intended for human consumption must not be slaughtered within 48 days of the last treatment. Do not use in female dairy cattle 20 months of age or older. Use in lactating dairy cows may cause drug residues in milk. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

5. The authority citation for 21 CFR part 556 continues to read as follows:


6. In § 556.227, revise paragraph (b) and add paragraph (c) to read as follows:

§ 556.227 Eprinomectin.

(b) Tolerances. The tolerances for eprinomectin B14 (marker residue) are:

1. Cattle—(i) Liver (target tissue): 1.5 parts per million.

(ii) Muscle: 100 parts per billion (ppb).

(iii) Milk: 12 ppb.

(2) [Reserved]

(c) Related conditions of use. See §§ 522.814 and 524.814 of this chapter.

Dated: November 17, 2011.
Bernadette Dunham, Director, Center for Veterinary Medicine.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524


Ophthalmic and Topical Dosage Form New Animal Drugs; Eprinomectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for addition of a warning statement against the use of eprinomectin topical solution in preruminating calves intended for veal.

DATES: This rule is effective November 25, 2011.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8341, email: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640 filed a supplement to NADA 141–079 for EPRINEX (eprinomectin) Pour-On for Beef and Dairy Cattle, a topical solution used for the treatment and control of internal and external parasites of cattle on pasture with persistent effectiveness. The supplemental NADA provides for addition of a warning statement against the use of eprinomectin topical solution in preruminating calves intended for veal. The NADA is approved as of September 23, 2011, and the regulations are amended in 21 CFR part 524 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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 environmental impact statement is required.

The 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 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:


2. Revise § 524.814 to read as follows:

§ 524.814 Eprinomectin.

(a) Specifications. Each milliliter (mL) contains 5 milligrams (mg) of eprinomectin.

(b) Sponsor. See No. 050604 in § 510.600(c) of this chapter.

(c) Related tolerances. See § 556.227 of this chapter.

(d) Special considerations. See § 500.25 of this chapter.

(e) Conditions of use in cattle—(1) Amount. Apply 5 mg (1 mL) per 10 kilograms (kg) of body weight (500 micrograms/kg) applied topically along backbone from withers to tailhead.

(2) Indications for use. For treatment and control of gastrointestinal roundworms (Haemonchus placei (adult and L4), Ostertagia ostertagi (adult and L4, including inhibited L4), Trichostrongylus axei (adult and L4), T. colubriformis (adult and L4), T. longissicularis (adult), Cooperia oncophora (adult and L4), C. punctata (adult and L4), C. surinabada (adult and L4), Nematodirus helvetianus (adult and L4), Bunostomum phlebotomum (adult and L4), Oesophagostomum radiatum (adult and L4), Strongyloides papillosus (adults), Trichuris spp. (adults)); lungworms (Dictyocaulus viviparus, adult and L4); cattle grubs (all parasitic stages Hypoderma lineatum, H. bovis); lice (Damalinia bovis, Linognathus vituli, Haematopinus euryserenus, Solenopotes capillatus); mange mites (Chorioptes bovis, Sarcoptes scabiei); and horn flies (Haematobia irritans). Controls and protects from reinfection of D. viviparus for 21 days after treatment and H. irritans for 7 days after treatment.

(3) Limitations. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

Dated: November 18, 2011.

Steven D. Vaughn, Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[TD 9559]

RIN 1545–BK24

User Fee To Take the Registered Tax Return Preparer Competency Examination

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains amendments to the user fee regulations. The final regulations redesignate rules pertaining to fees for obtaining a preparer tax identification number. These final regulations also establish a...
user fee for individuals to take the registered tax return preparer competency examination. The final regulations affect individuals who take the registered tax return preparer competency examination. The charging of user fees is authorized by the Independent Offices Appropriations Act of 1952.

DATES: Effective Date: These regulations are effective beginning November 25, 2011. Applicability Date: For date of applicability, see § 300.12(d).

FOR FURTHER INFORMATION CONTACT: Concerning the final regulations, Emily M. Lesniak at (202) 622–4570; concerning cost methodology Eva J. Williams at (202) 435–5514 (not toll-free numbers).

