

Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). 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; the collections of information in part 820, regarding design controls, have been approved under OMB control number 0910–0073; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

#### PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for part 884 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 884.5370 to subpart F to read as follows:

##### § 884.5370 Software application for contraception.

(a) *Identification.* A software application for contraception is a device that provides user-specific fertility information for preventing a pregnancy. This device includes an algorithm that performs analysis of patient-specific data (e.g., temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days, then provides patient-specific recommendations related to contraception.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate the contraceptive effectiveness of the software in the intended use population.

(2) Human factors performance evaluation must be provided to demonstrate that the intended users can self-identify that they are in the intended use population and can

correctly use the application, based solely on reading the directions for use for contraception.

(3) Software verification, validation, and hazard analysis must be performed. Documentation must include the following:

(i) A cybersecurity vulnerability and management process to assure software functionality; and

(ii) A description of the technical parameters of the software, including the algorithm used to determine fertility status and alerts for user inputs outside of expected ranges.

(4) Labeling must include:

(i) The following warnings and precautions:

(A) A statement that no contraceptive method is 100% effective.

(B) A statement that another form of contraception (or abstinence) must be used on days specified by the application.

(C) Statements of any factors that may affect the accuracy of the contraceptive information.

(D) A warning that the application cannot protect against sexually transmitted infections.

(ii) Hardware platform and operating system requirements.

(iii) Instructions identifying and explaining how to use the software application, including required user inputs and how to interpret the application outputs.

(iv) A summary of the clinical validation study and results, including effectiveness of the application as a stand-alone contraceptive and how this effectiveness compares to other forms of legally marketed contraceptives.

Dated: February 28, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

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#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[Docket Number USCG–2019–0126]

**RIN 1625–AA00**

##### Safety Zone; Lower Mississippi River, Port Gibson, MS

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing an emergency temporary

safety zone for all navigable waters of the Lower Mississippi River, extending the entire width of the river, from mile marker (MM) 405 to MM 408. This emergency safety zone is necessary to protect persons, property, and infrastructure from potential damage and safety hazards associated with vessels transiting this area during high water. This rule prohibits persons and vessels from entering the safety zone area unless specifically authorized by the Captain of the Port Sector Lower Mississippi River (COTP) or a designated representative.

**DATES:** This rule is effective without actual notice from March 6, 2019 through 7 p.m. on April 15, 2019, or until the high water event ceases, whichever occurs first. For the purposes of enforcement, actual notice will be used from February 28, 2019 through March 6, 2019.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2019–0126 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 Petty Officer Todd Manow, Sector Lower Mississippi River Prevention Department, U.S. Coast Guard; telephone 901–521–4813, email [Todd.M.Manow@uscg.mil](mailto:Todd.M.Manow@uscg.mil).

##### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port Sector Lower Mississippi River  
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 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 is impracticable. Increasing high water in

this area requires immediate action to protect persons, property and power plant infrastructure from the potential safety hazards associated with vessels transiting this area during high water. This safety zone must be established immediately to protect people and vessels associated with and resulting from the high water and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

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 contrary to public interest because immediate action is needed to protect personnel, vessels, and the marine environment from potential hazards created by the increasing high water.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Lower Mississippi River (COTP) has determined that there are potential hazards associated with increasing high water, including possible emergency operations to repair damage to power distribution infrastructure taking place on the left descending bank of the Lower Mississippi River between Mile Marker (MM) 405 and 408 in the vicinity of the Entergy Grand Gulf Nuclear Power Facility, in Port Gibson, MS. Loss of the power distribution lines system would be catastrophic to large areas of Louisiana and Mississippi. This rule is needed to protect persons, property, and infrastructure from potential damage and safety hazards associated with vessels transiting this safety zone during high water.

### IV. Discussion of the Rule

The Coast Guard is establishing a temporary safety zone for all navigable waters of the Lower Mississippi River, extending the entire width of the river, from MM 405 to MM 408. Transit into and through this area is prohibited for all traffic beginning on February 28, 2019 to continue through 7 p.m. on April 15, 2019. The COTP will terminate the enforcement of this safety zone before April 15, 2019, if the high water event ceases. Entry into this safety zone is prohibited unless specifically authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River.

