4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 117 and 507

[Docket Nos. FDA-2011-N-0920 and FDA-2011-N-0922]

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; Supply-Chain Programs and Onsite Audits; Announcement of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the effective date for requirements related to establishing and implementing supply-chain programs, records documenting supply-chain programs, and onsite audits in two final rules, 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, that appeared in the *Federal Register* of September 17, 2015.

DATES: The effective date for the amendments to 21 CFR 117.405(a)(2), 117.435(d), and 117.475(c)(2), which published in the *Federal Register* of September 17, 2015 (80 FR 55908), is [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The effective date for the amendments to 21 CFR 507.105(a)(2), 507.135(d), and 507.175(c)(2), which published in the *Federal Register* of September 17, 2015 (80 FR 56170), is [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: *For questions relating to Current Good Manufacturing Practice, 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 Current Good Manufacturing Practice, 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.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 17, 2015 (80 FR 55908), we published a final rule that established "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" in part 117 (21 CFR part 117). Section 117.405(a)(2) specifies circumstances in which a receiving facility that is an importer need not conduct certain supplier verification activities. Section 117.475(c)(2) provides for documentation related to its supply-chain program that a receiving facility that is an importer is required to maintain. Section 117.435(d) specifies that if an onsite audit is solely conducted to meet the supply-chain program requirements of part 117 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M (21 CFR part 1, subpart M), the audit is not subject to the requirements in those regulations.

At the time the final rule published, §§ 117.405(a)(2) and 117.475(c)(2) referred to provisions in a future final rule, "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (FSVP rule) (80 FR 74226; November 27, 2015), whereas § 117.435(d) referred to a provision in a future final rule, "Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications" (third-party certification rule) (80 FR 74570; November 27, 2015). In the final rule establishing part 117, we stated that we would publish a document in the *Federal Register* announcing the effective dates of §§ 117.405(a)(2), 117.475(c)(2), and 117.435(d) (80 FR 55908 at 56131).

In the *Federal Register* of September 17, 2015 (80 FR 56170), we published a final rule that established "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based

Preventive Controls for Food for Animals" in part 507 (21 CFR part 507) . Section 507.105(a)(2) specifies circumstances in which a receiving facility that is an importer need not conduct certain supplier verification activities. Section 507.175(c)(2) provides for documentation related to its supply-chain program that a receiving facility that is an importer is required to maintain. Section 507.135(d) specifies that if an onsite audit is solely conducted to meet the supply-chain program requirements of part 507 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, the audit is not subject to the requirements in those regulations.

At the time the final rule published, §§ 507.105(a)(2) and 507.175(c)(2) referred to provisions in a future final FSVP rule, whereas § 507.135(d) referred to a provision in a future final third-party certification rule. In the final rule establishing part 507, we stated that we would publish a document in the *Federal Register* announcing the effective dates of §§ 507.105(a)(2), 507.175(c)(2), and 507.135(d) (80 FR 56170 at 56330).

The final FSVP rule and the final third-party certification rule published in the *Federal Register* on November 27, 2015, with effective dates of January 26, 2016.

This document announces that the effective date for §§ 117.405(a)(2), 117.475(c)(2), 117.435(d), 507.105(a)(2), 507.175(c)(2), and 507.135(d) is [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: October 21, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

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