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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Pyrantel Tartrate

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 supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for revised feeding instructions for use of pyrantel tartrate Type A medicated articles to make Type C medicated horse feeds.

EFFECTIVE DATE: (*Insert date of publication in the Federal Register.*)

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 140-819 that provides for revised feeding instructions for use of Pfizer's pyrantel tartrate Type A medicated articles (Strongid® 48 (48 grams of pyrantel tartrate per pound (g/lb))) to make Type C medicated horse feeds (Strongid® C (4.8 g/lb) and Strongid® C2x (9.6 g/lb)) used for the prevention of *Strongylus vulgaris* larval infections, and control of several types of adult and 4th stage larval large and small strongyle, pinworm, and ascarid infections. The supplement provides for use of a top-dressed Type C feed containing up to 20,000 g of pyrantel tartrate per ton to be fed at the currently approved rate of 1.2 milligrams per pound of body weight daily. The supplemental NADA is approved as of August 24, 1999, and § 558.485 (21 CFR 558.485) is amended to reflect the approval.

Also, § 558.485(e)(2)(i)(A) is amended to reflect that the organism *Triodontophorus* is now classified as a small strongyle.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (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(a)(3) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.485 is amended by revising paragraphs (e)(2)(i), (e)(2)(i)(A), and the first sentence of paragraph (e)(2)(i)(B), and by adding and reserving paragraph (e)(2)(ii) to read as follows:

introductory text

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Ann M.
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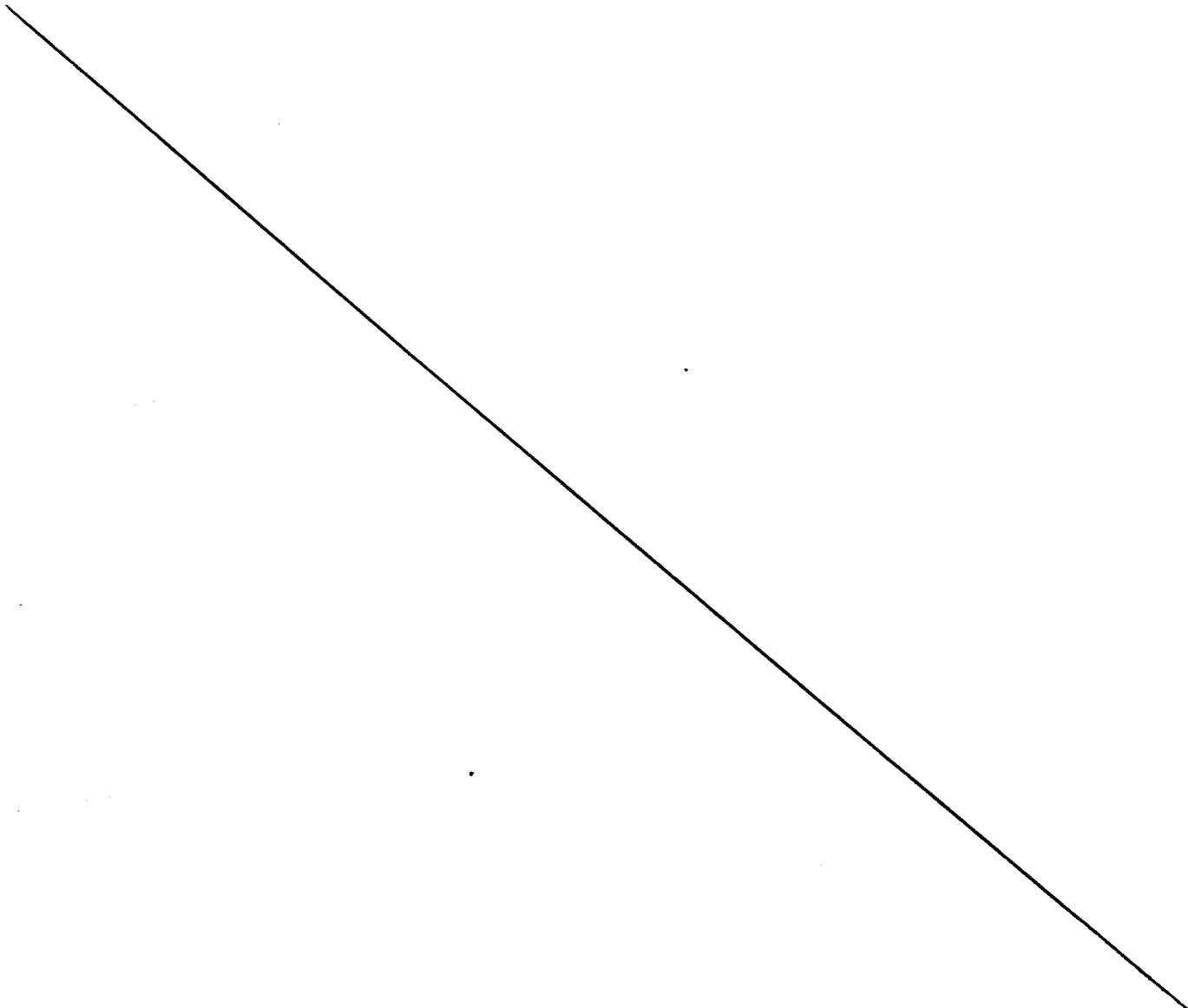
§ 558.485 Pyrantel tartrate.

* * * * *

(e) * * *

(2) *Horses*—(i) *Amount*. Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight.

(A) *Indications for use*. Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris*, and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).



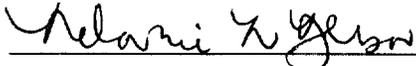
(B) *Limitations.* Administer either as a top-dress (not to exceed 20,000 grams per ton) or mixed in the horse's daily grain ration (not to exceed 1,200 grams per ton) during the time that the animal is at risk of exposure to internal parasites. * * *

(ii) [Reserved]

Dated: 9-9-99
September 9, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL





Melanie R. Berson
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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