effects

Bayer and Monsanto are among the largest domestic producers of all the vegetable seeds at issue. The Complaint alleges that the proposed merger would significantly increase concentration in each market, and each market would be highly concentrated with few, if any, other significant competitors. In carrots and cucumbers, the merged firm would enjoy near-complete dominance, with market shares of 94% and 90%, respectively. The combined company would also have high market shares in onion seeds (71%) and tomato seeds (55%). In watermelon seeds, Bayer holds a 37% market share while Monsanto has a 6% share, with only one other significant competitor. Monsanto's market share in watermelon seeds understates its competitive significance; its recent introduction of competitive seedless watermelon varieties, which are in high demand and already offered by Monsanto's competitors, will likely significantly improve its position going forward. In each of these markets, the proposed merger would eliminate the significant competition between Bayer and Monsanto, not only on price, but also on quality and innovation, to the overall detriment of American farmers and consumers.

c) Entry and Expansion

Firms that sell vegetable seeds use modern breeding techniques that require access to advanced technologies and elite seed varieties, making entry challenging. In addition, entering a new vegetable seed market can be expensive and time consuming because successful vegetable seed companies must invest continuously in developing new, improved varieties, some of which can take over a decade to breed and commercialize. Certain vegetable markets present additional unique challenges; for instance, onions are among the hardest vegetable seeds to produce, in part, because they are biennials, generating seed only every other growing season.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The proposed Final Judgment remedies the anticompetitive effects of the merger by requiring Bayer to divest its businesses in each relevant market, along with various supporting assets, to BASF, a global chemical company with an existing agricultural crop protection business. To ensure that BASF would replace Bayer as an effective competitor and innovator in each of the 17 markets in which the Complaint alleges that the proposed merger would harm competition, the United States carefully scrutinized the merging parties' and BASF's businesses and operations to identify a comprehensive package of businesses and supporting assets for divestiture. Collectively, these transfers encompass the suite of businesses and assets that constitute the divestiture package.

In evaluating the remedy, the United States recognized that fully preventing the competitive effects of a merger in some cases requires the inclusion of assets or projects that are beyond the affected relevant markets. As the *U.S. Department of Justice Antitrust Division Policy Guide to Merger Remedies* explains, the United States will exercise its enforcement discretion to accept a divestiture only when it is persuaded that the divested ''assets will create a viable entity that will effectively preserve competition.'' *See Antitrust Division Policy Guide to Merger Remedies* at 9 (June 2011) (available at https://www.justice.gov/atr/public/guidelines/272350.pdf). Because Bayer does not operate its businesses that compete with Monsanto as separate, standalone entities, to ensure effective relief the United States is also requiring the divestiture of assets that are complementary to the competitive products or that use shared resources. *See id.* at 11 (''[I]ntegrated firms can provide scale and scope economies that a purchaser may not be able to achieve by obtaining only those assets related to the relevant product(s).''). Finally, effective relief also requires divestiture of those ''pipeline'' research projects that Bayer is pursuing to ensure the future competitive significance of the divested businesses.

Guided by these principles, the United States identified a divestiture package that remedies the various dimensions of harm threatened by the proposed merger. First, the proposed Final Judgment requires Bayer to divest those businesses that vigorously compete head-to-head with Monsanto today. Second, to address certain vertical concerns, the proposed Final Judgment requires Bayer to divest seed treatment businesses that would give the combined company the incentive and ability to harm competition by raising the prices it charges rival seed companies. Third, because Bayer and Monsanto compete to develop new products and services for farmers, the

proposed Final Judgment requires the divestiture of associated intellectual property and research capabilities, including ''pipeline'' projects, to enable BASF to replace Bayer as a leading innovator in the relevant markets. Fourth, the proposed Final Judgment requires the divestiture of additional assets that will give BASF the scale and scope to compete effectively today and in the future.