Background

This document contains final regulations establishing a user fee to take the registered tax return preparer competency examination. New § 300.12 establishes a $27 IRS user fee to take the registered tax return preparer competency examination; this IRS user fee is in addition to any reasonable, IRS-approved fee charged by the third-party vendor. These regulations also redesignate prior § 300.12 as § 300.13.

The Independent Offices Appropriations Act of 1952 (IOAA), which is codified at 31 U.S.C. 9701, authorizes agencies to prescribe regulations establishing user fees for services provided by the agency. Regulations prescribing user fees are subject to the policies of the President, which are currently set forth in the Office of Management and Budget Circular A–25 (the OMB Circular), 58 FR 38142 (July 15, 1993). The OMB Circular requires agencies seeking to impose user fees for providing special benefits to identifiable recipients to calculate the full cost of providing those benefits.

These regulations are part of a broader IRS effort to increase the oversight of the tax return preparer community. As part of this effort, Treasury and the IRS published final regulations in the Federal Register (76 FR 32286) on June 3, 2011, amending the regulations governing practice before the IRS. These regulations are found in 31 CFR part 10 and have been reprinted as Treasury Department Circular No. 230 (Circular 230). The amendments to Circular 230, in part, include registered tax return preparers as practitioners under Circular 230. Registered tax return preparers must demonstrate the necessary qualifications and competency, which includes passing a minimum competency examination. Registered tax return preparers receive the special benefit of being able to prepare and sign tax returns, claims for refund, and other documents as provided in forms, instructions, or other appropriate guidance.

On September 26, 2011, Treasury and the IRS published a notice of proposed rulemaking (REG–116284–11) in the Federal Register (76 FR 59239) proposing a user fee to take the registered tax return preparer competency examination. The notice of proposed rulemaking also proposed to establish a user fee to be fingerprinted in conjunction with the preparer tax identification number, acceptance agent, and authorized e-file provider programs. These regulations only finalize the user fee to take the registered tax return preparer competency examination.

The notice of proposed rulemaking announced a public hearing on October 7, 2011. Four individuals testified at the public hearing. The testimony at the hearing focused on the proposed fingerprinting user fee. No individual at the hearing offered testimony on the competency examination user fee.

Treasury and the IRS received written comments responding to the notice of proposed rulemaking. These comments 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 modified by this Treasury decision.

Summary of Comments and Explanation of Revisions

Treasury and the IRS received more than twenty written comments in response to the notice of proposed rulemaking. Treasury and the IRS received four written comments relating to the user fee to take the registered tax return preparer competency examination. The majority of the written comments concerned the user fee to be fingerprinted in conjunction with the preparer tax identification number, acceptance agent, and authorized e-file provider programs. Treasury and the IRS also received a few comments regarding other aspects of the IRS’s efforts to regulate tax return preparers. To the extent that comments address other aspects of the IRS’s increased oversight of the tax return preparation industry, the comments will be addressed, as appropriate and practicable, in future guidance. Further, some of the comments received related to testing locations and whether an online examination would be offered. The IRS received similar comments in response to Notice 2011–48 (2011–26 IRB 927 [June 27, 2011] available at http://www.irs.gov/pub/irs-irsbs/irb11-26.pdf), which specifically requested comments regarding the registered tax return preparer competency examination. The IRS and the competency examination vendor continue to consider these comments, along with other comments received in response to Notice 2011–48, as they implement the competency testing program. The IRS is committed to addressing the concerns expressed in these comments to the extent practical and appropriate.

One comment regarding the proposed user fee to take the registered tax return preparer competency examination encouraged Treasury and the IRS to monitor the fee charged by the third-party vendor. The third-party vendor’s fee is approved by the IRS, including any changes to the vendor’s fee. Thus, the IRS will be aware of any possible fee changes and will approve the final vendor fee.

Three comments related to the total cost and the components of the user fee to take the registered tax return preparer competency examination. These comments expressed a general concern that the fee may be a financial burden on tax return preparation businesses. One commentator requested that a definite, specific fee amount be provided and expressed confusion over whether a single user fee covers multiple attempts to take the examination. Another commentator stated that the fee was duplicative for preparers who are independently tested under an employer’s program, and requested that the IRS develop a process to review and certify employer testing programs.

