and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.,* activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

Qualified end-user * * *

(1) Is located:

* * * * *

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

* * * * *

■ 7. In § 117.5, revise the first sentence of paragraph (a), and revise paragraph (h)(3)(v) to read as follows:

§ 117.5 Exemptions.

(a) Except as provided by subpart E of this part, subparts C and G of this part do not apply to a qualified facility.

* * *

* * * * *

(h) * * *

(3) * * *

(v) Extracting (including by pressing, by distilling, and by solvent extraction) dried/dehydrated herb and spice products (*e.g.,* dried mint), fresh herbs (*e.g.,* fresh mint), fruits and vegetables (*e.g.,* olives, avocados), grains (*e.g.,* oilseeds), and other herb and spice products (*e.g.,* chopped fresh mint, chopped dried mint);

* * * * *

■ 8. In § 117.136, revise paragraphs (a)(2) introductory text, (a)(5), and (b)(5) to read as follows:

§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) * * *

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented and you:

* * * * *

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document the implementation of that system.

(b) * * *

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food you distribute.

■ 9. In § 117.145, revise paragraph (a) to read as follows:

§ 117.145 Monitoring.

* * * * *

(a) *Written procedures.* You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and

* * * * *

■ 10. In § 117.201, revise paragraphs (b)(2)(i)(B) and (b)(2)(ii) to read as follows:

§ 117.201 Modified requirements that apply to a qualified facility.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) Write to the U.S. Food and Drug Administration (HFS–681), 5100 Paint Branch Pkwy., College Park, MD 20740; or

* * * * *

(ii) Send a paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS–681), 5100 Paint Branch Pkwy., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

* * * * *

■ 11. In § 117.257, revise paragraph (e) to read as follows:

§ 117.257 Contents of an order to withdraw a qualified facility exemption.

* * * * *

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 117.287;

* * * * *

■ 12. In § 117.264, revise paragraph (a)(1) to read as follows:

§ 117.264 Procedure for submitting an appeal.

(a) * * *

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

* * * * *

Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01091 Filed 1–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 507

[Docket No. FDA–2011–N–0922]

RIN 0910–AG10

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is amending a final rule that published in the **Federal Register** of September 17, 2015. That final rule established requirements for domestic and foreign facilities required to register under the Federal Food, Drug, and Cosmetic Act for current good manufacturing practice, hazard analysis, and risk-based preventive controls for food for animals. The final rule published with some editorial and inadvertent errors. This document corrects those errors.

DATES: Effective January 22, 2016.

FOR FURTHER INFORMATION CONTACT: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6246, email: *jenny.murphy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, September 17, 2015 (80 FR 56170), FDA published the final rule ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' with some editorial and inadvertent errors. This action is being taken to correct those errors by making the following correcting amendments.

List of Subjects in 21 CFR Part 507

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

Accordingly, FDA is amending 21 CFR part 507 with the following technical amendments:

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

■ 1. The authority citation for 21 CFR 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.

■ 2. In § 507.3, revise the definitions of ''audit'', ''harvesting'', ''hazard requiring a preventive control'', and ''small business'' to read as follows:

§ 507.3 Definitions.

* * * * *

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as animal food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.,* foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

* * * * *

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

* * * * *

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

* * * * *

■ 3. In § 507.5, revise paragraph (e)(5) to read as follows:

§ 507.5 Exemptions.

* * * * *

(e) * * *

(5) Molasses (*e.g.,* processed sugar cane, sugar beets, and citrus);

* * * * *

■ 4. In § 507.7, revise paragraphs (b)(2)(i)(B) and (b)(2)(ii) to read as follows:

§ 507.7 Requirements that apply to a qualified facility.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) Write to the U.S. Food and Drug Administration (HFS–681), 5100 Paint Branch Pkwy., College Park, MD 20740; or

* * * * *

(ii) Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS–681), 5100 Paint Branch Pkwy., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

* * * * *

■ 5. In § 507.19, revise paragraph (b)(2) to read as follows:

§ 507.19 Sanitation.

* * * * *

(b) * * *

(2) In wet processing of animal food, when cleaning and sanitizing are necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

* * * * *

■ 6. In § 507.27, revise paragraph (b) to read as follows:

§ 507.27 Holding and distribution.

* * * * *

(b) The labeling for the animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food for the intended animal species.

* * * * *

■ 7. In § 507.33, revise paragraph (c)(1) to read as follows:

507.33 Hazard analysis.

* * * * *

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

* * * * *

■ 8. In § 507.36, revise paragraphs (a)(2) introductory text and (3) introductory text and paragraphs (a)(5) and (b)(5) to read as follows:

§ 507.36 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) * * *

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented; and you:

* * * * *

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the animal food in accordance with applicable animal food safety requirements and you:

* * * * *

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the animal food you distribute and you document the implementation of that system.

* * * * *

(b) * * *

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent

distribution step, of the hazards in the animal food you distribute.

* * * * *

■ 9. In § 507.47, revise paragraphs (b)(1)(i)(A) and (b)(1)(i)(B)(*1*) to read as follows:

§ 507.47 Validation.

* * * * *

(b) * * *

(1) * * *

(i)(A) Prior to implementation of the food safety plan; or

(B) * * *

(*1*) Within 90 calendar days after production of the applicable animal food first begins; or

* * * * *

■ 10. In § 507.50, revise paragraph (c)(1) to read as follows:

§ 507.50 Reanalysis.

* * * * *

(c) * * *

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or

* * * * *

■ 11. In § 507.51, revise paragraph (a)(4)(iii) to read as follows:

§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged animal food.

(a) * * *

(4) * * *

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7-working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7-working days; and

* * * * *

■ 12. In § 507.65, revise paragraph (e) to read as follows:

§ 507.65 Contents of an order to withdraw a qualified facility exemption.

* * * * *

(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 507.85;

* * * * *

■ 13. In § 507.69, revise paragraph (a)(1) to read as follows:

§ 507.69 Procedure for submitting an appeal.

(a) * * *

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

* * * * *

Dated: January 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01290 Filed 1–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that USS *MONTGOMERY* (LCS 8) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective January 22, 2016 and is applicable beginning December 15, 2015.

FOR FURTHER INFORMATION CONTACT: Commander Theron R. Korsak, JAGC, U.S. Navy, Admiralty Attorney, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone number: 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS *MONTGOMERY* (LCS 8) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I paragraph 2(a)(i), pertaining to the location of the forward masthead light at a height not less than 12 meters above the hull; Annex I, paragraph 2(f)(i), pertaining to the placement of the masthead light or lights above and clear of all other lights and obstructions; Annex I, paragraph 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, and the horizontal distance between the forward and after masthead light; Annex I, paragraph 3(c), pertaining to the task light's horizontal distance from the fore and aft centerline of the vessel in the athwartship direction. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended by:

■ a. In Table One, adding, in alpha numerical order, by vessel number, an entry for USS *MONTGOMERY* (LCS 8);

■ b. In Table Four, under paragraph 15, adding, in alpha numerical order, by vessel number, an entry for USS *MONTGOMERY* (LCS 8);

■ c. In Table Four, under paragraph 16, adding, in alpha numerical order, by vessel number, an entry for USS *MONTGOMERY* (LCS 8); and

■ d. In Table Five, adding, in alpha numerical order, by vessel number, an entry for USS *MONTGOMERY* (LCS 8).