Because many of the divested assets will be separated from Bayer's existing business units and incorporated into BASF, the proposed Final Judgment includes provisions aimed at ensuring that the assets are handed off in a seamless and efficient manner. To that end, Bayer is required to transfer existing third-party agreements and customer information to BASF, as well as to enter transition services agreements that ensure that BASF can continue to serve customers immediately upon completion of the divestitures. The transition services and interim supply agreements are time-limited to ensure that BASF will become fully independent of Bayer as soon as practicable. The proposed Final Judgment also requires Bayer to warrant that the assets being divested are sufficient for BASF to maintain the viability and competitiveness of the divested businesses following BASF's acquisition of the assets. In addition, it gives BASF a one-year window after closing to identify any additional assets that are reasonably necessary to ensure the continued competitiveness of the divested businesses. The United States will have the sole discretion to determine if Bayer must divest these additional assets. Finally, the proposed Final Judgment gives BASF the ability to hire all of the personnel from Bayer needed to support these businesses.

BASF is the only buyer the United States has evaluated and deemed suitable to resolve the range of competitive concerns raised by the merger. BASF already has extensive agricultural experience, but it lacks a seeds and traits business. Combining the businesses and assets being divested with BASF's existing portfolio will allow it to become an integrated player and an effective industry competitor to the merged company and the other integrated players. BASF will have full control over these divested businesses, including the ability to assign licenses and other rights.

In sum, the proposed remedies will ensure that BASF can step into Bayer's shoes, thereby preserving the competition that the merger would otherwise destroy. The monitoring trustee to be appointed will have close oversight over the divestitures to ensure they proceed efficiently (*see, infra,* Section III.H). And, as additional protection, the proposed Final Judgment includes robust mechanisms that will allow the United States and the Court to monitor the effectiveness of the relief and to enforce compliance.

A. GM Seeds and Traits

Section IV of the proposed Final Judgment requires Bayer to divest all assets used by Bayer's GM seeds and traits businesses in the United States, including Bayer's cotton, canola, and soybean seeds and traits businesses, as well as almost all of the assets associated with Bayer's other global GM seeds and traits businesses. Because Bayer and Monsanto are currently competing to introduce the next blockbuster trait or plant variety, BASF can replace Bayer as a competitor only if BASF obtains all the assets required to continue Bayer's legacy of innovation. This includes all assets needed to offer farmers the new products that Bayer was poised to commercialize in the coming years. Notably, BASF will receive all of Bayer's trait research centers (including facilities in Morrisville, North Carolina; Ghent, Belgium; and Astene, Belgium). The proposed Final Judgment also requires Bayer to transfer all intangible assets used by these businesses, such as patents, know-how, and licenses or permits issued by government agencies.

There are limited exceptions to Bayer's obligation to divest all of the assets used by its global GM seeds and traits businesses. Certain assets used exclusively to support a handful of Bayer's small seed businesses or research programs outside of the United States are excluded from the Divestiture Assets. These exceptions are related to (1) rice seed, which Bayer sells only in Asia; (2) Bayer's millet, mustard, and cotton seed businesses in India; (3) R&D programs for Brazilian sugarcane and European sugarbeets; and (4) Bayer's cotton seed business in South Africa. None of these is closely related to the divested U.S. seeds and traits businesses. Bayer will also retain a number of general office facilities that house employees of businesses not affected by the divestitures, as well as one seed cleaning and bagging facility in Germany that is part of Bayer's Crop Science headquarters.

The proposed Final Judgment also requires Bayer to provide BASF with certain complementary assets, which will give scale and scope benefits to the divested GM seeds and traits businesses, and supply agreements, which will allow BASF to maintain the competitiveness of those businesses as they are transitioned from Bayer.

