

new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit any update report in electronic format and shall include in the report the number assigned by FDA to the PMA. These updates are considered to be amendments to the PMA. The time frame for review of a PMA will not be extended due to the submission of an update report unless the update is a major amendment under § 814.37(c)(1). The applicant shall submit these reports—

\* \* \* \* \*

(f) If a color additive subject to section 721 of the Federal Food, Drug, and Cosmetic Act is used in or on the device and has not previously been listed for such use, then, in lieu of submitting a color additive petition under part 71 of this chapter, at the option of the applicant, the information required to be submitted under part 71 may be submitted as part of the PMA. When submitted as part of the PMA, the information shall be submitted in electronic format. A PMA for a device that contains a color additive that is subject to section 721 of the Federal Food, Drug, and Cosmetic Act will not be approved until the color additive is listed for use in or on the device.

\* \* \* \* \*

(h) \* \* \*

(1) For devices regulated by the Center for Devices and Radiological Health, send it to the current address displayed on the website <http://www.fda.gov/cdrhsubmissionaddress>.

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it to the current address displayed on the website <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm>.

\* \* \* \* \*

■ 9. Amend § 814.39 by revising paragraph (c)(1) to read as follows:

**§ 814.39 PMA supplements.**

\* \* \* \* \*

(c)(1) All procedures and actions that apply to an application under § 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change. A summary under

§ 814.20(b)(3) is required for only a supplement submitted for new indications for use of the device, significant changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device, or when otherwise required by FDA. The applicant shall submit a PMA supplement in electronic format and shall include information relevant to the proposed changes in the device. A PMA supplement shall include a separate section that identifies each change for which approval is being requested and explains the reason for each such change. The applicant shall submit additional information, if requested by FDA, in electronic format. The time frames for review of, and FDA action on, a PMA supplement are the same as those provided in § 814.40 for a PMA.

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■ 10. Amend § 814.104 by revising paragraphs (d) introductory text and (d)(1) and (2) to read as follows:

**§ 814.104 Original applications.**

\* \* \* \* \*

(d) *Address for submissions and correspondence.* All original HDEs, amendments and supplements, as well as any correspondence relating to an HDE, must be provided in electronic format. These materials must be sent or delivered to one of the following:

(1) For devices regulated by the Center for Devices and Radiological Health, send it to the current address found on the website <https://www.fda.gov/cdrhsubmissionaddress>.

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it to the current address displayed on the website <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm385240.htm>.

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Dated: September 7, 2018.

**Scott Gottlieb,**

*Commissioner of Food and Drugs.*

[FR Doc. 2018–19865 Filed 9–12–18; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket Number USCG–2018–0713]

RIN 1625–AA00

**Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to reduce the size of the Navy Pier Southeast Safety Zone within the Chicago Harbor. This action is necessary to alleviate congestion near the Chicago Lock during regularly scheduled fireworks events. The current safety zone encompasses part of the lock restricting vessels during events. This proposed rulemaking would still prohibit persons and vessels from entering the safety zone, but would allow the lock to remain in full operation during the fireworks display. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before October 15, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG–2018–0713 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 rule, call or email LT John Ramos, Waterways Management Division, Marine Safety Unit Chicago, U.S. Coast Guard; telephone (630) 986–2155, email [D09-DG-MSUChicago-Waterways@uscg.mil](mailto:D09-DG-MSUChicago-Waterways@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, Purpose, and Legal Basis**

The Coast Guard regularly enforces the Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL listed in 33 CFR 165.931 for weekly fireworks events during the boating season. The

current safety zone encompasses all waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53'26.5" N, 087°35'26.5" W; then south to 41°53'7.6" N, 087°35'26.3" W; then west to 41°53'7.6" N, 087°36'23.2" W; then north to 41°53'26.5" N, 087°36'24.6" W; then east back to the point of origin (NAD 83).

