

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2011-N-0179 for “Prior Notice of Imported Food Questions and Answers (Edition 3): Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the

electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Regulatory Affairs, Office of Food and Feed Operations, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Angel M. Suarez, Office of Regulatory Affairs, Office of Food and Feed Operations, Division of Food Defense Targeting, Food and Drug Administration, Element Bldg., HFC-180, 12420 Parklawn Dr., Rockville, MD 20857-20993, 866-521-2297.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Prior Notice of Imported Food Questions and Answers (Edition 3): Guidance for Industry.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or on the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Since publication of edition two of the guidance, FDA has issued a final rule requiring the submission to FDA of prior notice of food, including animal feed, imported or offered for import into the United States (November 7, 2008, 73 FR 66294) and, in accordance with section 304 of FSMA, a final rule requiring the name of any country to which an article has been refused entry be reported in prior notices (May 30, 2013, 78 FR 32359). FDA is issuing a third edition of its prior notice guidance to address questions received since publication of the second edition, clarify previous responses, update previous responses as appropriate to reflect the 2008 final rule, and include information about the new prior notice information requirement created by FSMA.

FDA issued the first and second editions of this guidance on December

16, 2003, and May 3, 2004, respectively. Both editions were issued as Level 1 guidance documents under 21 CFR 10.115. Consistent with FDA’s good guidance practices regulations (21 CFR 10.115(g)(2)), the Agency accepted comments, but implemented the documents immediately because it determined that prior public participation was not feasible or appropriate.

In the **Federal Register** of March 31, 2014 (79 FR 17947), we made available a draft guidance for industry entitled “Draft Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)” and gave interested parties an opportunity to submit comments by May 30, 2014, for us to consider before beginning work on the final version of the guidance. We carefully considered all comments received when preparing the final guidance. No substantive changes were made in finalizing the guidance. The guidance announced in this notice finalizes the draft guidance dated March 2014.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-14231 Filed 6-15-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2016-0322]

RIN 1625-AA08

Special Local Regulation; Cumberland River, Mile 190.5 to 194.0; Nashville, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard is establishing a special local regulation for all waters of the Cumberland River beginning at mile marker 190.5 and ending at mile marker 194.0. This special local regulation is necessary to

provide safety for the participants in the “Thunder on the Cumberland” marine event. This rulemaking restricts transits into, through and within the regulated area unless authorized by the Captain of the Port Ohio Valley or a designated representative. We invite your comments on this rulemaking to assess for future and events and similar rulemakings.

DATES: This rule is effective from 9 a.m. on June 17, 2016 through 6 p.m. on June 19, 2016. Comments and related material must be received by the Coast Guard on or before July 18, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0322 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 on this rule, call or email Petty Officer Ashley Schad, MSD Nashville, Nashville, TN, at 615–736–5421 or at Ashley.M.Schad@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 Information and Regulatory History

Fairchild Racing is conducting power boat races daily beginning on June 17, 2016 through June 19, 2016. 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 the scheduled race event, consisting of various sized power vessels with at least 50 participants on the Cumberland River, presents potential navigational safety hazards. The Captain of the Port Ohio Valley (COTP) was notified of this event earlier this year and upon receiving and

understanding all the details of the racing event, determined that additional safety measures are necessary to protect participants, spectators, and waterway users during this event. It is impracticable to publish an NPRM because we must establish this special local regulation by June 17, 2016. This rule provides for a comment period and comments received will be reviewed and analyzed to assist the Coast Guard in future rulemakings establishing similar regulatory requirements. The Coast Guard will notify the public and maritime community that this special local regulation will be in effect and of its enforcement periods via broadcast notices to mariners (BNM).

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 contrary to public interest because immediate action is needed to establish a special local regulation to protect participants and spectators during the “Thunder on the Cumberland” racing event beginning on June 17, 2016.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Ohio Valley (COTP) has determined that potential safety hazards associated with a speed-boat race on a navigable waterway present safety concerns for participants, spectators, and other person and vessels on the waterway. This rule is needed to protect personnel, vessels, and these navigable waters before, during, and after the scheduled racing event.

IV. Discussion of the Rule

This rule establishes a special local regulation which will be enforced from 9 a.m. to 11 a.m. and 12 p.m. to 6 p.m. daily from June 17, 2016 through June 19, 2016, for all waters of the Cumberland River beginning at mile marker 190.5 and ending at mile marker 194.0. The duration of the special local regulation is intended to ensure the safety of vessels, participants, spectators and other waterway users before, during, and after the scheduled event. No vessel or person would be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative. The regulatory text for this rule appears at the end of this document.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and

Executive order 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 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.

This regulatory action determination is based on the size, location, duration, and time-of-day of the special local regulation. This special local regulation restricts transit on the Cumberland River from mile 190.5 to mile 194.0, for 8 hours a day for three days in June; Broadcast Notices to Mariners and Local Notices to Mariners will inform the community of this special local regulation and any changes in the planned schedule so that they may plan accordingly for transits during this short restriction. Vessel traffic may request permission from the COTP Ohio Valley or a designated representative to enter the restricted area.

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 special local regulated area may be small entities, for the reasons stated in section V.A above this rule would 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 an 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 special local regulated area that would prohibit entry to unauthorized vessels. It is categorically excluded from further review under paragraph 34(h) of Figure 2-1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are 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 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.

