hearing,’’ which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects 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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule by preparing a certification that it will not have a significant economic impact on a substantial number of small entities. On February 10, 2014, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these four synthetic cannabinoids into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 79 FR 7577. On February 5, 2016, the DEA published a final order extending the temporary placement of these substances in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). 81 FR 6175. Accordingly, all entities that currently handle or plan to handle these synthetic cannabinoids are estimated to have already established and implemented the systems and processes required to handle 5F-PB-22, 5F-PB-22, AB-FUBINACA, and ADB-PINACA. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on businesses that currently handle PB-22, 5F-PB-22, AB-FUBINACA, or ADB-PINACA for lawful purposes. This estimate applies to entities large and small. Accordingly, the DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 et seq., that this action will not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: “an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets.” However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

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, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

2. Amend § 1308.11 as follows:

a. Add paragraphs (d)(51) through (54); 

b. Remove paragraphs (h)(4) through (7); 

c. Redesignate paragraphs (h)(8) through (22) as paragraphs (h)(4) through (18); and 

d. Redesignate paragraphs (h)(26) and (27) as paragraphs (h)(19) and (20).

The additions read as follows:

§ 1308.11 Schedule I.

(d) * * * * *(d) * * * * *(51) quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC) ............................................ (7222)

(52) quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) ............................................ (7225)

(53) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA) (7012)

(54) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA) ............................... (7035)

* * * * *

Dated: August 30, 2016.

Chuck Rosenberg,
Acting Administrator.
[PR Doc. 2016–21345 Filed 9–2–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0241]

RIN 1625–AA00

Safety Zone; Swim Around Charleston; Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.
I. Background Information and Regulatory History

On March 17, 2016, Kathleen Wilson notified the Coast Guard that she will be sponsoring the Swim Around Charleston from 9 a.m. to 3:30 p.m. on September 25, 2016. In response, on June 6, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone, Swim Around Charleston; Charleston, SC. There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this special local regulation. During the comment period that ended July 7, 2016, we received no comments.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the Federal Register. Delaying the effective date of this rule would be impracticable due to the date of the event. The Coast Guard did not receive any adverse comments during the period outlined in the NPRM with regard to this rule.

III. Legal Authority and Need for Rule

The legal basis for this rule is the Coast Guard’s Authority to establish regulated navigation areas and other limited access areas: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; and Department of Homeland Security Delegation No. 0170.1.

The purpose of the rule is to ensure the safety of the swimmers, participant vessels, spectators, and the general public life during the Swim Around Charleston.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published June 6, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 8:45 a.m. to 3:45 p.m. on September 25, 2016. The safety zone will cover a portion of the waters of the Wando River, Cooper River, Charleston Harbor, and Ashley River, in Charleston, South Carolina. Approximately 120 swimmers are anticipated to participate in the race. Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative. The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entity” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. 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 discussed in the Regulatory Planning and Review section above, this rule will not have a
significant economic impact on a substantial number of small entities. Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Enforcement 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 1–888–639–FARIR (1–888–639–3274). 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.

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 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 Management 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 temporary safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist and a Categorical Exclusion Determination was completed for 2016. The environmental analysis checklist and Categorical Exclusion Determination are available in the docket folder where indicated under ADDRESSES. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

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

§ 165.0241 Swim Around Charleston, Charleston, SC

(a) Regulated area. The following regulated area is a moving safety zone: All waters within a 50-yard radius in front of the lead safety vessel preceding the first race participants, 50 yards behind the safety vessel trailing the last race participants, and at all times extend 100 yards on either side of safety vessels. The Swim Around Charleston swimming race consists of a 12 mile course that starts at Remley Point on the Wando River in approximate position 32°48'49" N., 79°54'27" W., crosses the main shipping channel of Charleston Harbor, and finishes at the General William B. Westmoreland Bridge on the Ashley River in approximate position 32°50'14" N., 80°03'23" W. All coordinates are North American Datum 1983.

(b) Definition. The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated area.

(c) Regulations. (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, or anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Marine Safety Information Bulletins, Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) Effective date. This rule will be effective on September 25, 2016 and
will be enforced from 8:45 a.m. until 3:45 p.m.

B.D. Falk,  
Commander, U.S. Coast Guard, Acting  
Captain of the Port Charleston.

[FR Doc. 2016–21272 Filed 9–2–16; 8:45 am]  
BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION  
AGENCY

40 CFR Part 81  
OAR]

Air Quality Designations for the 2012  
Primary Annual Fine Particle (PM2.5)  
National Ambient Air Quality Standard  
(NAAQS) for Areas in Georgia and Florida

AGENCY: Environmental Protection  
Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection  
Agency (EPA) is establishing air quality  
designations in the United States (U.S.)  
for the 2012 primary annual fine  
particle (PM2.5) National Ambient Air  
Quality Standard (NAAQS) for areas in  
Georgia and Florida. When the EPA  
designated the majority of areas in the  
country in December 2014, and March 2015,  
the EPA deferred initial area designations  
for several locations, including these  
areas, because the EPA could not  
determine using available data whether  
the areas were meeting or not meeting  
the NAAQS, but we believed that  
forthcoming data in 2015 would allow  
the EPA to make that determination.  
Georgia and Florida have recently  
submitted complete, quality-assured,  
and certified air quality monitoring data  
for 2015 for the areas identified in this  
notice, and based on these data, the EPA  
is designating these areas as  
unclassifiable/attainment for the 2012  
primary annual PM2.5 NAAQS.