The purpose of this proposed rulemaking is to reduce the size of the pre-existing safety zone to reduce congestion near the Chicago Lock. This safety zone will help ensure the safety of vessels and the navigable waters near the fireworks barge before, during, and after the scheduled events and alleviate congestion issues around the Chicago Lock. The proposed rule would not significantly change the regulatory language found in 33 CFR 165.931. The change would only reduce the size of the safety zone and update the coordinates found in 33 CFR 165.931 (a).

### III. Discussion of Proposed Rule

The COTP proposes to reduce the established safety zone outlined in 33 CFR 165.931. The current safety zone encompasses all waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53'26.5" N, 087°35'26.5" W; then south to 41°53'7.6" N, 087°35'26.3" W; then west to 41°53'7.6" N, 087°36'23.2" W; then north to 41°53'26.5" N, 087°36'24.6" W; then east back to the point of origin (NAD 83).

The newly proposed safety zone would ensure a safe distance for spectators. It would encompass all waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53'23.74" N, 087°35'35.70" W; then south to 41°53'3.95" N, 087°35'35.11" W; then west to 41°53'3.48" N, 087°36'8.52" W; then north to 41°53'23.30" N, 087°36'9.08" W; then east back to the point of origin (NAD 83).

### 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.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and will be enforced intermittently only for a short period of time. Under certain conditions, moreover, vessels may still transit through the safety zones when permitted by the Captain of the Port.

#### 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 proposed rule would 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 IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

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 (Pub. L. 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 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 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 enforced intermittently. 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 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.

#### 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 165.931 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. Amend § 165.931 by revising paragraph (a) to read as follows:

#### § 165.931 Safety Zone, Chicago Harbor, Navy Pier Southeast, Chicago, IL.

(a) *Location.* The following area is a safety zone: The waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53'23.74" N, 087°35'35.70" W; then south to 41°53'3.95" N, 087°35'35.11" W; then west to 41°53'3.48" N, 087°36'8.52" W; then north to 41°53'23.30" N, 087°36'9.08" W; then east back to the point of origin (NAD 83).

\* \* \* \* \*

Dated: August 16, 2018.

**Thomas J. Stuhlreyer,**

*Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.*

[FR Doc. 2018–19934 Filed 9–12–18; 8:45 am]

**BILLING CODE 9110–04–P**

#### DEPARTMENT OF AGRICULTURE

#### Forest Service

#### 36 CFR Part 228

**RIN 0596–AD32**

#### Locatable Minerals

**AGENCY:** Forest Service, USDA.

**ACTION:** Advance notice of proposed rulemaking; request for comment.

**SUMMARY:** The Forest Service is requesting comments from the public regarding the need to clarify or to otherwise enhance its regulations that minimize adverse environmental impacts on National Forest System surface resources in connection with

operations authorized by the United States mining laws. These rules and procedures govern prospecting, exploration, development, mining, and processing operations conducted on National Forest System lands authorized by the Mining Law of 1872, as amended, subsequent reclamation of the land, and any necessary long-term post-closure resource management. The goals of the regulatory revision are to expedite Forest Service review of certain proposed mineral operations authorized by the United States mining laws, and, where applicable, Forest Service approval of some of these proposals by clarifying the regulations, to increase consistency with the United States Department of the Interior, Bureau of Land Management (BLM) surface management regulations governing operations authorized by the United States mining laws to assist those who conduct these operations on lands managed by each agency, and to increase the Forest Service's nationwide consistency in regulating mineral operations authorized by the United States mining laws by clarifying its regulations.

**DATES:** Comments must be received by October 15, 2018.

**ADDRESSES:** Please submit comments via one of the following methods:

- *Electronically:* Go to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. In the Search box, enter FS–2018–0052, which is the docket number for this Advanced Notice of Proposed Rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Notice link to locate this document. You may submit a comment by clicking on “Comment Now!”

- *By hard copy:* Submit by U.S. mail to: USDA-Forest Service. Attn: Director—MGM Staff, 1617 Cole Boulevard, Building 17, Lakewood, CO 80401.

We request that you send comments only by the methods described above. We will post all comments on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us.

**FOR FURTHER INFORMATION CONTACT:** Cheryl Nabahe, Minerals and Geology Management, 202–205–0800.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** This advance notice is intended to give the