

| Pyrantel tartrate g/ton | Indications for use | Limitation | Sponsor |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| (i) 120 to 1,200 to provide 1.2 mg/lb body weight. | For prevention of <i>Strongylus vulgaris</i> larval infections; control of adult large strongyles (<i>S. vulgaris</i> , and <i>S. edentatus</i>), adult and 4th stage larvae small strongyles (<i>Cyathostomum</i> spp., <i>Cylicocycclus</i> spp., <i>Cylicostephanus</i> spp., <i>Cylicodontophorus</i> spp., <i>Poteriostomum</i> spp., and <i>Triodontophorus</i> spp.), adult and 4th stage larvae pinworms (<i>Oxyuris equi</i>), and adult and 4th stage larvae ascarids (<i>Parascaris equorum</i>). | Feed continuously as the horse's daily grain ration during the time that the animal is at risk of exposure to internal parasites. Do not use in horses intended for human consumption. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism. | 017135 054771 |

(ii) *Top dress medicated feed*—(A) *Proprietary Formulas*. The following feed can be manufactured only per an approved proprietary formula and specifications:

| Pyrantel tartrate amount | Indications for use | Limitations | Sponsor |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| (1) 9.6 g/lb to provide 1.2 mg/lb body weight. | Prevention of <i>Strongylus vulgaris</i> larval infections; control of adult large strongyles (<i>S. vulgaris</i> , and <i>S. edentatus</i>), adult and 4th stage larvae small strongyles (<i>Cyathostomum</i> spp., <i>Cylicocycclus</i> spp., <i>Cylicostephanus</i> spp., <i>Cylicodontophorus</i> spp., <i>Poteriostomum</i> spp., and <i>Triodontophorus</i> spp.), adult and 4th stage larvae pinworms (<i>Oxyuris equi</i>), and adult and 4th stage larvae ascarids (<i>Parascaris equorum</i>). | Feed continuously as a top dress during the time that the animal is at risk of exposure to internal parasites. Do not use in horses intended for human consumption. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism. | 017135 054771 |
| (2) [Reserved]. | | | |

(B) [Reserved] * * * * *

■ 31. In § 558.500, revise (b)(1), (b)(2), and (e)(1)(i) to read as follows:

§ 558.500 Ractopamine.
* * * * *
(b) * * *
(1) Nos. 016592 and 058198: Type A medicated articles containing 9 or 45.4 grams per pound (g/lb) ractopamine hydrochloride.
(2) Nos. 051311 and 054771: Type A medicated articles containing 45.4 g/lb ractopamine hydrochloride.
* * * * *
(e) * * *
(1) * * *

| Ractopamine in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsors |
|--------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------------|
| (i) 4.5 to 9.0 | | For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing not less than 150 lb, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter. | Feed continuously as sole ration. | 016592 054771 058198 |

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Dated: May 9, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2024–10586 Filed 5–14–24; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 516

[Docket No. FDA–2006–N–0239]

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending the animal drug regulations for labeling of new animal drugs included on FDA’s Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (indexed products) to reflect the 2018 statutory changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act). This amendment is intended to ensure accuracy and clarity in the Agency’s regulations. This amendment is nonsubstantive.

DATES: This rule is effective May 15, 2024.

FOR FURTHER INFORMATION CONTACT: Lucy Lee, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0563, lucy.lee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act of 2004) (Pub. L. 108–282) amended the FD&C Act to establish regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species.

In 2007, FDA issued final regulations (72 FR 69108, December 6, 2007) to implement section 572 of the MUMS Act entitled “Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.” These regulations establish administrative procedures and criteria for index listing a new animal drug that provide a basis for legally marketing an unapproved new animal drug for use in a minor species.

The MUMS Act and the 2007 regulations derived from it required indexed products to state their

unapproved status on labeling. Subsequently, section 302 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (User Fee Amendments of 2018; Pub. L. 115–234) amended the required labeling statement found in section 572(h)(1) of the FD&C Act (21 U.S.C. 360ccc–1(h)(1)) to reinforce that indexed products are legally marketed.