First, the proposed Final Judgment requires divestiture of Bayer's R&D programs associated with wheat. Bayer does not currently sell wheat in the United States, but it has been pursuing wheat-related research to expand the scope of its global seeds and traits portfolio and sustain the level of R&D investment these businesses require. Because seed and trait innovations can often be applied across multiple crops, a broader seed and trait portfolio will provide the promise of higher returns on investment and increase the incentive to innovate. The proposed Final Judgment preserves the scope efficiencies that Bayer enjoys today by keeping these businesses together. Moreover, separating the wheat business from Bayer's other seeds and traits businesses would have required disentangling and dividing integrated operations and assets. For instance, Bayer's research facility in Ghent, Belgium is used to support R&D for wheat as well as other crops. By requiring the divestiture of Bayer's wheat R&D programs and related facilities, the proposed Final Judgment ensures that BASF has all of the tools needed to run the divested businesses and can leverage these common resources as effectively as Bayer does today.

Second, under Paragraph IV.G of the proposed Final Judgment, Bayer will supply BASF with the seed treatments Bayer currently applies to its row crop seeds for a period of up to two years, with extensions subject to approval by the United States. This will allow BASF to offer farmers the same combinations of seeds and seed treatments that Bayer offers today without interruption. During the term of these supply agreements, BASF will transition to using (1) its own seed treatments, (2) the seed treatments it is acquiring from Bayer pursuant to the proposed Final Judgment (discussed in more detail below), (3) seed treatments from alternate suppliers, or (4) a combination thereof.

Third, Paragraph IV.N of the proposed Final Judgment requires Bayer to divest certain groups of Monsanto soybeans used for research and breeding (referred to in the industry as ''germplasm''). As discussed in the Complaint, Bayer has aggressively challenged Monsanto in the soybean market, and planned to continue to expand. However, Bayer currently lacks soybeans suitable for the Midwest, an important soybean growing region in the United States. By providing BASF with a richer pool of genetic material, the proposed Final Judgment creates a strong incentive for

BASF to continue Bayer's efforts to disrupt the market and provide new benefits to farmers and consumers.

B. Foundational Herbicides

Section IV of the proposed Final Judgment also requires Bayer to divest assets relating to its foundational herbicides business. The proposed Final Judgment requires Bayer to divest all intellectual property related to glufosinate, the active ingredient in Bayer's Liberty herbicide, including intellectual property relating to mixtures of glufosinate with other chemicals. Bayer is also required to divest its R&D projects, which will incentivize BASF to continue to develop new innovations for farmers.

In addition, Bayer will be required to divest all facilities used to manufacture glufosinate. Bayer will also divest certain facilities used to ''formulate'' (*i.e.,* mix with water and other inactive ingredients) and package glufosinate to create Liberty for sale to customers. Specifically, the proposed Final Judgment requires Bayer to divest its large North American facilities in Regina, Canada and Muskegon, Michigan, which formulate and package a significant percentage of the Liberty sold in the United States. Because Bayer's global formulation facilities are also used for unrelated products not being divested and supply very little of the Liberty used in the United States, the proposed Final Judgment permits Bayer to retain some formulation facilities, most of which are located outside the United States. However, Paragraph IV.G of the proposed Final Judgment requires Bayer to enter into an agreement to formulate Liberty for BASF, at cost, for up to three years to ensure that BASF can meet farmer demand for the product during the transition. The proposed Final Judgment limits the duration of these formulation services to ensure that BASF will become fully independent of Bayer as soon as practicable.

In certain countries outside of the United States, the proposed Final Judgment also provides that Bayer will distribute glufosinate products on BASF's behalf for a limited period. This accommodation affects only a small portion of total glufosinate sales and ensures business continuity in those international jurisdictions in which BASF requires time to develop the business infrastructure or to secure the local regulatory authorizations necessary to sell the product. To encourage BASF to become fully independent from Bayer as soon as practicable, the proposed Final Judgment limits the duration of these services, and BASF can terminate these distribution contracts on a country-by-country basis as soon as it is able to distribute these products on its own.