DATES: This final rule is effective on  
October 6, 2016.

ADDRESSES: The EPA has established  
docket for this action under Docket ID  
No. EPA–HQ–OAR–2012–0918. All  
documents in the docket are listed in  
the http://www.regulations.gov Web  
site. Although listed in the index, some  
information is not publicly available,  
C.

CONFIDENTIAL BUSINESS INFORMATION  
or other information whose disclosure  
is restricted by statute. Certain other  
material, such as copyrighted material,  
is not placed on the Internet and will be  
publicly available only in hard copy  
form. Publicly available docket  
materials are available either  
electronically in http://  
www.regulations.gov.

In addition, the EPA has established  
a Web site for the rulemakings to  
initially designate areas for the 2012  
primary annual PM2.5 NAAQS at:  
https://www3.epa.gov/pm25designations/  
2012standards/index.htm. This Web  
site includes the EPA’s final area  
designations for the PM2.5 NAAQS, as  
well as state and tribal initial  
recommendation letters, the EPA’s  
modification letters, technical support  
documents, responses to comments and  
other related technical information.

FOR FURTHER INFORMATION CONTACT: For  
general questions concerning this  
action, please contact Carla Oldham,  
U.S. EPA, Office of Air Quality Planning  
and Standards, Air Quality Planning  
Division, C539–04, Research Triangle  
Park, North Carolina 27711, telephone  
(919) 541–3347, email at oldham.carla@  
epa.gov. The Region 4 contact is  
Madolyn Sanchez, U.S. EPA, Air  
Regulatory Management Section, Air  
Planning and Implementation Branch,  
Air, Pesticides and Toxics Management  
Division, 61 Forsyth Street SW., Atlanta,  
Georgia 30303–8960, telephone (404)  
562–9644, email at sanchez.madolyn@  
epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 2012, the EPA  
promulgated a revised primary annual  
PM2.5 NAAQS to provide increased  
protection of public health from fine  
particle pollution (78 FR 3086; January  
15, 2013). In that action, the EPA  
strengthened the primary annual PM2.5  
standard from 15.0 micrograms per  
cubic meter (µg/m³) to 12.0 µg/m³, which  
is attained when the 3-year  
average of the annual arithmetic means  
does not exceed 12.0 µg/m³.  
Section 107(d) of the Clean Air Act  
(CAA), 42 U.S.C. 7470(d), governs the  
process for initial area designations  
after the EPA establishes a new or revised  
NAAQS. Under CAA section 107(d),  
each governor is required to, and each  
tribal leader may, if they so choose,  
recommend air quality designations,  
including the appropriate boundaries  
for “nonattainment” areas, to the EPA  
by a date which cannot be later than 1  
year after the promulgation of a new or  
revised NAAQS. The EPA considers  
these recommendations as part of its  
duty to promulgate the area  
designations and boundaries for the new  
or revised NAAQS. If, after careful  
consideration of these  
recommendations, the EPA believes that  
it is necessary to modify a state’s  
recommendation and intends to  
promulgate a designation different from  
a state’s recommendation, the EPA must  
notify the state at least 120 days prior  
to promulgating the final designation  
and the EPA must provide the state an  
opportunity to demonstrate why any  
proposed modification is inappropriate.  
These modifications may relate either to  
an area’s designation or boundaries.  
On December 18, 2014, the  
Administrator of the EPA signed a final  
action promulgating initial designations  
for the 2012 PM2.5 NAAQS for the  
majority of the U.S., including areas of  
Indian country (80 FR 2206 FR; January  
15, 2015). That action designated  
14 areas in six states, including two multi-  
state areas, as nonattainment for the  
2012 PM2.5 NAAQS. The EPA also  
designated three areas, including the  
entire state of Illinois, as  
“unclassifiable” because the ambient air  
quality monitoring sites in these areas  
lacked complete data for the relevant  
period from 2011–2013. In the absence  
of complete monitoring data, the EPA  
could not determine, based on available  
information, whether these areas meet  
or do not meet the NAAQS, and also  
could not determine whether these areas  
contribute to a nearby violation.  
Consistent with the EPA’s “Policy for  
Establishing Separate Air Quality  
Designations for Areas of Indian  
Country” (December 20, 2011), the EPA  
designated the lands of the Pechanga  
Band of Luiseño Mission Indians in  
Southern California as an unclassifiable/  
attainment area separate from its  
adjacent/annexed counties.

Except for the 10 areas discussed in the next  
paragraph, the EPA designated all the  
remaining state areas and areas of  
Indian country as unclassifiable/  
attainment.

The EPA deferred initial area  
designations for 10 areas where  
available data, including air quality  
monitoring data, were insufficient to  
determine whether the areas met or did  
not meet the NAAQS, but where  
forthcoming data were likely to result in  
complete and valid air quality data  
sufficient to determine whether these  
areas meet the NAAQS. Accordingly,  
the EPA stated that it would use the  
additional time available as provided  
under section 107(d)(1)(B) of the CAA  
to assess relevant information and  
subsequently promulgate initial  
designations for the identified areas  
through a separate rulemaking action or  
actions. The 10 deferred areas included:  
Eight areas in the state of Georgia,  
including two neighboring counties in  
the bordering states of Alabama and  
South Carolina; the entire state of  
Tennessee, excluding three counties in  