4164-01-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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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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:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-

2, 362, 371, 374, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271.

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.

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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 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.

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

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

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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. * * *

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5. 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?

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(b) * * *

(3) * * *

(ii) If your foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 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). * * *

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(iii) 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)(iii) 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. * * *

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Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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