Dated: January 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01296 Filed 1–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2016–D–2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of another draft chapter of a multichapter guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry.'' This multichapter draft guidance is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under our rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'' The newly available draft chapter is entitled ''Chapter 15—Supply-Chain Program for Human Food Products.''

DATES: Submit either electronic or written comments by May 25, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- 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–2016–D–2343 for ''Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry.'' 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 draft guidance to Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–300), 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 draft guidance.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2166.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g) by adding requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations, in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21 U.S.C. 350d). We have established regulations to implement these requirements within part 117 (21 CFR part 117).

In the **Federal Register** of August 24, 2016 (81 FR 57816), we announced the availability of several chapters (Chapters 1–5) of a multichapter draft guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' In the **Federal Register** of August 31, 2017 (82 FR 41364), we announced the availability of an additional chapter (Chapter 6). We now are announcing the availability of an additional draft chapter of this multichapter guidance for industry.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Hazard Analysis and Risk-Based Preventive Controls for Human Food''. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The multichapter draft guidance for industry is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under part 117, principally in subparts C and G. The chapter that we are announcing in this document is entitled ''Chapter 15—Supply-Chain Program for Human Food Products.''

We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them.

III. Paperwork Reduction Act of 1995

This draft 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 part 117 have been approved under OMB control number 0910–0751.

IV. Electronic Access

Persons with access to the internet may obtain the draft 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: January 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01299 Filed 1–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2017–0993]

RIN 1625–AA00

Special Local Regulation: Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a recurring special local regulation for navigable waters of the Atlantic Ocean, east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet. This action is necessary to ensure the safety of the general public, spectators, vessels, and the marine environment from potential hazards during aerobatic maneuvers conducted by high-speed, low-flying airplanes and any high speed vessels performing inside of the regulated area during the Fort Lauderdale Air Show. This proposed rulemaking would prohibit persons and non-participant vessels from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami 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 February 26, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2017–0993 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 Petty Officer Mara J. Brown, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305–535–4317, email *Mara.J.Brown@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 City of Fort Lauderdale notified the Coast Guard that it will be hosting the Fort Lauderdale Air Show annually on one weekend (Saturday and Sunday) during the month of May. The regulated area would cover all navigable waters of the Atlantic Ocean, east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet and continues north for approximately six miles. The regulated area is intended to protect personnel, vessels, and the marine environment from potential hazards during aerobatic maneuvers by high speed, low flying airplanes and high speed vessels during the air show. Over the years, there have been unfortunate instances of aircraft mishaps during performances at various air shows around the world. Occasionally, these incidents result in a wide area of scattered debris in the water that can damage property or cause significant injury or death to the public observing the air shows. The Captain of the Port Miami has determined that a special local regulation is necessary to protect the general public from hazards associated with aerial flight demonstrations.

The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

This rule establishes a special local regulation on the waters of the Atlantic Ocean, east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet and continuing north for approximately six miles. The duration of the regulated area is intended to ensure the safety of the public during the aerial flight demonstrations and high speed boat races. Non participant vessels are not permitted to enter, transit through, anchor in, or remain within the regulated area without obtaining permission from the Captain of the Port Miami or a designated representative. The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners and on-scene designated representatives. The regulatory text we are proposing appears at the end of this document.