AIRAC date	State	City	Airport	FDC No.	FDC date	Subject.
21–Apr–22	KS	Emporia	Emporia Muni	2/3952	1/13/22	RNAV (GPS) RWY 19, Orig-B.
21–Apr–22	KS	Emporia	Emporia Muni	2/3953	1/13/22	RNAV (GPS) RWY 1, Orig-B.
21–Apr–22	TN	Humboldt	Humboldt Muni	2/6094	2/22/22	RNAV (GPS) RWY 4, Orig-A.
21–Apr–22	OK	Tahlequah	Tahlequah Muni	2/6583	2/28/22	RNAV (GPS) RWY 35, Amdt 1B.
21–Apr–22	MN	Wheaton	Wheaton Muni	2/9026	2/11/22	RNAV (GPS) RWY 34, Orig-A.
21–Apr–22	MN	Wheaton	Wheaton Muni	2/9028	2/11/22	RNAV (GPS) RWY 16, Orig-A.
21–Apr–22	MN	Roseau	Roseau Muni/Rudy Billberg Fld.	2/9034	2/14/22	VOR RWY 16, Amdt 8.
21–Apr–22	MN	Roseau	Roseau Muni/Rudy Billberg Fld.	2/9036	2/14/22	VOR RWY 34, Amdt 1.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 112, 117, 121, and 507

[Docket No. FDA–2021–D–0563]

Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions; 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 a final guidance for industry entitled ''Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions.'' This guidance states Agency policy regarding enforcement of certain requirements related to supply-chain programs for contract manufacturers/processors, the intentional adulteration regulation, and supplier approval and verification requirements in the Current Good Manufacturing Practice and Preventive Controls Regulations and the Foreign Supplier Verification Programs (FSVP) Regulation.

DATES: The announcement of the guidance is published in the **Federal Register** on March 14, 2022.

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–2021–D–0563 for ''Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions.'' 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 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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: Jennifer Erickson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7382.

For questions relating to Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Kevin Kwon, Center for Food Safety and Applied Nutrition (HFS–600), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 703–785–1125.

For questions relating to Mitigation Strategies to Protect Food Against Intentional Adulteration: Ryan Newkirk, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–3712.

For questions relating to Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions.'' We are issuing the guidance consistent with our good guidance practices regulation (21 CFR 10.115). We are implementing the 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 presents a less burdensome policy consistent with the public health. Although this guidance is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation.

This guidance concerns five of the seven foundational rules 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). The five final rules are entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' (published in the **Federal Register** of September 17, 2015, 80 FR 55908) (part 117); ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' (published in the **Federal Register** of September 17, 2015, 80 FR 51670) (part 507); ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'' (published in the **Federal Register** of November 27, 2015, 80 FR 74226) (FSVP regulation); ''Mitigation Strategies to Protect Food Against Intentional Adulteration'' (published in the **Federal Register** of May 27, 2016, 81 FR 34166) (IA regulation or part 121); and ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (published in the **Federal Register** of November 27, 2015, 80 FR 74354) (*https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm*) (Produce Safety regulation or part 112).

In the guidance we state that, at this time and based on our current understanding of the risks, we do not intend to enforce certain regulatory requirements for certain entities and/or activities covered by these five rules:

- Extension of FDA's intent not to take enforcement action in certain circumstances against a receiving facility that is a contract manufacturer/processor not in compliance with certain supply-chain program requirements for food manufactured for a brand owner.
- Under the intentional adulteration regulation:
  - Intent not to enforce the intentional adulteration regulation requirements for facilities under the preexisting farm-activity related enforcement policy, and
  - Intent not to enforce the requirement for reanalysis in certain circumstances, for example, when there is a single failure that is addressed through implementation of corrective action procedures.
- Intent not to enforce the supplier approval and verification requirements in parts 117 and 507 and the FSVP regulation with regard to supplier compliance with requirements that are already associated with an enforcement discretion policy.

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. 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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. The collections of information in 21 CFR part 1, subpart L have been approved under OMB control number 0910–0752. The collections of information in 21 CFR part 121 have been approved under OMB control number 0910–0812. The collections of information in part 112 have been approved under OMB control number 0910–0816.

III. Electronic Access

Persons with access to the internet may obtain the document at either *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm, 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: March 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05315 Filed 3–11–22; 8:45 am]

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