



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 112, 117, and 507

[Docket Nos. FDA-2011-N-0920, FDA-2011-N-0921, and FDA-2011-N-0922]

RINs 0910-AG10, 0910-AG35, and 0910-AG36

Implementing the Food and Drug Administration Food Safety Modernization Act; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is correcting with technical amendments two final rules that published in the *Federal Register* of September 17, 2015, and one final rule that published in the *Federal Register* of November 27, 2015. The final rules published with editorial and inadvertent errors. This document corrects those errors.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Sylvia Kim, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7599.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 17, 2015 (80 FR 55908 and 80 FR 56170), FDA published the 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” with editorial and inadvertent errors in the regulatory text. In the *Federal Register* of

November 27, 2015 (80 FR 74354), FDA published the final rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” with editorial and inadvertent errors in the regulatory text. This action is being taken to correct those editorial and inadvertent errors.

List of Subjects

21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

PART 112--STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

1. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

2. In § 112.4, revise paragraph (a) to read as follows:

§ 112.4 Which farms are subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as “produce” is defined in § 112.3) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a “covered farm” subject to this

part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

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3. In § 112.5, revise paragraphs (a)(1) and (2) to read as follows:

§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) * * *

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3) the farm sold directly to qualified end-users (as defined in § 112.3) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

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4. In § 112.161, revise paragraph (b) to read as follows:

§ 112.161 What general requirements apply to records required under this part?

* * * * *

(b) Records required under §§ 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

PART 117--CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS,
AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

5. The authority citation for part 117 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C.
243, 264, 271.

6. In § 117.126, revise paragraph (b)(5) to read as follows:

§ 117.126 Food safety plan.

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(b) * * *

(5) The written procedures for monitoring the implementation of the preventive controls
as required by § 117.145(a);

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PART 507--CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS,
AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

7. The authority citation for part 507 continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C.
243, 264, 271.

8. In § 507.31, revise paragraph (c)(5) to read as follows:

§ 507.31 Food safety plan.

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(c) * * *

(5) The written procedures for monitoring the implementation of the preventive controls
as required by § 507.40(a);

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9. In § 507.130, revise paragraph (c)(2)(ii) to read as follows:

§ 507.130 Conducting supplier verification activities for raw materials and other ingredients.

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(c) * * *

(2) * * *

(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign countries.

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Dated: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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