or more and 18,000 total flight cycles or fewer as of April 14, 2022 (phase-in Effective Date of TR ALI–0763): Within 5,000 flight cycles from April 14, 2022, or before exceeding 20,000 total flight cycles, whichever occurs first.

(3) For a MLG retract actuator piston rod that has accumulated more than 18,000 total flight cycles as of April 14, 2022 (phase-in Effective Date of TR ALI–0763): Within 2,000 flight cycles from April 14, 2022.

(h) No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless they are approved as an alternative method of compliance in accordance with paragraph (i)(1) of this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j)(3) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or MHI RJ Aviation ULC Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

(1) Refer to Transport Canada AD CF–2022–56, dated September 26, 2022, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2023–1992.

(2) For more information about this AD, contact Gabriel D. Kim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7343; email *9-avs-nyaco-cos@faa.gov.*

(3) For MHI RJ service information identified in this AD that is not incorporated by reference, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* website *mhirj.com.*

(k) Material Incorporated by Reference

None.

Issued on October 4, 2023.

Victor Wicklund,

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

[FR Doc. 2023–22486 Filed 10–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0179]

Prior Notice of Imported Food Questions and Answers (Edition 4): Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled ''Prior Notice of Imported Food Questions and Answers (Edition 4): Guidance for Industry.'' The guidance document updates the current version of the guidance by including three additional questions. One question relates to any effect systems recognition or equivalency determinations have on prior notice requirements. The other two questions relate to FDA's notice to a submitter or transmitter of prior notice of an FDA refusal for inadequate prior notice or hold, if the food article is from a foreign facility that is not registered and addresses the timeframe for making requests for FDA review of such refusal or hold. FDA is also making other technical editorial changes. The guidance announced in this notice finalizes the draft guidance of the same title dated September 13, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on October 13, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2011–N–0179 for ''Prior Notice of Imported Food Questions and Answers (Edition 4): 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, 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.

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 Division of Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Peter Ajuonuma, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852, 301–796–2277, *Peter.Ajuonuma@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Prior Notice of Imported Food Questions and Answers (Edition 4): Guidance for Industry.'' In the **Federal Register** of September 13, 2022 (87 FR 55932), FDA announced the availability of the draft guidance entitled ''Prior Notice of Imported Food Questions and Answers (Edition 4); Draft Guidance for Industry.'' FDA received no comments on the draft guidance. As a result, we are publishing the guidance as drafted, with minor editorial changes to improve clarity, such as replacing the term ''animal feed'' with ''animal food.'' The guidance announced in this notice finalizes the draft guidance dated September 13, 2022, and replaces ''Prior Notice of Imported Food Questions and Answers (Edition 3): Guidance for Industry,'' dated June 2016.

FDA continues to believe that it is reasonable to maintain responses to questions concerning prior notice of imported food in a single document that is periodically updated in response to additional questions or regulatory or policy changes. As in the previous editions, the following indicators are used to help users identify revisions: (1) the guidance is identified as a revision of a previously issued document; (2) the revision date appears on the cover of the guidance; (3) the edition number of the guidance is included in its title; and (4) revised or added questions and answers are identified as such in the body of the guidance.

On November 7, 2008, we published a final rule in the **Federal Register** requiring submission to FDA of prior notice of food, including food for animals, that is imported or offered for import into the United States (73 FR 66294). The rule implements section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188) and requires that FDA receive prior notice of food imported or offered for import into the United States.

On December 16, 2003, FDA issued a guidance entitled ''Prior Notice of Imported Food Questions and Answers (Edition 1).'' FDA issued a second edition of the guidance on May 3, 2004, and a third edition on June 16, 2016. FDA issued a draft fourth edition, which was published for public comment from September 13, 2022, to November 14, 2022. We are issuing this guidance entitled ''Prior Notice of Imported Food Questions and Answers (Edition 4): Guidance for Industry'' as a level 1 guidance, finalizing the draft guidance issued on September 13, 2022.

The fourth edition of the prior notice guidance adds three additional questions. One question relates to any effect systems recognition or equivalency determinations have on prior notice requirements. The other two questions relate to FDA's notice of a refusal under 801(m)(1) of the FD&C Act (in accordance with § 1.283 (21 CFR 1.283)) for inadequate prior notice or a hold under 801(l) (in accordance with § 1.285 (21 CFR 1.285)) if the food article is from a foreign facility that is not registered, as well as address the timeframe for making requests for FDA review of such a refusal or hold. The guidance is intended to help clarify whether food imported from a country with which FDA has a Systems Recognition Arrangement or equivalence determination is exempted from prior notice requirements. The guidance also clarifies when FDA will provide notice of the refusal or hold to the relevant party, and when the 5-calendar-day clock to request a review of the refusal or hold begins.