Requests for entry will be considered and reviewed on a case-by-case basis. The COTP may be contacted by telephone at 1-866-777-2784 or can be reached by VHF-FM channel 16. Persons and vessels permitted to transit this safety zone shall not meet, pass, or overtake any vessel currently transiting, shall maintain slowest speed for safe navigation, and shall comply with all lawful directions issued by the COTP or the designated representative.

This safety zone may include closures and/or navigation restrictions and requirements that are vital to maintaining safe navigation on the Lower Mississippi River during the high water. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone.

### 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, and duration of the safety zone. This emergency safety zone will restrict vessel traffic from entering or transiting through a three-mile section of the navigable waterways of the Lower Mississippi River from MM 405 to MM 408, in the vicinity of Port Gibson, MS, from February 28, 2019 through 7 p.m. on April 15, 2019.

#### 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 temporary 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 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 an emergency safety zone lasting approximately one and a half months that will prohibit entry into a three-mile stretch of the Lower Mississippi River during a hazardous high-water event. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration (REC) supporting this determination will be made 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:** 46 U.S.C. 70034; 46 U.S.C. 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.35T08–0229 to read as follows:

##### **§ 165.35T08–0229 Safety Zone; Lower Mississippi River; Port Gibson, MS.**

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River, extending the entire width of the river, from mile marker (MM) 405 to MM 408, in the vicinity of Port Gibson, MS.

(b) *Period of enforcement.* This section is effective without actual notice from March 6, 2019 through 7 p.m. on April 15, 2019, or until the high water event ceases, whichever occurs first. For the purposes of enforcement, actual notice will be used from February 28, 2019 through March 6, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Lower Mississippi River (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Lower Mississippi River.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. To seek entry into the safety zone, contact the COTP or the COTP's representative by telephone at 1–866–777–2784 or on VHF–FM channel 16.

(3) Persons and vessels permitted to enter this safety zone shall not meet, pass, or overtake any vessel currently transiting, shall maintain slowest speed for safe navigation, and shall comply with all lawful directions issued by the COTP or the designated representative.

(d) *Informational broadcasts.* This safety zone may include closures and/or navigation restrictions and requirements that are vital to maintaining safe

navigation on this section of the Lower Mississippi River during the high water. The COTP or a designated representative will inform the public through broadcast notices to mariners of any changes in the enforcement period for the safety zone.

Dated: February 28, 2019.

**R. Tamez,**

*Captain, U. S. Coast Guard, Captain of the Port Sector Lower Mississippi River.*

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#### **DEPARTMENT OF HOMELAND SECURITY**

##### **Coast Guard**

##### **33 CFR Part 165**

[Docket No. USCG–2019–0116]

##### **Safety Zone for Fireworks Displays; Upper Potomac River, Washington Channel, DC**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulations.

**SUMMARY:** The Coast Guard will enforce a temporary safety zone for two fireworks displays taking place over the Washington Channel, adjacent to The Wharf DC, Washington, DC; the first on March 2, 2019, (no alternate date) and the second on April 6, 2019, (with an alternate date on April 7, 2019). This action is necessary to ensure the safety of life on navigable waterways during these fireworks displays. Our regulation for recurring fireworks displays from January 12, 2019, through December 31, 2019 identifies the temporary safety zones for these fireworks display events. During the enforcement periods, persons and vessels are prohibited from entering the safety zone unless authorized by the Captain of the Port Maryland-National Capital Region or a designated representative.

**DATES:** The regulations in 33 CFR 165.T05–1011 will be enforced for the location specified in paragraph (a) of that section from 5:30 p.m. through 7 p.m. on March 2, 2019; from 8 p.m. through 9:30 p.m. on April 6, 2019, and if necessary due to inclement weather, from 8 p.m. through 9:30 p.m. on April 7, 2019.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email Mr. Ron Houck, U.S. Coast Guard Sector Maryland-National Capital Region, Waterways Management Division; telephone 410–576–2674, email D05-