

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

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

- For written/paper comments submitted to the Dockets Management Staff, 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-2012-D-1002 for “Questions and Answers Regarding Food Facility Registration (Seventh Edition).” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. 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:** Courtney Buchanan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2487.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a guidance for industry entitled “Questions and Answers Regarding Food Facility Registration (Seventh Edition).” This guidance provides updated information relating to the food facility registration requirements in the FD&C Act. 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 the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

In the **Federal Register** of December 27, 2016 (81 FR 95068), we made available a draft guidance for industry entitled “Questions and Answers Regarding Food Facility Registration (Seventh Edition)” and gave interested parties an opportunity to submit comments by March 27, 2017, for us to consider before beginning work on the final version of the guidance. We received numerous comments on the draft guidance and have modified the final guidance where appropriate. In

addition, we made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2016.

FDA is also publishing elsewhere in this issue of the **Federal Register** notification of availability of a supplemental draft guidance document entitled “Supplemental Questions and Answers Regarding Food Facility Registration” that includes additional questions and answers to clarify our thinking about who should register in certain situations involving more than one possible registrant, such as a lessor and one or more lessees for an establishment. When the draft guidance is finalized, we intend to incorporate it into a future edition of the guidance document that is the subject of this notification.

##### **II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 1.230 through 1.235 and 21 CFR 1.245 have been approved under OMB control number 0910-0502.

##### **III. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: August 14, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-17853 Filed 8-17-18; 8:45 am]

**BILLING CODE 4164-01-P**

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## **DEPARTMENT OF DEFENSE**

### **Office of the Secretary**

#### **32 CFR Part 295**

[Docket ID: DOD-2017-OS-0024]

RIN 0790-AJ65

#### **Office of the Inspector General, Freedom of Information Act Program**

**AGENCY:** Office of Inspector General, DoD.

**ACTION:** Final rule.

**SUMMARY:** This final rule removes DoD’s regulation concerning the Office of the Inspector General (OIG), Freedom of

Information Act program. On February 6, 2018, the DoD published a revised FOIA program rule as a result of the FOIA Improvement Act of 2016. When the DoD FOIA program rule was revised, it included DoD component information and removed the requirement for component supplementary rules. The DoD now has one DoD-level rule for the FOIA program that contains all the codified information required for the Department. Therefore, this part can be removed from the CFR.

**DATES:** This rule is effective on August 20, 2018.

**FOR FURTHER INFORMATION CONTACT:** Mark Dorgan at 703-604-9873.

**SUPPLEMENTARY INFORMATION:** It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is based on removing DoD internal policies and procedures that are publically available on the Department's website.

OIG internal guidance concerning the implementation of the FOIA within OIG will continue to be published in Inspector General Instruction 5400.7 (available at <http://www.dodig.mil/Portals/48/Documents/Policy/IGDINST%205400.7%20AIG-AM%20signed%204-16-10.pdf>).

This rule is one of 14 separate DoD FOIA rules. With the finalization of the DoD-level FOIA rule at 32 CFR part 286, the Department is eliminating the need for this separate FOIA rule and reducing costs to the public as explained in the preamble of the DoD-level FOIA rule published at 83 FR 5196-5197.

This rule is not significant under Executive Order (E.O.) 12866, "Regulatory Planning and Review," therefore, E.O. 13771, "Reducing Regulation and Controlling Regulatory Costs" does not apply.

#### List of Subjects in 32 CFR Part 295

Freedom of information.

#### PART 295—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 295 is removed.

Dated: August 15, 2018.

**Aaron T. Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2018-17884 Filed 8-17-18; 8:45 am]

**BILLING CODE 5001-06-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG-2018-0781]

#### Special Local Regulation; Wheeling Vintage Regatta, Wheeling, WV

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce a special local regulation for certain navigable waters of the Ohio River during the Wheeling Vintage Regatta on September 1, 2018 and September 2, 2018, to provide for the safety of persons, vessels, and the marine environment on the navigable waterways during this event. Our special local regulations for annual marine events in the Eighth Coast Guard District identify the regulated area for this event in Wheeling, WV. During the enforcement period, entry into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

**DATES:** The regulations in 33 CFR 100.801, Table 1, line 25, will be enforced from 9 a.m. to 6 p.m. each day from September 1, 2018 through September 2, 2018.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email Petty Officer Charles Morris, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412-221-0807, email [Charles.F.Morris@uscg.mil](mailto:Charles.F.Morris@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce a temporary special local regulation for the Wheeling Vintage Regatta in 33 CFR 100.801, Table 1, Sector Ohio Valley Annual and Recurring Marine Events, line 25 from 9 a.m. to 6 p.m. each day from September 1, 2018 through September 2, 2018. This action is being taken to provide for the safety of persons, vessels, and the marine environment on the navigable waters of the Ohio River during this event. Our regulation for marine events within the Eighth Coast Guard District, § 100.801, specifies the location of the regulated area for the Wheeling Vintage Regatta, which covers a one-mile stretch of the Ohio River. Persons and vessels must not enter the regulated area unless registered with the sponsor as participants, official patrol vessels, or authorized by the Captain of the Port Marine Safety Unit Pittsburgh (COTP) or

a designated representative. Persons or vessels desiring to enter into or pass through the area must request permission from the COTP or a designated representative. They can be reached on VHF-FM channel 16. If permission is granted, all persons and vessel shall comply with the instructions of the COTP or designated representative.

In addition to this notice of enforcement in the **Federal Register**, the COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), Marine Safety Information Bulletins (MSIBs), and/or through other means of public notice as appropriate at least 24 hours in advance of each enforcement.

Dated: August 14, 2018.

**A.W. Demo,**

*Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.*

[FR Doc. 2018-17856 Filed 8-17-18; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2018-0750]

**RIN 1625-AA00**

#### Safety Zone; Allegheny River Miles 0.7 to 1.0, Pittsburgh, PA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for all navigable waters of the Allegheny River, extending the entire width of the river, from mile marker (MM) 0.7 to MM 1.0. This safety zone is necessary to protect persons, vessels, and the marine environment from potential hazards associated with a fireworks display. Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

**DATES:** This rule is effective from 7:30 p.m. through 9 p.m. on September 11, 2018.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0750 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.