Treasury and the IRS have considered these comments, and for the reasons described in this preamble, the portion of the proposed regulations relating to the user fee for the competency examination is finalized without substantive change.

As stated earlier in this preamble, the OMB Circular generally requires agencies to recover the full cost of providing a special benefit to an identifiable recipient. The full cost to the IRS to administer the registered tax return preparer competency examination is $27 per applicant each time the applicant takes the examination. The costs to the IRS to administer the competency examination include conducting background checks on employees of the third-party vendor who are involved in the administration of the examination and the personnel, administrative, management, and information technology costs to the IRS.
for developing and reviewing the competency examination, overseeing the competency examination, validating the competency examination results, and establishing a review procedure for applicants who contest any portion of the competency examination. The IRS will make expenditures for all of these costs associated with the competency examination and, thus, is generally required to recover these costs through a user fee as provided by the OMB Circular. The IRS will inform the public of the total finalized testing fee amount before the test becomes available. Because each examination-sitting will involve the same costs, a user fee will be charged each time an applicant takes the examination.

Further, these regulations are part of Treasury’s and the IRS’s effort to increase oversight of the tax return preparer industry based upon findings and recommendations made by the IRS in Publication 4832, “Return Preparer Review” (the Report), which was published on January 4, 2010. All individuals who wish to become a registered tax return preparer must pass the competency examination because, during the implementation process, Treasury and the IRS concluded that all registered tax return preparers should be subject to uniform standards of qualification and practice, which includes demonstrating a minimum level of competency. When obtaining tax return preparation services, taxpayers should know that all registered tax return preparers are subject to the same federal regulations and standards, regardless of where the registered tax return preparer is employed or in what state the individual resides. Requiring all registered tax return preparers to fulfill the same competency examination requirements ensures that all registered tax return preparers have met the same minimum competency standards. Additionally, requiring all registered tax return preparers to pass the IRS approved competency examination addresses concerns raised by several commentators during the IRS’s study of the tax return preparation industry about the potential for unfairness if certain tax return preparers are exempt from these requirements. Accordingly, Treasury and the IRS do not believe that a process to review and certify employer testing is appropriate.

The comments on the user fee to be fingerprinted in conjunction with the preparer tax identification number, acceptance agent, and authorized e-file provider programs by and large expressed concern with the IRS’s plan to fingerprint participants in these programs generally, as well as the imposition and amount of the proposed user fee. In light of the significant issues raised at the hearing and in the written comments received on the fingerprinting user fee, Treasury and the IRS have decided not to finalize the proposed user fee to be fingerprinted in conjunction with the preparer tax identification number, acceptance agent, and authorized e-file provider programs at this time. Rather, Treasury and the IRS will consider alternatives as to how the IRS can best implement the Circular 230 provision authorizing the IRS to conduct a suitability check to become a registered tax return preparer. In evaluating these alternatives, consideration will be given to how the suitability check achieves the goals of increasing oversight of the tax return preparer community and how the suitability check can be conducted most efficiently while not creating undue burden on the individual applicants and the firms or other entities that employ them. Thus, Treasury and the IRS are still interested in receiving further comments regarding the use of fingerprinting as part of the suitability check to become a registered tax return preparer. If the result of this reconsideration will require any individual to pay a user fee in conjunction with the implementation of the suitability check, including a possible fingerprinting requirement, Treasury and the IRS will publish a new notice of proposed rulemaking with respect to this user fee.

Treasury and the IRS adopt the proposed regulations after eliminating the proposed user fee to be fingerprinted in conjunction with the preparer tax identification number, acceptance agent, and authorized e-file provider programs. The portion of the proposed regulations pertaining to the user fee to take the registered tax return preparer competency examination is adopted without substantive modification.

