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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Doramectin

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 further use of doramectin in cattle for treatment and control of the gastrointestinal roundworm *Trichostrongylus axei* L4 and for control of and protection from reinfection with *Haemonchus placei* for 35 days after treatment.

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

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7576.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 141-095 that provides for topical use of Dectomax® (doramectin) pour-on solution for further use on cattle for treatment and control of *T. axei* L4 and for control of and protection from reinfection with *H. placei* for 35 days after treatment. The supplemental NADA is approved as of August 10, 1999, and the regulations are amended in 21 CFR 524.770(d)(2) to reflect this approval. The basis of approval is discussed in the freedom of information summary.

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 supplemental 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 10, 1999, because the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin topical in cattle for treatment and control of *T. axei* L4 and for control of and protection from reinfection with *H. placei* for 35 days after treatment.

The agency has determined under 21 CFR 25.33(a)(1) 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 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:

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

2. Section 524.770 is amended by revising paragraph (d)(2) to read as follows:

§ 524.770 Doramectin.

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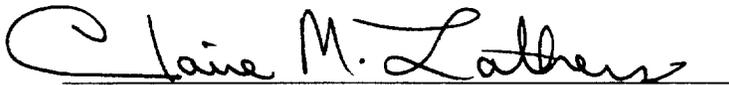
(d) * * *

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days,

Ostertagia ostertagi, *C. punctata*, and *Oesophagostomum radiatum* for 28 days, and *Haemonchus placei* for 35 days after treatment.

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Dated: 8/27/99
August 27, 1999



Claire M. Lathers
Director
Office of New Animal Drug Evaluation

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

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