DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

Amendment of Class E Airspace; Deer Lodge MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, correction.

SUMMARY: This action corrects a final rule published in the Federal Register of March 29, 2016, amending Class E airspace extending upward from 700 feet above the surface at Deer Lodge-County Airport, Deer Lodge, MT. The FAA identified that the Class E airspace area extending upward from 1,200 feet above the surface was omitted from the Class E airspace description for the airport.

DATES: Effective 0901 UTC, May 26, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Operations Support Group, Western Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (425) 203–4517.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the Federal Register amending Class E Airspace extending upward from 700 feet above the surface at Deer Lodge-County Airport, Deer Lodge, MT. (81 FR 17377, March 29, 2016) Docket No. FAA–2015–3773. Subsequent to publication, the Aeronautical Information Services branch identified that the Class E airspace extending upward from 1,200 feet above the surface was inadvertently left out of the regulatory text describing the boundary for the airport. This action reestablishes the airspace extending upward from 1,200 feet above the surface as part of that description.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9 and publication of conforming amendments.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, in the Federal Register of March 29, 2016 (81 FR 17377) FR Doc. 2016–06934, Amendment of Class E Airspace; Deer Lodge, MT, is corrected as follows:

§71.1 [Amended]

ANM MT E5 Deer Lodge, MT [Corrected]

On page 17378, column 3, after line 48, add the following text:

“That airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 46°41′00″ N., long. 114°08′00″ W.; to lat. 47°03′00″ N., long. 113°33′00″ W.; to lat. 46°28′00″ N., long. 112°15′00″ W.; to lat. 45°41′00″ N., long. 112°13′00″ W.; to lat. 45°44′00″ N., long. 113°03′00″ W.; thence to the point of origin.”

Issued in Seattle, Washington, on April 18, 2016.

Tracey Johnson,
Manager, Operations Support Group, Western Service Center.

[FR Doc. 2016–09699 Filed 4–27–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1
[Docket No. FDA–2011–N–0143]

RIN 0910–AG64

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a final rule published in the Federal Register of November 27, 2015. That final rule established requirements for importers to verify that food they import into the United States is produced consistent with the hazard analysis and risk-based preventive controls and standards for produce safety provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. The final rule published with some editorial and inadvertent errors. This document corrects those errors.

DATES: Effective April 28, 2016.

FOR FURTHER INFORMATION CONTACT: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4614, email: brian.pendleton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 27, 2015 (80 FR 74226), FDA published the final rule “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” with some editorial and inadvertent errors. We are taking this action to correct inadvertent errors in the preamble to the final rule.
and to improve the accuracy of the provisions added to the Code of Federal Regulations.

1. On page 74271, in the second paragraph of section III.E.5, in the discussion of allowing importers to obtain certain information needed to meet their FSVP requirements from other entities as described in certain sections of the document, the reference to “sections III.E.5, III.F.4, and III.G.4” is corrected to read “sections III.A.7, III.F.4, and III.G.4”.

2. On page 74332, in the third column, in the second “bullet” point in Response 334, “For the importation of food from a supplier that is subject to the preventive controls regulations for human food or animal food or the produce safety regulation, 6 months after the foreign supplier of the food is required to comply with the relevant regulations;” is corrected to read “For the importation of food from a supplier that is subject to the preventive controls regulation for human food, the preventive controls or CGMP requirements in the preventive controls regulation for animal food, or the produce safety regulation, 6 months after the foreign supplier of the food is required to comply with the relevant regulations;”.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:


2. Amend § 1.500 by revising the definitions of “Environmental pathogen”, “Harvesting”, and “Manufacturing/processing” to read as follows:

§ 1.500 What definitions apply to this subpart?

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include Listeria monocytogenes and Salmonella spp., but do not include the spores of pathogenic sporeforming bacteria.

Harvesting applies to 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 where they were grown or raised and preparing them for use as 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.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

3. Revise the section heading of § 1.501 to read as follows:

§ 1.501 To what foods do the requirements in this subpart apply?

4. Revise the section heading and the paragraph headings in paragraphs (a) and (b) of § 1.511 to read as follows:

§ 1.511 What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?

(a) Importers subject to certain requirements in the dietary supplement current good manufacturing practice regulation.

(b) Importers whose customer is subject to certain requirements in the dietary supplement current good manufacturing practice regulation.

In § 1.512, revise the first sentence of paragraphs (b)(3)(ii) introductory text and (c)(1)(i) and revise paragraphs (b)(3)(iii) and (iv) to read as follows:

§ 1.512 What FSVP may I have if I am a very small importer or I am importing certain food from certain small foreign suppliers?

(i) If your foreign supplier is a qualified facility as defined by § 117.3 or § 503.3 of this chapter and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(ii) If your foreign supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter, and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the produce and at least every 2 years thereafter, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws...
and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(iv) If your foreign supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens and you choose to comply with the requirements in this section, you must obtain written assurance, before importing the shell eggs and at least every 2 years thereafter, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(c) * * * *

(1) * * *

(i) Except as specified in paragraph (c)(1)(ii) of this section, in approving your foreign suppliers, you must evaluate the applicable FDA food safety regulations and information relevant to the foreign supplier’s compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

* * * *

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09784 Filed 4–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA–2016–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) published a document in the Federal Register of April 18, 2016 (81 FR 22520), amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January and February 2016. That rule included two amendatory instructions that cited incorrect sections of 21 CFR part 524. Effective: April 28, 2016.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In FR Doc. 2016–08827, appearing on page 22520 in the Federal Register of Monday, April 18, 2016, the following corrections are made:

On page 22524, in the third column, remove amendatory instructions 35 and 36.

List of Subjects in 21 CFR Part 524

Animal drugs.

Accordingly, 21 CFR part 524 is corrected by making the following correcting amendments:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for part 524 continues to read as follows:


§ 524.1193 [Amended]

2. In paragraph (b)(2) of § 524.1193, remove “000859” and in its place add “016592”.

§ 524.1484k [Amended]

3. In § 524.1484k, revise the section heading to read: Neomycin and prednisolone suspension.

Dated: April 22, 2016.

Tracey Forfa,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2016–09865 Filed 4–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9764]

RIN 1545–BF39

Section 6708 Failure To Maintain List of Advises With Respect to Reportable Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the penalty under section 6708 of the Internal Revenue Code for failing to make available lists of advisees with respect to reportable transactions. Section 6708 imposes a penalty upon material advisors for failing to make available to the Secretary, upon written request, the list required to be maintained by section 6112 of the Internal Revenue Code within 20 business days after the date of such request. The final regulations primarily affect individuals and entities who are material advisors, as defined in section 6111 of the Internal Revenue Code.

DATES: Effective Date: These regulations are effective on April 28, 2016.

Applicability Date: For date of applicability see § 301.6708–1(i).

FOR FURTHER INFORMATION CONTACT: Hilary March, (202) 317–5406 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–2245.

The collection of information in the final regulations is in § 301.6708–1(c)(3)(ii). This information is required for the IRS to determine whether good cause exists to allow a person affected by these regulations an extension of the legislatively established 20-business-day period to furnish a lawfully requested list to the IRS. The collection of information is voluntary to obtain a benefit. The likely respondents are persons (individuals and entities) who qualify as material advisors, as defined in section 6111, who are unable to respond to a valid and statutorily authorized section 6112 list request within the statutory period of time provided by section 6708.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number.

Books and records relating to a collection of information must be retained as long as their contents might become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103 of the Internal Revenue Code.