The User Fee Amendments of 2018 also amended the required label statements found in section 572(h)(2) of the FD&C Act regarding, except for use in a non-food early life stage, the prohibition of indexed drugs for use in food-producing animals.

At this time, we are revising the animal drug regulations at § 516.155 (21 CFR 516.155) for labeling of indexed drugs to reflect the amendments made by the User Fee Amendments of 2018 to section 572(h) of the FD&C Act.

II. Paperwork Reduction Act

The labeling statements required under section 572(h) of the FD&C Act, as reflected in § 516.155, are public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)); therefore, they are exempt from the Office of Management and Budget review and approval under the Paperwork Reduction Act.

III. Legal Authority

This final rule sets forth a technical amendment to the regulations to improve the accuracy and completeness of the regulations, and as such does not impose any burden on regulated entities. Although denominated a rule pursuant to the FD&C Act, this document 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 through 808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as “an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.”

List of Subjects in 21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs, 21 CFR part 516 is amended as follows:

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 1. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 2. In § 516.155, revise paragraphs (a) and (b) to read as follows:

§ 516.155 Labeling of indexed drugs.

(a) The labeling of an indexed drug that is found to be eligible for indexing under § 516.129(c)(7)(i) shall state, prominently and conspicuously: “LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF # (followed by the applicable minor species index file number and a period).” “Extra-label use is prohibited.” “This product is not to be used in animals intended for use as food for humans or food-producing animals.”

(b) The labeling of an indexed drug that is found to be eligible for indexing for use in an early, non-food life stage of a food-producing minor species animal, under § 516.129(c)(7)(ii), shall state, prominently and conspicuously: “LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF # (followed by the applicable minor species index file number and a period).” “Extra-label use is prohibited.”

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Dated: May 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10602 Filed 5–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[TD 9997]

RIN 1545–BQ77, 1545–BQ78

Preparer Tax Identification Number (PTIN) User Fee Update

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule.

SUMMARY: This document contains final regulations relating to the imposition of certain user fees on tax return preparers. The final regulations adopt without change the text of interim final and proposed regulations that reduced the user fee to apply for or renew a preparer tax identification number (PTIN) from \$21 to \$11. The final regulations affect individuals who apply for or renew a PTIN. The Independent Offices Appropriation Act of 1952 authorizes the charging of user fees.

DATES:

Effective date: These regulations are effective on June 14, 2024.

Applicability date: For date of applicability, see § 300.11(d).

FOR FURTHER INFORMATION CONTACT:

Concerning the final regulations, Jamie Song at (202) 317–6845; concerning cost methodology, Michael A. Weber at (202) 803–9738 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 300—User Fees. On October 4, 2023, the Department of the Treasury (Treasury Department) and the IRS published in the **Federal Register** (88 FR 68525) a notice of proposed rulemaking (proposed regulations) by cross-reference to an interim final rule (REG–106203–23) proposing amendments to regulations under 26 CFR part 300. On the same date, the Treasury Department and the IRS published in the **Federal Register** (88 FR 68456) an interim final rule (TD 9980) that reduced the PTIN user fee from \$21 per application or application for renewal to \$11, plus the fee payable directly to a third-party contractor. The interim final rule and the proposed regulations took into account the February 2023 memorandum opinion of the United States District Court for the District of Columbia in *Steele v. United States*, 657 F.Supp.3d 23 (D.D.C. 2023). The preamble to the interim final rule contains a detailed explanation of the legal background and user fee calculations regarding the amendments to these regulations. No public hearing was requested or held, and no comments were received on the proposed regulations. These final regulations therefore adopt the text of the interim final rule and proposed regulations without change.

Special Analyses

I. Regulatory Planning and Review

The OMB’s Office of Information and Regulatory Analysis has determined that