

If finalized, the proposed rule will affect all persons who would handle, or propose to handle fenfluramine. Fenfluramine as a pharmaceutical product (Fintepla) is currently available and marketed in the U.S. Because fenfluramine is currently a schedule IV drug, all legal handling of fenfluramine is currently done under appropriate DEA license. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities that are affected by this rulemaking. There are currently 40 unique registrations authorized to handle fenfluramine specifically, as well as a number of registered analytical labs that are authorized to handle schedule IV controlled substances generally. From review of entity names, DEA estimates these 40 registrations represent 27 entities. Some of these entities are likely to be small entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 27 entities are small entities. Therefore, DEA conservatively estimates as many as 27 small entities are affected by this proposed rule. However, because this rule would remove fenfluramine from regulatory controls of the CSA, it is likely to result in some cost savings. Any person planning to handle fenfluramine will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements. Because of these factors, DEA projects that this rule will not result in a significant economic impact 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, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, (2 U.S.C. 1501 *et seq.*), that this proposed action would 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 annually for inflation) in any 1 year. . . ." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

#### *Paperwork Reduction Act of 1995*

This proposed action does not impose a new collection of information requirement under the Paperwork

Reduction Act of 1995. (44 U.S.C. 3501–3521).

#### **Signing Authority**

This document of the Drug Enforcement Administration was signed on July 13, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

#### **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, DEA proposes to amend 21 CFR part 1308 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), 956(b), unless otherwise noted.

##### **§ 1308.14 [Amended]**

- 2. In § 1308.14, remove and reserve paragraph (d).

**Scott Brinks,**

*Federal Register Liaison Officer, Drug Enforcement Administration.*

[FR Doc. 2022–15335 Filed 7–18–22; 8:45 am]

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

##### **Coast Guard**

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

**[Docket Number USCG–2022–0595]**

**RIN 1625–AA00**

##### **Safety Zone; Ironman Michigan, Frankfort Harbor, MI**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary safety zone for certain waters of Betsie Lake in Frankfort, MI. This action is necessary

to provide for the safety of life on these navigable waters during the swim portion of an Ironman event on September 11, 2022. This proposed rulemaking would restrict usage by persons and vessels within the safety zone. At no time during the effective period may vessels transit the waters of Betsie Lake in the vicinity of a triangular shaped race course enclosed by the following three coordinates: 44°37.80' N, –086°13.91' W to 44°37.81' N, –086°14.22' W to 44°37.58' N, –086°13.75' W, then back to the starting point. The race course will be marked by buoys. These restrictions would apply to all persons and vessels during the effective period unless authorized by the Captain of the Port Lake Michigan 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 August 18, 2022.

**ADDRESSES:** You may submit comments identified by docket number USCG–2022–0595 using the Federal eRulemaking Portal at <https://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 Chief Petty Officer Jeromy Sherrill, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7148, email [Jeromy.N.Sherrill@uscg.mil](mailto:Jeromy.N.Sherrill@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

On June 23, 2022, the Coast Guard was notified by the event sponsor of its intent to host Ironman Michigan in Frankfort, MI on September 11, 2022 from 8:00 a.m. to 10:15 a.m. The swim will begin near Frankfort Municipal Marina in Betsie Lake. The race course will be triangular shaped area enclosed by the following coordinates: 44°37.80' N, –086°13.91' W to 44°37.81' N, –086°14.22' W to 44°37.58' N, –086°13.75' W, then back to the starting point. The race course will be marked by buoys. The COTP has determined that potential hazards associated with the triathlon would be

a safety concern for anyone within the safety zone that is not participating in the triathlon.

The purpose of this rulemaking is to ensure the safety of person, vessels and the navigable waters of Betsie Lake, MI. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

### III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone from 6:00 a.m. through 12:00 a.m. on September 11, 2022. The safety zone will cover all waters of Betsie Lake in the vicinity of a triangular shaped race course near Frankfort Municipal Marina in Frankfort, MI. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the triathlon event. No vessels or person would be permitted to enter the safety zone without obtaining permission from 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. 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).

This regulatory action determination is based on the characteristics of the safety zone. The safety zone created by this proposed rule will relatively small and is designed to minimize its impact on navigable waters. This proposed rule will prohibit entry into certain navigable waters of Betsie Lake in Frankfort, MI, and it is not anticipated to exceed 6 hours in duration. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Moreover, under certain conditions vessels may still transit through the safety zone when permitted by the COTP Lake Michigan.

#### 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 call or email 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 call or email 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, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), 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 6 hours that would prohibit entry within a relatively small portion of Betsie Lake. 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. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. 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 call or email 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 <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, call or email 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 <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://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:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T09–0595 to read as follows:

#### § 165.T09–0595 Safety Zone; Ironman Michigan, Frankfort, MI.

(a) *Location.* All waters of Betsie Lake in the vicinity of a triangular shaped race course enclosed by the following three coordinates: 44°37.80' N, –086°13.91' W to 44°37.81' N, –086°14.22' W to 44°37.58' N, –086°13.75' W, then back to the starting point.

(b) *Enforcement Period.* The safety zone described in paragraph (a) would be effective on September 11, 2022 from 6:00 a.m. through 12:00 p.m.

(c) *Regulations.*

(1) In accordance with the general regulations in section § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan (COTP) or a designated representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) The “designated representative” of the COTP is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Persons and vessel operators desiring to enter or operate within the safety zone during the marine event must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

Dated: July 13, 2022.

**Doreen McCarthy,**

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

[FR Doc. 2022–15333 Filed 7–18–22; 8:45 am]

**BILLING CODE 9110–04–P**

### POSTAL REGULATORY COMMISSION

#### 39 CFR Part 3050

[Docket No. RM2022–10; Order No. 6225]

#### Periodic Reporting

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Commission is acknowledging a recent filing requesting the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports (Proposal Four). This document informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* August 31, 2022.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at <https://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202–789–6820.

#### SUPPLEMENTARY INFORMATION:

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#### I. Introduction

On July 11, 2022, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports.<sup>1</sup> The Petition identifies the proposed analytical changes filed in this docket as Proposal Four.

#### II. Proposal Four

*Proposal.* The Postal Service proposes the following five changes to improve and streamline the International Cost and Revenue Analysis (ICRA) model: (1) using Outbound International Service Agreement (negotiated service agreement, referred to as NSA) System for International Revenue and Volume, Outbound (SIRVO) data to attribute outbound settlement expenses and international transportation expenses to NSA products; (2) adding all countries to the outbound piece of the ICRA database and eliminating the 999X countries; (3) using the Settlement Workbooks file as the source for outbound settlement calculations instead of manually entering rates; (4)

<sup>1</sup> Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Four), July 11, 2022 (Petition). The Postal Service also filed a notice of filing of non-public materials relating to Proposal Four. Notice of Filing of USPS–RM2022–10–NP1 and Application for Nonpublic Treatment, July 11, 2022.