**Effective/Applicability Date**

The Administrative Procedure Act provides that substantive rules will not be effective until thirty days after the final regulations are published in the *Federal Register* (5 U.S.C. 553(d)). Final regulations may be effective prior to thirty days after publication if the publishing agency finds that there is good cause for an earlier effective date. This regulation is part of the IRS’s continued efforts to implement the recommendations in the Report. The recently published amendments to Circular 230 and established registered tax return preparers as practitioners under Circular 230 and required that individuals must pass a competency examination, among other requirements, to become a registered tax return preparer. Before the competency examination can be offered, the competency examination user fee must be in place. Further, to enable the IRS to begin designating individuals as registered tax return preparers in time for the 2012 filing season, the competency examination user fee must be finalized significantly before the 2012 filing season.

Thus, the Treasury and the IRS find that there is good cause for these regulations to be effective upon the publication of these final regulations in the *Federal Register*.

**Special Analyses**

It has been determined that these final regulations are not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563.

It has been determined that a final regulatory flexibility analysis under 5 U.S.C. 603 is required for this final rule. The analysis is set forth under the heading, “Final Regulatory Flexibility Analysis.”

Pursuant to 26 U.S.C. 7805(f), the notice of proposed rulemaking preceding these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business. The Chief Counsel for Advocacy did not submit comments on the notice of proposed rulemaking.

**Final Regulatory Flexibility Analysis**

When an agency either promulgates a final rule that follows a required notice of proposed rulemaking or promulgates a final interpretative rule involving the internal revenue laws that imposes a collection of information requirement on small entities as described in 5 U.S.C. 603(a), the Regulatory Flexibility Act (5 U.S.C. chapter 6) requires the agency to “prepare a final regulatory flexibility analysis.” A final regulatory flexibility analysis must, pursuant to 5 U.S.C. 604(a), contain the five elements listed in this final regulatory flexibility analysis. For purposes of this final regulatory flexibility analysis, a small entity is defined as a small business, small nonprofit organization, or small governmental jurisdiction. See 5 U.S.C. 601(3)–(6). The Treasury and the IRS conclude that the final regulations (together with other contemplated guidance provided for in these regulations) will impact a substantial
number of small entities and the economic impact may be significant.

A Statement of the Need for, and the Objectives of, the Final Rule

The Treasury and the IRS are implementing regulatory changes that increase the oversight of the tax return preparer industry based upon findings and recommendations in the Report. These regulatory changes include establishing registered tax return preparers as Circular 230 practitioners. Individuals who wish to become a registered tax return preparer must pass a competency examination. Individuals who pass the competency examination and become a registered tax return preparer will receive a special benefit that the general public does not receive because a registered tax return preparer is allowed to prepare and sign Form 1040 series returns (and accompanying schedules) for compensation. The regulations under section 6109 (75 FR 60309) in conjunction with Notice 2011–6 (2011–1 IRB 315 [January 17, 2011]), provide that only attorneys, certified public accountants, enrolled agents, and registered tax return preparers can prepare and sign all or substantially all of a Form 1040 series return (and accompanying schedules) for compensation. This final rule recovers the full costs to the IRS to oversee the registered tax return preparer competency examination.

Summaries of the Significant Issues Raised in the Public Comments Responding to the Initial Regulatory Flexibility Analysis and of the Agency’s Assessment of the Issues, and a Statement of Any Changes Made to the Rule as a Result of the Comments

Treasury and the IRS received no public comments responding to the initial regulatory flexibility analysis related to competency testing in the proposed regulations that preceded these final regulations. Treasury and the IRS did receive comments from the public on the proposed regulations in general. A summary of these comments along with Treasury’s and the IRS’s assessment of the issues raised in the comments and descriptions of any revisions resulting from the comments is set forth elsewhere in this preamble under the Summary of Comments and Explanation of Revisions heading.

A Description and an Estimate of the Number of Small Entities to Which the Rule Will Apply or an Explanation of Why an Estimate is Not Available

These final regulations affect all individuals who want to become a registered tax return preparer under the new oversight rules in Circular 230. Only individuals, not businesses, can practice before the IRS or become a registered tax return preparer. Thus, the economic impact of these regulations on any small entity generally will be a result of applicants owning a small business or a small entity employing applicants. The NAICS code that relates to tax preparation services (NAICS code 541213) is the appropriate code for the registered tax return preparer program. Entities identified as tax preparation services are considered small under the Small Business Administration size standards (13 CFR 121.201) if their annual revenue is less than $7 million. The IRS estimates that approximately 350,000 individuals will become registered tax return preparers. The IRS estimates that approximately 70 to 80 percent of the individuals who apply to become registered tax return preparers are operating as or employed by small entities.

