

airspace action makes minor updates to certain boundary coordinates of restricted areas R-2516, R-2517, R-2534A and R-2534B; Vandenberg AFB, CA, to match the digital shoreline data received from the NOAA

Administration. This ensures that the affected boundaries continue to match the NOAA-defined position of the U.S. shoreline. It does not alter the location, altitudes, or activities conducted within the airspace; therefore, it is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73, as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.25 [Amended]

■ 2. Section 73.25 is amended as follows:

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R-2516 Vandenberg AFB, CA [Amended]

By removing the current boundaries and inserting the following:

Boundaries. Beginning at lat. 35°00'06" N., long. 120°42'12" W.;
to lat. 34°54'00" N., long. 120°33'04" W.;
to lat. 34°50'00" N., long. 120°32'04" W.;
to lat. 34°46'00" N., long. 120°27'04" W.;
to lat. 34°42'00" N., long. 120°30'04" W.;
to lat. 34°38'35" N., long. 120°31'24" W.;
to lat. 34°42'00" N., long. 120°34'34" W.;
to lat. 34°42'00" N., long. 120°40'01" W.;
thence 3 NM from and parallel to the shoreline to the point of beginning.

R-2517 Vandenberg AFB, CA [Amended]

By removing the current boundaries and inserting the following:

Boundaries. Beginning at lat. 34°42'00" N., long. 120°40'01" W.;
to lat. 34°42'00" N., long. 120°34'34" W.;
to lat. 34°38'35" N., long. 120°31'24" W.;
to lat. 34°35'00" N., long. 120°32'04" W.;
to lat. 34°25'00" N., long. 120°27'04" W.;
to lat. 34°24'04" N., long. 120°29'51" W.;
thence 3 NM from and parallel to the shoreline to the point of beginning.

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R-2534A Vandenberg AFB, CA [Amended]

By removing the current boundaries and inserting the following:

Boundaries. Beginning at lat. 34°38'35" N., long. 120°31'24" W.;
to lat. 34°35'45" N., long. 120°28'14" W.;
to lat. 34°36'20" N., long. 120°27'24" W.;
to lat. 34°30'00" N., long. 120°15'34" W.;
to lat. 34°25'00" N., long. 120°15'34" W.;
thence 3 NM from and parallel to the shoreline
to lat. 34°24'39" N., long. 120°19'13" W.;
to the point of beginning.

R-2534B Vandenberg AFB, CA [Amended]

By removing the current boundaries and inserting the following:

Boundaries. Beginning at lat. 34°38'35" N., long. 120°31'24" W.;
to lat. 34°24'39" N., long. 120°19'13" W.;
to lat. 34°25'00" N., long. 120°27'04" W.;
to lat. 34°35'00" N., long. 120°32'04" W.;
to the point of beginning.

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Issued in Washington, DC, on October 31, 2017.

Rodger A. Dean, Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2017-24103 Filed 11-3-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 117, and 507

[Docket No. FDA-2017-D-5996]

Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: 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 guidance for industry entitled "Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food." The guidance announces that we do not intend to take enforcement action against a receiving facility that is a co-manufacturer and that is not in compliance with certain supply-chain program requirements in the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" regulations (preventive controls regulations) for food manufactured for the brand owner, under certain

circumstances, until November 6, 2019. Furthermore, we do not intend to take enforcement action under the Foreign Supplier Verification Programs (FSVP) regulation against an importer whose supply-chain program is subject to enforcement discretion under the preventive controls regulations until November 6, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on November 6, 2017.

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-2017-D-5996 for "Supply-Chain Program Requirements and Co-

Manufacturer Supplier Approval and Verification for Human Food and Animal Food.” 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 21CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-300), 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:

For questions relating to the guidance as it applies to 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 the guidance as it applies to animal food: 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 guidance for industry entitled “Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry.” We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because the guidance represents a less burdensome policy consistent with the public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA’s GGP regulation. This guidance is not subject to Executive Order 12866.

The guidance is intended for persons who participate in certain “co-manufacturing” agreements in the production of human or animal food. By “co-manufacturing,” we mean a contractual arrangement whereby one party (the brand owner) arranges for a second party (the co-manufacturer) to manufacture/process human or animal food on behalf of the first party. The guidance concerns three 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 (FSMA; Pub. L. 111-353). (For more information on the Agency’s implementation of FSMA, see <https://www.fda.gov/fsma>.) These three regulations are part 117 (21 CFR part 117) (published in the **Federal Register** on September 17, 2015, 80 FR 55908), part 507 (21 CFR part 507) (published in the **Federal Register** on September 17, 2015, 80 FR 56170), and the FSVP regulation (published in the **Federal Register** of November 27, 2015, 80 FR 74226). Subpart G of part 117 and subpart E of part 507 establish

requirements for a supply-chain program for those raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain-applied control.

