flight standards district office/certificate holding district office.

(i) Additional Information

(1) Refer to European Union Aviation Safety Agency (EASA) AD 2022–0008, dated January 19, 2022, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1302.

(2) For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

(j) Material Incorporated by Reference

None.

Issued on October 7, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–22399 Filed 10–21–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 314

[Docket No. FDA–2021–N–0862]

RIN 0910–AH62

Nonprescription Drug Product With an Additional Condition for Nonprescription Use; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule that appeared in the **Federal Register** of June 28, 2022. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published on June 28, 2022 (87 FR 38313). Either electronic or written comments must be submitted by November 25, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2021–N–0862 for ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–0151, *Chris.Wheeler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 28, 2022, FDA published a proposed rule entitled ''Nonprescription Drug Product With an Additional Condition for Nonprescription Use.'' The 120-day comment period for the proposed rule is scheduled to close on October 26, 2022. The proposed rule, if finalized, would establish requirements for a nonprescription drug product that has an additional condition for nonprescription use that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner.

The Agency has received separate requests for a 30-day and 90-day

extension of the comment period for the proposed rule. Each request conveyed concern that the current 120-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule until November 25, 2022. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23033 Filed 10–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket Number USCG–2022–0313]

RIN 1625–AA00

Safety Zone; Vito Floating Production System, Outer Continental Shelf Facility, Mississippi Canyon Block 939, Gulf of Mexico

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a safety zone around the Vito Floating Production System (FPS), located in Mississippi Canyon Block 939 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. Establishing a safety zone around the facility would significantly reduce the threat of allisions, collisions, security breaches, oil spills, releases of natural gas, and thereby protect the safety of life, property, and the environment. Only vessels measuring less than 100 feet in length overall and not engaged in towing, attending vessels, or those vessels specifically authorized by the Eighth Coast Guard District Commander or a designated representative are permitted to enter or remain in the safety zone. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before November 23, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0313 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 LCDR David Newcomb, District Eight OCS, U.S. Coast Guard; telephone 504–671–2106, *David.T.Newcomb@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. 544, 43 U.S.C. 1333, and Department of Homeland Security Delegation No. 0170.1, 33 CFR part 147 permits the establishment of safety zones for facilities located on the OCS for the purpose of protecting life and property on the facilities. The protections included in a safety zone established under 33 CFR part 147 are promoting safety of life and property on the facilities as well as their appurtenances and attending vessels and also for the adjacent waters located in and around each facility. Therefore, a safety zone under 33 CFR part 147 may also include provisions to restrict, prevent, or control certain activities, including access by vessels or persons to maintain safety of life, property and the environment. Shell Exploration and Production Company requested that the Coast Guard establish a safety zone around its facility located in the deepwater area of the Gulf of Mexico on the OCS. The Coast Guard determined that establishing a safety zone around this facility would significantly reduce the threat of allisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the environment.

III. Discussion of Proposed Rule

The safety zone proposed by this rulemaking is on the OCS in the deepwater area of the Gulf of Mexico in Mississippi Canyon Block 939 at the center point of N 28°01′32.325″, W 89°12′33.254″. The safety zone would be permanent. For the purpose of safety zones established under 33 CFR part 147, the deepwater area is 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. 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 vessel. The deepwater area also includes an extensive system of fairways.

Only vessels measuring less than 100 feet in length overall and not engaged in towing, attending vessels as defined in 33 CFR 147.20, or those vessels specifically authorized by the Eighth Coast Guard District Commander or a designated representative are permitted to enter or remain in the safety zone. The transit of other vessels into and through the safety zone area would be prohibited. Requests for entry will be considered and reviewed on a case-by-case basis. These proposed regulations are consistent with the existing safety zones on other OCS platforms in the Gulf of Mexico. Persons or vessels that require authorization to enter the safety zone must request it from the Commander, Eighth Coast Guard District or a designated representative. If permission is granted, all persons and vessels shall comply with the instructions of the Commander or a designated representative.

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).

Aligning with 33 CFR 147.15, the safety zone established will extend to a maximum distance of 500 meters around the OCS facility measured from each point on its outer edge, but may not interfere with the use of recognized sea lanes essential to navigation. Vessel traffic would be able to safely transit