VI. 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 future regulations and rulemakings. 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, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this TFR 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 Web site'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 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233

■ 2. Add § 100.35T08-0322 to read as follows:

§ 100.35T08-0322 Special Local Regulation; Cumberland River Mile 190.5 to 194.0, Nashville, TN.

(a) *Regulated area.* All waters of the Cumberland River beginning at mile marker 190.5 and ending at mile marker 194.0 at Nashville, TN.

(b) *Periods of enforcement.* This rule will be enforced from 9 a.m. to 11 a.m. and from 12 p.m. to 6 p.m. daily June 17, 2016 through June 19, 2016.

(c) *Regulations.* (1) Entry into or transit through this area is prohibited unless authorized by the Captain of the Port Ohio Valley or a designated representative.

(2) Persons or vessels requiring entry into or passage through the area must request permission from the Captain of the Port Ohio Valley or a designated representative. U.S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1-800-253-7465.

(d) *Informational broadcasts.* The Captain of the Port Ohio Valley or a designated representative will inform

the public through broadcast notices to mariners of the enforcement period for this special local regulation as well as any changes in the dates and times of enforcement.

Dated: May 26, 2016.

R. V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016-14276 Filed 6-15-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2015-1039]

RIN 1625-AA08

Special Local Regulations; Sector Ohio Valley Annual and Recurring Special Local Regulations Update

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending and updating its special local regulations relating to recurring marine parades, regattas, and other events that take place in the Coast Guard Sector Ohio Valley area of responsibility (AOR). This rule informs the public of regularly scheduled events that require additional safety measures through the establishing of a special local regulation. Through this rulemaking the current list of recurring special local regulations is updated with revisions, additional events, and removal of events that no longer take place in Sector Ohio Valley's AOR. When these special local regulations are enforced, certain restrictions are placed on marine traffic in specified areas.

DATES: This rule is effective June 16, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2015-1039 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 James Robinson, Sector Ohio Valley, U.S. Coast Guard; telephone (502) 779-5347, email James.C.Robinson@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations

DHS Department of Homeland Security
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II. Background Information and Regulatory History

The Captain of the Port (COTP) Ohio Valley is establishing, amending, and updating its current list of recurring special local regulations codified under 33 CFR 100.801 in Table no. 1, for the COTP Ohio Valley zone.

On January 25, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Sector Ohio Valley Annual and Recurring Special Local Regulations Update (81 FR 3976). During the comment period that ended April 25, 2016, the Coast Guard received information regarding dates for three events from the event sponsors. This information is discussed in this document.

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**. Though we are not providing a full 30-day delay in the effective date, the Coast Guard did provide notice and the opportunity to comment through the NPRM process and is now providing as much notice as possible before the first recurring event enforcement is required on June 19. It is impracticable to provide a full 30-days notice because this rule must be effective June 19, 2016 to accommodate the first event.

III. Legal Authority and Need for Rule

The Coast Guard's authority for establishing a special local regulation is contained at 33 U.S.C. 1233. The Coast Guard is amending and updating the special local regulations under 33 CFR part 100 to include the most up to date list of recurring special local regulations for events held on or around navigable waters within the Sector Ohio Valley AOR. These events include marine parades, boat races, swim events, and others. The current list under 33 CFR 100.801 requires amending to provide new information on existing special local regulations, include new special local regulations expected to recur annually or biannually, and to remove special local regulations that are no longer required. Issuing individual regulations for each new special local regulation, amendment, or removal of an existing special local regulation creates unnecessary administrative costs and burdens. This rulemaking reduces administrative overhead and provides the public with notice through

publication in the **Federal Register** of the upcoming recurring special local regulations.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received information regarding three recurring events from the event sponsors during the NPRM comment period. This information requires changes to the regulatory text of this rule from the proposed rule in the NPRM. Those changes are as follows:

Change 1: The sponsor of the Owensboro Air show requested a change to the proposed event date as listed in Table 1, Line 54. Instead of occurring 3 days during the first or second weekend in September, the new date will be published in the final rule as: 3 days during one of the last three weekends in September. This change was requested to enable the Air Show to take place without conflicting with other events occurring in September.

Change 2: The sponsor of the REV3 Triathlon requested a change to the proposed date as listed in Table 1, Line 4. Instead of occurring 1 day during the first or second weekend in May, the new date will be published in the final rule as: 1 day during the third or fourth weekend in May starting in 2016. This change was requested due to scheduling conflicts with other events. This final rule was not published in time for the May 22, 2016 occurrence of this event. Therefore, a temporary final rule for this event was issued on May 20, 2016. That rule is accessible as indicated under **ADDRESSES**.

Change 3: The sponsor of the Hadi-Shrine/Evansville Freedom Festival Air Show informed the Coast Guard that the proposed expanded date period from 3 to 4 days was no longer needed and the currently published date period of 3 days fits the air show portion of their event. Therefore, the date for this event as listed in Table 1, Line 46 will remain: 3 days during the second or third weekend in June. The event sponsor also informed the Coast Guard that the 2016 occurrence of this event fell on the fourth weekend in June. Therefore, a separate temporary final rule is being issued to establish the necessary special local regulation on June 24-26, 2016. That rule is available as indicated under **ADDRESSES**.

These requested changes are based on the individual sponsors' efforts to coordinate events alongside others in the local community. In some instances, these changes have been advertised to and planned on by the local community, and minimally impact the dates of 3 events as listed in the NPRM. These