A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of the Classes of Small Entities Subject to the Requirements and the Type of Professional Skills Necessary for Preparation of a Report or Record

The final regulations do not directly impose any reporting or recordkeeping requirements on any small entities. The final regulations, however, require certain tax return preparers to pay a user fee to take the registered tax return preparer competency examination. Small entities may be affected by these costs if the entities choose to pay some or all of these fees for their employees. Under the amendments to Circular 230, tax return preparers may also incur costs for exam preparation courses, plus incidental costs, such as for travel and accommodations, in order to obtain the designation of registered tax return preparer under Circular 230. Course prices can vary greatly, from free to hundreds of dollars. Many small tax return preparation firms may choose, as with the user fee, to bear these costs for their employees. In some cases, small entities may lose sales and profits while their employed tax return preparers attend exam preparation classes or are studying and sitting for the examination. Some small entities that employ tax return preparers may even need to alter their business operations if a significant number of their employees cannot satisfy the necessary registration and competency requirements. Treasury and the IRS conclude, however, that only a small percentage of small entities, if any, may need to cease doing business or radically change their business model due to these final regulations.

A Description of the Steps the Agency Has Taken to Minimize the Significant Economic Impact On Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting Any Alternative Adopted in the Final Rule and Why Other Significant Alternatives Affecting the Impact on Small Entities That the Agency Considered Were Rejected

Treasury and the IRS are not aware of any steps that could be taken to minimize the economic impact on small entities that would also be consistent with the objectives of these final regulations and have determined that there is no viable alternative to these final regulations. These regulations do not impose any more requirements on small entities than are necessary to effectively administer the internal revenue laws. Further, the regulations do not subject small entities to any requirements that are not also applicable to larger entities covered by the regulations.

The IOAAA authorizes the charging of user fees for agency services, subject to policies designated by the President. The OMB Circular implements presidential policies regarding user fees and encourages user fees when a government agency provides a special benefit to a member of the public. As Congress has not appropriated funds to the registered tax return preparer program, there are no viable alternatives to the imposition of user fees, which fees recover the costs to the IRS for providing the special benefits associated with the registered tax return preparer program.

Drafting Information

The principal author of these regulations is Emily M. Lesniak, Office of the Associate Chief Counsel (Procedure and Administration).

List of Subjects in 26 CFR Part 300

Reporting and recordkeeping requirements, User fees.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 300 is amended as follows:

PART 300—USER FEES

■ Paragraph 1. The authority citation for part 300 continues to read in part as follows:
SUMMARY: This document finalizes the Bureau’s Literacy Program regulations, published as an interim rule on September 26, 1997 (62 FR 50791). The Bureau amended its regulations on the literacy program for the sake of clarification or simplification.

DATES: This document is effective December 27, 2011.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: This document finalizes the Bureau’s Literacy Program regulations, published as an interim rule on September 26, 1997 (62 FR 50791). In the interim rule document, the Bureau revised its regulations on the literacy program in order to include a definition of “satisfactory progress.” This definition is one determinant which is statutorily required for the awarding and/or vesting of good conduct time for certain inmates. The interim rule also further revised Bureau regulations on the literacy program for the sake of clarification or simplification.

No comments were received during the comment period for the interim rule. We therefore finalize the interim rule without change.

Executive Order 12866

This regulation falls within a category of actions that the Office of Management and Budget (OMB) has determined to constitute “significant regulatory actions” under section 3(f) of Executive Order 12866 and, accordingly, it was reviewed by OMB. The Bureau of Prisons has assessed the costs and benefits of this regulation as required by Executive Order 12866 Section 1(b)(6) and has made a reasoned determination that the benefits of this regulation justify its costs. There will be no new costs associated with this regulation.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, under Executive Order 13132, we determine that this regulation does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation and by approving it certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This regulation pertains to the correctional management of offenders and immigration detainees committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau’s appropriated funds.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This regulation is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This regulation will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 540

Prisoners.