We are also making other technical amendments to the guidance due to the expanded capabilities of the U.S. Customs and Border Protection's (CBP) Automated Broker Interface of the Automated Commercial Environment (ABI/ACE) system and FDA's 2017 technical amendments to the prior notice rule (82 FR 15627, March 30, 2017), such as replacing references to the Automated Commercial System (ACS) and successor system with the ABI/ACE system, removing references to requirements that certain prior notice submissions be submitted in FDA's Prior Notice System Interface (FDA PNSI), and updating outdated links and FDA contact information. The fourth edition guidance clarifies that the existence of a Systems Recognition Arrangement with or an equivalence determination of a foreign country does not exempt foods imported from that country from FDA's prior notice requirements.

FDA's policy on and practice of communicating prior notice refusals and holds has changed over time. FDA previously stated that we intended to provide notice regarding refusals to carriers. Those carriers could then notify others, such as the entity that hired the carrier to transport the article of food, of a problem with the prior notice (see 73 FR 66294 at 66365). Subsequently, FDA's Guidance for Industry ''Prior Notice of Imported Food Questions and Answers (Edition 3)'' was published with the explanation that FDA will communicate the decision to examine articles of food to CBP.

The fourth edition clarifies that notification of these prior notice refusals and holds will be communicated to CBP and provided to the relevant party (*i.e.,* the submitter or transmitter of prior notice) upon arrival of the article. FDA is clarifying its policy because providing advanced notice of a refusal or hold to a submitter or transmitter could create incentives for bad actors, who may attempt to reroute their entries for the purpose of evading FDA requirements and importing unsafe food.

The fourth edition of the guidance also clarifies the 5-calendar-day clock to request a review of these refusals and

holds. Under §§ 1.283(d) and 1.285(j), certain parties may, for the enumerated reasons, request reviews of the prior notice refusals and holds within 5 calendar days of the hold or refusal. The fourth edition clarifies that FDA considers the 5-calendar-day clock to begin when FDA provides notice of the refusal or hold to the submitter or transmitter.

Additionally, in 2016, CBP issued a notice announcing that ABI/ACE would replace ACS as the sole electronic data interchange system authorized by CBP for the processing of electronic entries of FDA-regulated products (see 81 FR 30320, May 16, 2016). ABI/ACE became the successor system to ACS. In 2017, we amended 21 CFR part 1, subpart I to replace references to ACS and successor system with ABI/ACE (see 82 FR 15627). As part of this rulemaking, we eliminated some requirements for submitting prior notice due to the expanded capabilities of ABI/ACE, such as the requirement to submit articles that have been refused under section 801(m)(1) of the FD&C Act or subpart I in FDA PNSI. Further, ABI/ACE can now accommodate entries it previously could not, such as articles of food arriving through international mail. Therefore, to reflect these changes that were implemented in the rulemaking and the expanded capabilities of ABI/ACE, we are replacing references in the prior notice guidance to ACS with the successor system ABI/ACE. In addition, we are providing clarification regarding how persons may submit prior notice for articles of food imported or offered for import by international mail.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on guidance for industry on the prior notice requirements. 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1.278 to 1.282 have been approved under OMB control number 0910–0520.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22649 Filed 10–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0735]

RIN 1625–AA00

Safety Zone; Atlantic Ocean, Jacksonville Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waterways surrounding Jacksonville, Florida during the 2023 Jacksonville Beach Sea and Sky Air Show. The safety zone is necessary to ensure the safety of event participants and spectators. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Jacksonville or a designated representative.

DATES: This rule is effective from 7 a.m. until 5 p.m. on October 20, 2023, through October 22, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0735 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Marine Science Technician First Class Anthony DeAngelo, Waterways Management Division, Sector Jacksonville, FL, U.S. Coast Guard; telephone 904–714–7631; email *Anthony.DeAngelo@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port
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

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 it is impracticable. The Coast Guard was notified of the event without ample time for the NPRM process. We must establish the safety zone by October 20, 2023, and lack sufficient time to provide for a reasonable comment period and then consider those comments before issuing this rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to ensure the safety of the participants and vessels during the 2023 Jacksonville Beach Sea and Sky Air Show.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Jacksonville (COTP) has determined that potential hazards associated with the 2023 Jacksonville Beach Sea and Sky Air Show will be a safety concern for persons and vessels in the regulated area. This rule is needed to ensure the safety of the event participants, the general public, vessels and the marine environment in the navigable waters within the safety zone during the 2023 Jacksonville Beach Sea and Sky Air Show.

IV. Discussion of the Rule

This rule establishes a safety zone on certain waters of Jacksonville, Florida, during the 2023 Jacksonville Beach Sea