Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 117 and 507

[Docket No. FDA–2018–D–0671]

Determining the Number of Employees for Purposes of the ''Small Business'' Definition in Parts 117 and 507: Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry describing the Agency's current thinking on how to determine the number of employees for purposes of the ''small business'' definition in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for human and animal food rules. The draft guidance, when finalized, will help industry subject to those rules determine the number of employees for purposes of the ''small business'' definition.

DATES: Submit either electronic or written comments on the draft guidance by May 21, 2018 to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.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–2018–D–0671 for ''Determining the Number of Employees for Purposes of the 'Small Business' Definition in Parts 117 and 507: 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 the 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 draft guidance.

FOR FURTHER INFORMATION CONTACT: *For questions relating to CGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food:* 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.

For questions relating to CGMP, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish

Pl., Rockville, MD 20855, 240–402–6246.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Determining the Number of Employees for Purposes of the 'Small Business' Definition in Parts 117 and 507: Guidance for Industry.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

This draft guidance concerns two regulations that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (Pub. L. 111–353). These two regulations are 21 CFR part 117 (part 117) (published in the **Federal Register** on September 17, 2015, 80 FR 55907) and 21 CFR part 507 (part 507) (published in the **Federal Register** on September 17, 2015, 80 FR 56170). Under parts 117 and 507, whether a business is a ''small business'' has two main implications. First, certain small businesses are exempt from the human food preventive controls requirements and the animal food preventive controls requirements if they are engaged only in specified low-risk activity/food combinations. Second, small businesses have later compliance dates for parts 117 and 507 than larger businesses. This guidance will provide additional information to assist businesses in determining their status as a ''small business.''

II. 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: March 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05705 Filed 3–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket Number USCG–2017–0446]

RIN 1625–AA00

Safety Zone; Appomattox FPS, Mississippi Canyon 437, Outer Continental Shelf on the Gulf of Mexico

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a safety zone around the Appomattox Floating Production System (FPS) facility located in Mississippi Canyon Block 437 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. The purpose of the safety zone is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Placing a safety zone around the facility will significantly reduce the threat of allisions, collisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the environment. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before April 19, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2017–0446 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 Ms. Laura Knoll, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504–671–2139, *laura.b.knoll@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FPS Floating production system
FR Federal Register
NPRM Notice of proposed rulemaking
OCS Outer Continental Shelf
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

Under the authority provided in 14 U.S.C. 85, 43 U.S.C. 1333, and Department of Homeland Security Delegation No. 0170.1(90), Title 33, CFR 147.1, 147.5, and 147.10 permit the establishment of safety zones for facilities located on the Outer Continental Shelf (OCS) for the purpose of protecting life and property on the facilities, their appurtenances and attending vessels, and on the adjacent waters within the safety zones.

The safety zone proposed by this rulemaking is on the OCS in the deepwater area of the Gulf of Mexico at Mississippi Canyon Block 437. The area for the safety zone would be 500 meters (1640.4 feet) from each point on the facility, which is located at 28°34′25.47″ N, 87°56′03.11″ W. The deepwater area would be considered to be waters of 304.8 meters (1,000 feet) or greater depth extending to the limits of the Exclusive Economic Zone (EEZ) contiguous to the territorial sea of the United States and extending to a distance up to 200 nautical miles from the baseline from which the breadth of the sea is measured. The deepwater area would also include an extensive system of fairways. Navigation in the vicinity of the safety zone consists of large commercial shipping vessels, fishing vessels, cruise ships, tugs with tows and the occasional recreational vessels. The establishment of this safety zone will not interfere with these vessels' navigation in the area.

III. Discussion of Proposed Rule

Shell Exploration and Production Co. requested that an OCS safety zone extending 500 meters from each point on the Appomattox Floating Production System (FPS) facility structure's outermost edge be established. There are safety concerns for both the personnel aboard the facility and the environment. The District Commander has determined that it was highly likely that any allision with the facility would result in a catastrophic event. Placing a safety zone around the facility will significantly reduce the threat of allisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the living marine resources.

In evaluating this request, the Coast Guard explored relevant safety factors and considered several criteria, including but not limited to (1) the level of the existing and foreseeable shipping activity, the presence of unusually harmful or hazardous substances and obstructions within 500 meters of the