

withdrawing that part of the proposed rule.

On September 20, 2002, FDA held a meeting of the Nonprescription Drugs Advisory Committee to discuss safety issues related to the use of aspirin and other OTC nonsteroidal anti-inflammatory drugs (NSAIDs), including ibuprofen.<sup>1</sup> Safety issues discussed included stomach bleeding. As a result of this meeting and subsequent FDA review of the data and additional comments submitted to the public docket (see Docket No. FDA-1977-N-0025), all OTC ibuprofen products marketed under NDAs and ANDAs bear warnings about gastrointestinal bleeding. Warnings state that the risk of bleeding is higher in persons who are age 60 or older, have stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or nonprescription nonsteroidal anti-inflammatory drugs (NSAIDs), have three or more alcoholic drinks every day, or who take more or for a longer time than directed. These requirements are codified under 21 CFR 201.326(a)(2).

On February 10 and 11, 2014, FDA held a joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss cardiovascular safety issues related to the use of NSAIDs, including ibuprofen.<sup>2</sup> Safety issues included increased risk of heart attack and stroke that may be worsened with using too much NSAID or using NSAIDs for longer than recommended. Thus, FDA sent letters on August 18, 2016, to all manufacturers of ibuprofen requesting supplements to their applications to update labels with this new safety information. All OTC ibuprofen products now include label warnings against increased risk of heart attack and stroke with the use of NSAIDs other than aspirin.

To help ensure the continued utility of the consumer labeling as it relates to the safety of nonprescription ibuprofen drug products, FDA carefully monitors adverse event reporting.

The safety issues that have arisen subsequent to the 2002 proposed rule have caused the Agency to question whether ibuprofen can be “generally recognized as safe and effective” for use as an active ingredient in OTC IAAA drug products. For this reason, the Agency is withdrawing the 2002 proposed amendments to 21 CFR part

343. Our withdrawal of the 2002 proposed amendment to the IAAA TFM has no effect on the continued approval and marketing of the NDA and ANDA OTC ibuprofen drug products. As noted above, FDA has addressed the safety issues associated with ibuprofen through the NDA and ANDA safety framework, which is different from the safety framework for drugs marketed under the OTC monograph framework.

FDA is not withdrawing those portions of the 2002 proposed rule to amend its regulations to include consistent pregnancy and allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients.

## II. Partial Withdrawal of the Proposed Rule

For the reasons described in this document, FDA is withdrawing portions of the 2002 proposed rule, which would have amended the OTC IAAA TFM.

Dated: May 8, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2018-0348]

RIN 1625-AA00

#### Safety Zone; Lower Mississippi River, New Orleans, LA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish a temporary safety zone for certain navigable waters of the Lower Mississippi River. This action is necessary to provide for the safety of life on these navigable waters near New Orleans, LA, during a fireworks display on August 25, 2018. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 13, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG-2018-0348 using the Federal

eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rulemaking, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans Waterways Management Division, U.S. Coast Guard; telephone 504-365-2231, email [Benjamin.P.Morgan@uscg.mil](mailto:Benjamin.P.Morgan@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

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

CFR Code of Federal Regulations  
COTP Captain of the Port Sector New Orleans  
DHS Department of Homeland Security  
FR Federal Register  
MM Mile marker  
NPRM Notice of proposed rulemaking  
§ Section  
U.S.C. United States Code

##### **II. Background, Purpose, and Legal Basis**

On April 9, 2018, AFX Pro, LLC, notified the Coast Guard that it would be conducting a fireworks display from 9 p.m. through 10 p.m. on August 25, 2018, for the National Guard Association of the United States Annual Conference. The fireworks will be launched from a barge in the Mississippi River at approximate mile marker (MM) 96.2 above Head of Passes, New Orleans, LA. Hazards from firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a one-mile stretch of the river.

The purpose of this rulemaking is to ensure the safety of vessels on the navigable waters within a one-mile stretch of the river before, during, and after the fireworks display. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

##### **III. Discussion of Proposed Rule**

The COTP proposes to establish a safety zone from 8:45 p.m. through 10 p.m. on August 25, 2018. The safety zone would cover all navigable waters of the Mississippi River above Head of Passes between mile markers (MM) 95.7 and 96.7. The duration of the zone is intended to ensure the safety of vessels

<sup>1</sup> <https://www.fda.gov/ohrms/dockets/ac/cder02.htm#NonprescriptionDrugs>.

<sup>2</sup> <https://wayback.archive-it.org/7993/20170404145443/https://www.fda.gov/AdvisoryCommittees/Calendar/ucm380871.htm>.

and these navigable waters before, during, and after the scheduled fireworks display. No vessel or person would be permitted to enter the safety zone without obtaining permission from 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 New Orleans.

Vessels requiring entry into this safety zone would have to request permission from the COTP or a designated representative. They may be contacted on VHF-FM Channel 16 or 67 or by telephone at (504) 365-2200. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

#### IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes 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 NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM 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 and duration of the safety zone. This safety zone is for only one hour and fifteen minutes on a one-mile section of the waterway. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners (BNM) via VHF-FM marine channel 16 about the zone, and the rule would allow 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 that under 5 U.S.C. 605(b) this proposed rule would not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

##### C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of

power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

##### F. Environment

We have analyzed this proposed 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 made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting one hour and fifteen minutes that would prohibit entry between mile marker 95.7 and mile marker 96.7 on the Lower Mississippi River above Head of Passes. Normally such actions are 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 preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

##### G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. 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.

## V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

### 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 proposes to amend 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, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0348 to read as follows:

#### § 165.T08–0348 Safety Zone; Lower Mississippi River, New Orleans, LA

(a) *Location.* The following area is a safety zone: All navigable waters of the Lower Mississippi River, New Orleans,

LA from mile marker (MM) 95.7 to MM 96.7 above Head of Passes.

(b) *Effective period.* This section is effective from 8:45 p.m. through 10 p.m. on August 25, 2018.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless authorized by the Captain of the Port Sector New Orleans (COTP) or 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 New Orleans.

(2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67 or by telephone at (504) 365–2200.

(3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate.

Dated: May 9, 2018.

**Wayne R. Arguin,**

*Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R08–OAR–2018–0026; FRL–9978–02—Region 8]

### Approval and Promulgation of Air Quality Implementation Plans; North Dakota; Revisions to Air Pollution Control Rules

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of North Dakota on January 28, 2013, and November 11, 2016. The EPA is proposing to approve amendments to North Dakota's general provisions,

permit to construct, prevention of significant deterioration (PSD) of air quality, oil and gas, and fees regulations. In addition, amendments to the permit program include the regulation of hazardous air pollutants (HAPs), which may be regulated under section 112 of the Clean Air Act (CAA). Thus, the EPA is taking this action pursuant to sections 110 and 112 of CAA.

**DATES:** *Comments:* Written comments must be received on or before June 13, 2018.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R08–OAR–2018–0026, to the Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [www.regulations.gov](http://www.regulations.gov). The 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. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

*Docket:* All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. The EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through