C. Pipeline Herbicides

The proposed Final Judgment requires the divestiture of certain crop protection products that are complementary to Bayer's trait business. Today, Bayer engages in parallel research across its various seeds and crop protection businesses, developing new herbicides and new traits that confer tolerance to those herbicides. Bayer is motivated to pursue trait research in part because successful commercialization of a trait will generate additional returns through the sale of the associated herbicide, and vice versa. Therefore, Section IV of the proposed Final Judgment also requires Bayer to divest its R&D projects relating to ketoenole and N,O-chelator (''NOC'') herbicides. These herbicides, if successful, would be sold in conjunction with the ketoenole- and NOC-tolerant traits Bayer is developing, which also are being divested. By requiring divestiture of both the trait projects and the associated herbicide projects, the proposed Final Judgment preserves BASF's incentive to pursue these innovations.

The proposed Final Judgment also provides BASF full access to Bayer's Balance Bean herbicide. Bayer recently introduced BalanceGT soybeans, which contain a GM trait conveying tolerance to both glyphosate and isoxaflutole, a selective herbicide contained in Bayer's Balance Bean product. BalanceGT soybeans are poised to compete with Monsanto's herbicide-tolerant soybeans, but Balance Bean is not yet approved for spraying over the top of crops. The proposed Final Judgment requires Bayer to transfer intellectual property associated with its Balance Bean herbicide business to BASF; Paragraph IV.G gives BASF the option of entering a temporary isoxaflutole supply agreement with Bayer; and Paragraph IV.L commits Bayer to using best efforts to obtain the remaining regulatory approvals for use of isoxaflutole over the top of crops. These requirements ensure that BASF will have the same ability to offer farmers the combination of both the BalanceGT trait and the Balance Bean herbicide as Bayer would have if the merger had not occurred.

D. Seed Treatments

Section IV of the proposed Final Judgment also requires Bayer to divest assets relating to its seed treatment businesses. Collectively, these divestitures remedy the likely anticompetitive effects of the merger that would arise both from the horizontal combination of Bayer's and Monsanto's nematicidal seed treatments, as well as from the vertical integration of Bayer's dominant seed treatments and Monsanto's dominant seed businesses.

First, the proposed Final Judgment requires Bayer to divest all intellectual property associated with its Poncho, VOTiVO, and TWO.0 seed treatment brands. The Complaint alleges that the merged firm could use its control over Poncho, which is uniquely effective against corn rootworm, to disadvantage its corn seed rivals and diminish competition in the GM corn seed market. VOTiVO is an important nematicidal seed treatment for corn, soy, and cotton, and in combination with other divestitures described below, its divestiture to BASF remedies the merger's likely harm in the market for nematicidal seed treatments. Because VOTiVO and TWO.0 are each typically sold in combination with Poncho, divestiture of the intellectual property associated with all three products will allow BASF to offer American farmers the same packages of Poncho-branded seed treatments as Bayer does today.

The proposed Final Judgment also requires Bayer to divest intellectual property associated with its ILeVO and COPeO seed treatments, which are both based on the same active ingredient, fluopyram. ILeVO and COPeO protect soybeans and cotton seeds, respectively, from nematodes; ILeVO is also the first seed treatment to combat soybean SDS effectively. The ILeVO and COPeO divestitures, in combination with the divestiture of VOTiVO, will address the merger's likely harm in the markets for nematicidal seed treatments. The divestiture of ILeVO will also prevent Bayer from using its control over ILeVO to disadvantage Monsanto's soybean seed rivals and diminish competition in the market for GM soybean seeds, as alleged in the Complaint.

Bayer also will transfer all intellectual property used by these divested seed treatment businesses, including all patents, licenses, know-how, trade names, and data or information collected on the products. The only exception is patents related to fluopyram, which Bayer primarily uses in other non-seed treatment products, such as fungicides applied to foliage. Therefore, the proposed Final Judgment requires Bayer to provide BASF with a perpetual, royalty-free license for all patents related to the use of fluopyram in seed treatments. The proposed Final Judgment also requires Bayer to divest all R&D projects associated with these seed treatment products, as well as a

product in development that would expand and improve on these existing seed treatment businesses.

