

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).

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(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.

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

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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.

DATES: *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:

Authority: 21 U.S.C. 360b.

§ 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.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9764]

RIN 1545-BF39

Section 6708 Failure To Maintain List of Advisees 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.