

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 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 and by approving it certifies 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 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)	*	*	*	
(51)	quinolin-8-yl 1-pentyl-1 <i>H</i> -indole-3-carboxylate (PB-22; QUPIC) .....	(7222)		
(52)	quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) .....	(7225)		
(53)	<i>N</i> -(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamide (AB-FUBINACA) .....	(7012)		
(54)	<i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (ADB-PINACA) .....	(7035)		
*	*	*	*	*

Dated: August 30, 2016.

**Chuck Rosenberg,**

*Acting Administrator.*

[FR 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.

**SUMMARY:** The Coast Guard is establishing a temporary moving safety zone during the Swim Around Charleston, a swimming race occurring on the Wando River, the Cooper River, Charleston Harbor, and the Ashley River, in Charleston, South Carolina on September 25, 2016. The temporary safety zone is necessary for the safety of the swimmers, participant vessels, spectators, and the general public during the event. The temporary safety zone will restrict vessel traffic in portions of the Charleston Harbor and surrounding rivers. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

**DATES:** This rule is effective on September 25, 2016 from 8:45 a.m. until 3:45 p.m.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> type USCG-2016-0241 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 Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740-3184, email [John.Z.Downing@uscg.mil](mailto:John.Z.Downing@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Table of Abbreviations**

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

##### **II. 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 regulated area 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.

##### **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 protesters.

##### **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 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

The economic impact of this rule is not significant for the following reasons: (1) The temporary safety zone will be enforced for a total of seven hours; (2) the safety zone will move with the participant vessels so that once the swimmers clear a portion of the waterway, the safety zone will no longer be enforced in that portion of the waterway; (3) although persons and vessels may not enter, transit through, anchor in, or remain within the safety zone without authorization from the Captain of the Port Charleston or a designated representative; they may operate in the surrounding area during the enforcement period; (4) persons and vessels may still enter, transit through, anchor in, or remain within the safety zone if authorized by the Captain of the Port Charleston or a designated representative; and (5) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

##### **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 entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this 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 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.

#### 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.ID, 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

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 160.5; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T07–0241 to read as follows:

#### § 165.T07–0241 Safety Zone; 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°01'23" 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 areas.

(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, 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

[EPA–HQ–OAR–2012–0918; FRL–9951–91–OAR]

#### Air Quality Designations for the 2012 Primary Annual Fine Particle (PM<sub>2.5</sub>) 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 (PM<sub>2.5</sub>) National Ambient Air Quality Standard (NAAQS) for three areas in Georgia and 62 counties in 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 PM<sub>2.5</sub> NAAQS.

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

**ADDRESSES:** The EPA has established a 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, *i.e.*, 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 PM<sub>2.5</sub> NAAQS at: <https://www3.epa.gov/pmdesignations/2012standards/index.htm>. This Web site includes the EPA's final area designations for the PM<sub>2.5</sub> 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](mailto: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](mailto:sanchez.madolyn@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 14, 2012, the EPA promulgated a revised primary annual PM<sub>2.5</sub> 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 PM<sub>2.5</sub> standard from 15.0 micrograms per cubic meter (µg/m<sup>3</sup>) to 12.0 µg/m<sup>3</sup>, which is attained when the 3-year average of the annual arithmetic means does not exceed 12.0 µg/m<sup>3</sup>.

Section 107(d) of the Clean Air Act (CAA), 42 U.S.C. 7407(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 PM<sub>2.5</sub> 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 PM<sub>2.5</sub> 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/surrounding state areas. 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