Paragraph IV.G of the proposed Final Judgment requires Bayer, at BASF's option, to toll manufacture the active ingredients used in the divested seed treatments for an initial period of up to two years, and to provide formulation and distribution services for the seed treatments for up to two years. With prior approval of the United States, certain of these arrangements may be extended for up to an additional four years. These agreements ensure that BASF can immediately replace Bayer as an effective competitor with the divested seed treatments. BASF has its own existing seed treatment businesses and will use the time under the agreements to prepare its own facilities to manufacture and distribute the seed treatments, or to arrange for other suppliers to do so.

E. Digital Agriculture

Section IV of the proposed Final Judgment also requires Bayer to divest its digital agriculture business to BASF. Currently, the leading global agricultural businesses project that the industry will move toward ''integrated solutions,'' which are combinations of traditional agricultural input products that are optimized for use with one another or combined with other services. These companies have described digital agriculture as the ''glue'' that binds the products together and the core of any future integrated solution. This trend has led them to develop digital agriculture products to protect their position in traditional agricultural markets, including GM seed markets. To provide BASF with the digital agriculture capabilities needed to replace Bayer as a competitor going forward, the proposed Final Judgment requires Bayer to divest all assets related to its digital agriculture portfolio and pipeline of products.

F. Vegetables

Finally, Section IV of the proposed Final Judgment requires Bayer to divest a comprehensive set of tangible and intangible assets representing Bayer's entire global vegetable seed business. Bayer's vegetable seed business operates under the Nunhems brand name, a business acquired by Bayer in 2002.

The assets to be divested include all of Bayer's vegetable seed breeding capabilities, which encompass 24 different crops (including tomatoes, onions, carrots, cucumbers, and watermelons, among others) and approximately 2,400 varieties. Additional assets to be divested include Bayer's worldwide headquarters in Nunhem, Netherlands, and all global R&D facilities, sales offices, and operations centers. This will provide BASF with the necessary assets and infrastructure to continue vigorously competing, innovating, and developing new vegetable varieties. All customer information, including lists, accounts, and credit records will also be transferred to ensure that existing customers receive uninterrupted service.

Bayer also will divest intangible assets currently used by the vegetable seed business. Critically, all intellectual property—including patents, licenses, and copyrights—will be transferred to BASF. In addition, BASF will receive research data relating to historic and current R&D efforts. These divestitures will allow BASF to develop new and innovative vegetable seeds for current and future customers.

G. Employees

As part of the divestitures, over four thousand Bayer employees who currently support the various divestiture businesses will become BASF employees. These employees will immediately bring critical business experience to BASF. As an added safeguard, Paragraph IV.E of the proposed Final Judgment provides BASF the right to hire additional personnel to ensure that BASF can become as effective a competitor and innovator as Bayer is today in each of the relevant markets. Bayer is required to make information available to BASF about the employees supporting the businesses and assets to be divested, subject to applicable privacy and confidentiality protections. BASF then will have the right to make offers of employment to these individuals. To ensure that BASF will have the ability to hire experienced personnel, the proposed Final Judgment prohibits Bayer from interfering with BASF's efforts to hire any Bayer or Monsanto employees with relevant expertise.

H. Monitoring Trustee

Section VIII of the proposed Final Judgment provides the United States the option to seek the appointment of a Monitoring Trustee subject to the Court's approval. The United States intends to recommend a trustee for the Court's approval. The person selected will have the necessary expertise and experience to ensure that competition continues unabated across the various markets. Given the scope of the required divestitures, it is critical that the trustee be in a position to review and resolve any issues that may arise beginning immediately after the divestitures are completed.