Under the FSVP regulation, importers are required to develop, maintain, and follow a foreign supplier verification program that, among other things, provides adequate assurance that foreign suppliers are producing food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350g) (which authorized the supply-chain programs in parts 117 and 507) (see § 1.502(a) (21 CFR 1.502(a)). An importer that is a receiving facility subject to section 418 of the FD&C Act is deemed to be in compliance with the requirements of the FSVP regulation, except the importer identification requirements in 21 CFR 1.509, if the importer has established and implemented a risk-based supply-chain program in compliance with part 117, subpart G or part 507, subpart E (§ 1.502(c)(3)).

Under the definition of “receiving facility” established in parts 117 and 507, co-manufacturers that are subject to the human food or the animal food preventive controls requirements and that manufacture/process a raw material or other ingredient received from a supplier are receiving facilities. Co-manufacturers that are receiving facilities that have identified a hazard in a raw material or ingredient requiring a supply-chain-applied control are required to approve their suppliers for those raw materials or other ingredients. However, the supply-chain provisions permit an entity other than the receiving facility (e.g., permit the brand owner) to determine, conduct, or both determine and conduct, appropriate supplier verification activities, provided that the receiving facility documents its review and assessment of the other entity’s applicable documentation. (See §§ 117.415(a)(3) and 507.115(a)(3).) Specifically, the rules allow for a co-manufacturer to base its verification of suppliers on review of adequate documentation of the brand owner’s supplier verification activities.

Industry has expressed concerns that the requirements of the supply-chain program would require revisions to contracts between brand owners and their suppliers to allow brand owners to share certain information (e.g., audits of suppliers) with co-manufacturers, and that establishing new contracts would take a significant period of time, impeding their ability to meet

compliance dates (Ref. 1). If a contract prevents a co-manufacturer from being able to review a brand owner's documentation of supplier verification activities, the co-manufacturer would not be able to verify suppliers based on its review of that documentation. Consequently, the co-manufacturer would need to conduct supplier verification activities (e.g., on-site audits) that might otherwise not be required.

To provide time for contracts to be revised to allow co-manufacturers to review all necessary documentation from the brand owner, FDA is announcing that, under certain circumstances and on a temporary basis, we do not intend to take enforcement action against a receiving facility that is a co-manufacturer, and that is not in compliance with certain supply-chain program requirements (§§ 117.410(d) and 117.415(a)(3) or §§ 507.110(d) and 507.115(a)(3)) for food manufactured for the brand owner until November 6, 2019. Furthermore, we do not intend to take enforcement action under the FSVP regulation against an importer who is relying on § 1.502(c)(3) but whose supply-chain program is subject to enforcement discretion regarding §§ 117.410(d) and 117.415(a)(3) or §§ 507.110(d) and 507.115(a)(3).

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.

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 part 117 have been approved under OMB control number 0910–0751. The collections of information in part 507 have been approved under OMB control number 0910–0789.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm>, <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/default.htm>, or <https://www.regulations.gov>. Use the FDA Web sites listed in the previous sentence to

find the most current version of the guidance.

IV. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>.

1. Letter from Grocery Manufacturers Association to Dr. Stephen Ostroff, Acting Commissioner of Food and Drugs, February 7, 2017.

Dated: October 31, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24098 Filed 11–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–1011]

RIN 1625–AA00

Safety Zone, Delaware River; Pipeline Removal

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones in the Mifflin Range on the Delaware River to facilitate pipeline removal in preparation for the deepening of the Delaware River. The safety zones will be established for the waters in the vicinity of the dredge, dredge equipment, dive operations, and pipe removal operations. This regulation is necessary to provide for the safety of life on navigable waters of the Delaware River in the vicinity of pipeline removal operations and to protect mariners from the hazards associated with dredging and pipeline removal operations. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port Delaware Bay.

DATES: This rule is effective from November 6, 2017, through December 4, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2017–1011 in the “SEARCH” box and click “SEARCH.” Click on Open Docket

Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Edmund Ofalt, Waterways Management Branch, U.S. Coast Guard Sector Delaware Bay; telephone (215) 271–4814, email Edmund.J.Ofalt@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
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 due to the short time period between when Sector Delaware Bay received complete details of this project, October 20, 2017, and the date when these safety zones needed to go into effect by. It is impracticable and contrary to the public interest to publish an NPRM to provide a notice and opportunity for comment period because the safety zones must be established by November 6, 2017 to ensure safety of life on navigable waters in the vicinity of dredging operations, underwater cutting operations, and pipeline removal operations and to protect mariners from hazards associated with the same.

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 impracticable and contrary to the public interest because immediate action is needed to mitigate the hazards presented to safety of life on the Delaware River by the presence of dredge equipment, dredging operations, dive operations, and pipeline removal operations.