

NIST will implement the rulemaking as proposed.

Classification

Executive Order 12866

This rule is not a significant rule for the purposes of Executive Order 12866.

Executive Order 12612

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration, at the proposed rule stage, under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (1) The regulation is procedural and has no impact on any entity unless that entity chooses to participate, in which case, the cost to the participant is the same cost for any size participant; (2) access to NVLAP's accreditation system is not conditional upon the size of a laboratory or membership of any association or group, nor are there undue financial conditions to restrict participation; and (3) the technical criteria, against which individual laboratories are assessed, are not changed by this rule. No comments were received on this certification; therefore no regulatory flexibility analysis is required and none was prepared.

Paperwork Reduction Act

This rule does not involve a new collection of information subject to the Paperwork Reduction Act (PRA). The collection of information for NVLAP has been approved by the Office of Management and Budget (OMB) under control number 0693-0003. Notwithstanding any other provision of the law, no person is required to comply, nor shall any person be subject to penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the

National Environmental Policy Act of 1969.

List of Subjects in 15 CFR Part 285

Accreditation, Business and industry, Calibration, Commerce, Conformity assessment, Laboratories, Measurement standards, Testing.

For the reasons set forth in the preamble, title 15 of the Code of Federal Regulations is amended as follows:

PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

- 1. The authority citation for 15 CFR Part 285 continues to read as follows:

Authority: 15 U.S.C. 272 *et seq.*

- 2. Section 285.4 is amended by revising the last sentence to read as follows:

§ 285.4 Establishment of laboratory accreditation programs (LAPs) within NVLAP.

* * * For requests from private sector entities and government agencies, the Chief of NVLAP shall analyze each request, and, after consultation with interested parties through public workshops or other means to ensure open participation, shall establish the requested LAP, if the Chief of NVLAP determines there is need for the requested LAP.

Dated: December 8, 2011.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2011-32256 Filed 12-19-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0003]

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Cyclosporine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of cyclosporine oral solution, USP (MODIFIED) for the control of feline allergic dermatitis.

DATES: This rule is effective December 20, 2011.

FOR FURTHER INFORMATION CONTACT:

Angela K.S. Clarke, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276-8318, email: angela.clarke@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141-329 that provides for the use of ATOPIKA for Cats (cyclosporine oral solution, USP (MODIFIED)) by veterinary prescription for the control of feline allergic dermatitis in cats at least 6 months of age and weighing at least 3 pounds. The NADA is approved as of August 8, 2011, and 21 CFR 520.522 is amended to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

- 2. In § 520.522, revise paragraphs (a) and (d) to read as follows:

§ 520.522 Cyclosporine.

(a) *Specifications*—(1) Each cyclosporine capsule, USP (MODIFIED) contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

(2) Each milliliter of cyclosporine oral solution, USP (MODIFIED) contains 100 mg cyclosporine.

* * * * *

(d) *Conditions of use*—(1) *Dogs*. Use capsules described in paragraph (a)(1) of this section as follow:

(i) *Amount*. Administer 5 mg per kilogram (mg/kg) of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(ii) *Indications for use*. For the control of atopic dermatitis in dogs weighing at least 4 pounds.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*. Use the solution described in paragraph (a)(2) of this section as follow:

(i) *Amount*. Administer 7 mg/kg of body weight orally as a single daily dose for a minimum of 4 to 6 weeks or until resolution of clinical signs. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or twice weekly to maintain the desired therapeutic effect.

(ii) *Indications for use*. For the control of feline allergic dermatitis in cats at least 6 months of age and weighing at least 3 pounds.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 15, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–32526 Filed 12–19–11; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9570]

RIN 1545–BK16

Tax Return Preparer Penalties Under Section 6695

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that modify existing regulations related to the tax return

preparer penalties under section 6695 of the Internal Revenue Code (Code). The final regulations are necessary to monitor and to improve compliance with the tax return preparer due diligence requirements of section 6695(g). The final regulations affect paid tax return preparers.

DATES: *Effective date:* The final regulations are effective on December 20, 2011.

Applicability date: For date of applicability, see § 1.6695–2(e).

FOR FURTHER INFORMATION CONTACT:

Spence Hanemann, (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in the final regulations was previously 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 1545–1570. The collection of information is in § 1.6695–2(b)(1) and (b)(4) of the final regulations, and is an increase in the total annual burden from the burden in the prior regulations. The collection of this information will improve the IRS' ability to enforce compliance with the due diligence requirements under section 6695(g) with respect to determining eligibility for, or the amount of, the earned income credit (EIC) under section 32.

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 assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law.

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under section 6695 of the Code.

The Treasury Department and the IRS published a notice of proposed rulemaking (REG–140280–09) in the *Federal Register*, 76 FR 62689, on October 11, 2011 (the NPRM). A public hearing was scheduled for November 7, 2011. The IRS did not receive any requests to testify at the public hearing, and the public hearing was cancelled. Written comments responding to the NPRM were received and are available for public inspection at <http://www.regulations.gov> or upon request. After consideration of all the comments,

the proposed regulations are adopted as amended by this Treasury decision. The revisions to the regulations are discussed in this preamble.

Summary of Comments and Explanation of Revisions

The IRS received nine written comments in response to the NPRM, and this section addresses those public comments. This section also describes the significant differences between the rules proposed in the NPRM and those adopted in the final regulations.

1. 2011 Amendment to Section 6695(g)

On October 21, 2011, section 501 of the United States-Korea Free Trade Agreement Implementation Act, Public Law 112–41, 125 Stat 428, amended section 6695(g) of the Code by increasing the amount of the penalty from \$100 to \$500. To account for this change in the law, § 1.6695–2(a) of the final regulations has been conformed to the statutory language of section 6695(g), as amended.

2. Necessity of These Regulations

Two commenters stated that the proposed amendments to the due diligence standards in the NPRM were unnecessary in light of recent regulatory changes requiring tax return preparers to register with the IRS and comply with the ethical standards governing practice before the IRS (Circular 230), as well as the tax return preparer penalties under section 6694. They suggested that the IRS can apply these existing provisions to address misconduct by tax return preparers, including improper determination of eligibility for, and amount of, EIC by both individual tax return preparers and firms.

As reflected in section 6695(g), Congress has determined that noncompliance with the EIC rules poses a sufficiently significant problem to merit imposing unique due diligence requirements on tax return preparers involved in determining eligibility for, or amount of, the EIC. By recently quintupling the amount of the penalty for failure to comply with these requirements, Congress reaffirmed the need for specific rules to reduce EIC noncompliance. In order to address noncompliance with the EIC rules, the final regulations modify the due diligence requirements under section 6695(g) that have been in place for over a decade. Treasury and the IRS concluded that these regulations are consistent with section 6695(g), and no modification is made in the final regulations in response to these comments.