The Monitoring Trustee will ensure: (1) that Defendants expeditiously comply with all of their obligations and perform all of their responsibilities under the proposed Final Judgment and the Stipulation and Order, (2) that the Divestiture Assets remain economically viable, competitive, and ongoing businesses prior to being fully divested to BASF, and (3) that competition in the relevant businesses is maintained throughout the United States. The Monitoring Trustee will have the power and authority to monitor the Defendants' compliance with the terms of the proposed Final Judgment. The Monitoring Trustee also will have the authority to investigate complaints relating to Bayer and Monsanto's compliance with the proposed Final Judgment including, but not limited to, any complaints relating to the agreements Bayer and Monsanto have or will enter into with BASF. The Monitoring Trustee will have access to all personnel, books, records, and information necessary to monitor Defendants' compliance with the proposed Final Judgment, and will serve at the cost and expense of Bayer.

The Monitoring Trustee will file reports every 30 days with the United States and, as appropriate, the Court until the completion of the required divestitures. The reports will set forth the efforts by Bayer and Monsanto to comply with their obligations under the proposed Final Judgment and the Stipulation and Order. After completion of the divestitures, the Monitoring Trustee will provide reports as requested by the United States.

I. Firewall

Section IX of the proposed Final Judgment requires Bayer and BASF to implement firewall procedures to prevent each company's confidential business information from being used by the other for any purpose that could harm competition. Within twenty days of the Court approving the Stipulation and Order, Bayer and Monsanto must submit their planned procedures for maintaining firewalls. Additionally, Bayer and BASF must explain the requirements of the firewalls to certain officers and other business personnel responsible for the commercial relationships between the two companies about the required treatment of confidential business information. Bayer's and BASF's adherence to these procedures is subject to a semi-annual audit by the Monitoring Trustee. These measures are necessary to ensure that the supply and transition services

agreements between Bayer and BASF do not facilitate coordination or other anticompetitive behavior during the interim period before BASF becomes fully independent of Bayer.

J. Prohibition on Recombinations

To ensure that BASF and Bayer remain independent competitors, Section XI of the proposed Final Judgment prohibits Bayer and BASF from recombining any of the Divestiture Assets with competing Bayer businesses. First, Bayer is prohibited from reacquiring any of the Divestiture Assets during the term of the Final Judgment. Second, BASF may not acquire from Bayer any assets or businesses that compete with the Divestiture Assets. These provisions ensure that Bayer and BASF cannot undermine the purpose of the proposed Final Judgment by later entering into a new transaction that would reduce the competition that the divestitures have preserved. Finally, Section XI prohibits Bayer and BASF from entering into any new collaboration, such as a research and development joint venture, or from expanding the scope of any existing collaboration, involving the Divestiture Assets. This provision prevents Bayer and BASF from circumventing the purpose of the proposed Final Judgment by, for example, entering into a partnership to jointly develop new traits, which could reduce or eliminate BASF's incentive to innovate independently in some or all of the relevant markets. The provision permits BASF and Bayer to engage in certain ordinary-course-of-business commercial relationships, such as crop protection product supply agreements. They also may engage in other collaborations if approved by the United States in its sole discretion.

K. Enforcement Provisions

The proposed Final Judgment contains provisions designed to promote compliance and make the enforcement of consent decrees as effective as possible. As set forth in the Stipulation and Order, BASF has agreed to be joined to this action for purposes of the divestiture. Including BASF is appropriate because, after extensive analysis, the United States has determined that BASF is a necessary party to effectuate complete relief; the divestiture package was crafted specifically taking into consideration BASF's existing assets and capabilities, and divesting the package to another purchaser would not preserve competition. Thus, as discussed above, the proposed Final Judgment imposes certain obligations on BASF to ensure that the divestitures take place expeditiously and that BASF and Bayer reduce entanglements as quickly as possible after BASF acquires the Divestiture Assets.

Paragraph XIV.A provides that the United States retains and reserves all rights to enforce the provisions of the proposed Final Judgment, including rights to seek an order of contempt from the Court. Under the terms of this Paragraph, all Defendants, including BASF, have agreed that in any civil contempt action, any motion to show cause, or any other similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence, and that the Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance obligations with the standard of proof that applies to the underlying offense that the compliance commitments address.

Paragraph XIV.B provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. The proposed Final Judgment was drafted to restore all competition that would otherwise be harmed by the merger. The Defendants agree that they will abide by the proposed Final Judgment, and that they may be held in contempt of this Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of this procompetitive purpose.

Paragraph XIV.C of the proposed Final Judgment further provides that should the Court find in an enforcement proceeding that the Defendants have violated the Final Judgment, the United States may apply to the Court for a one-time extension of the Final Judgment, together with such other relief as may be appropriate. In addition, in order to compensate American taxpayers for any costs associated with the investigation and enforcement of violations of the proposed Final Judgment, Paragraph XIV.C provides that in any successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved prior to litigation, that Defendant agrees to reimburse the United States for attorneys' fees, experts' fees, or costs incurred in connection with any enforcement effort, including the investigation of the potential violation.

Finally, Section XV of the proposed Final Judgment provides that the Final Judgment will expire ten years from the date of its entry, except that after six (6) years from the date of its entry, the Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestitures have been completed and that the continuation of the Final Judgment is no longer necessary or in the public interest.

L. Stipulation and Order

Bayer, Monsanto, and BASF have entered into the Stipulation and Order, which was filed with the Court at the same time as the Complaint, to ensure that, pending the divestitures, the Divestiture Assets are maintained such that the divestitures will be effective. The Stipulation and Order also requires Bayer to hold Monsanto as a separate entity until the divestitures are complete, so that the merger can be unwound if Bayer fails to complete the required divestitures to BASF. This step is necessary in this case because the divestiture package was crafted specifically taking into consideration BASF's existing assets and capabilities, and if BASF is unable to acquire the assets, simply divesting the package to another purchaser would not preserve competition. The Stipulation and Order also binds all three defendants to the terms of the proposed Final Judgment pending the Judgment's entry by the Court.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

Section 4 of the Clayton Act, 15 U.S.C. § 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damages action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. § 16(a), the proposed Final Judgment has no prima facie effect in any subsequent lawsuit that may be brought against Defendants.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENT

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the Antitrust Division's internet website and, in certain circumstances, published in the **Federal Register**.

Written comments should be submitted by mail to:

Kathleen S. O'Neill
Chief, Transportation, Energy & Agriculture Section
Antitrust Division
United States Department of Justice
450 5th Street, NW, Suite 8000
Washington, DC 20530

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any necessary or appropriate modification, interpretation, or enforcement of the Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT

The United States considered, as an alternative to the proposed Final Judgment, seeking preliminary and permanent injunctions against the merger and proceeding to a full trial on the merits. The United States is satisfied, however, that the relief in the proposed Final Judgment will preserve competition in each relevant market in the United States. Thus, the proposed Final Judgment will protect competition as effectively as, and will achieve all or substantially all of the relief the United States would have obtained through, litigation, but avoids the time, expense, and uncertainty of a full trial on the merits.

VII. STANDARD OF REVIEW UNDER THE APPA FOR THE PROPOSED FINAL JUDGMENT

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. § 16(e)(1). In making such a determination, the court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1, 15–17 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States* v. *U.S. Airways Group, Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009–2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, at *3, (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable'').[2]

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[3] In determining whether a proposed settlement is in the public interest, a court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that a court should not reject the proposed remedies because it believes others are preferable); *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect

[2] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for courts to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004), *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

[3] *Cf. BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have greater flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.''' *United States* v. *Am. Tel. & Tel. Co.,* 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (noting that room must be made for the government to grant concessions in the negotiation process for settlements (citing *Microsoft,* 56 F.3d at 1461)); *United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged.''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60. As a court in this district confirmed in *SBC Communications,* courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' 489 F. Supp. 2d at 15.

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). The language wrote into the statute what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11.[4] A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 38 F. Supp. 3d at 76.

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: May 29, 2018

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[4] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); *United States* v. *Mid-Am. Dairymen, Inc.,* No. 73–CV–681–W–1, 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980, *22 (W.D. Mo. 1977) (''Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.''); S. Rep. No. 93–298, at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

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