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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.

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**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 an increased period of protection from reinfection with three species of internal parasites following topical administration of doramectin solution on cattle.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Janis Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: [janis.messenheimer@fda.gov](mailto:janis.messenheimer@fda.gov).

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141-095 for DECTOMAX (doramectin) Pour-On Solution for Cattle. The supplemental application provides for an increased period of protection from reinfection with three species of internal parasites following topical administration of doramectin solution on cattle. Specifically, the period of persistent effectiveness is increased from 21 days to 28 days for *Cooperia oncophora*, from 28 days to 35 days for *C. punctata*, and from 21 days to 28 days for *Dictyocaulus viviparus*. The supplemental

NADA is approved as of June 30, 2004, and the regulations in 21 CFR 524.770 are amended to reflect the approval and a current format. 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 21 CFR 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 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.

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 approval qualifies for 3 years of marketing exclusivity beginning June 30, 2004. Exclusivity applies only to the extension of the persistent effectiveness claims for the three species of parasites listed previously.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 revised to read as follows:

#### **§ 524.770 Doramectin.**

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) doramectin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

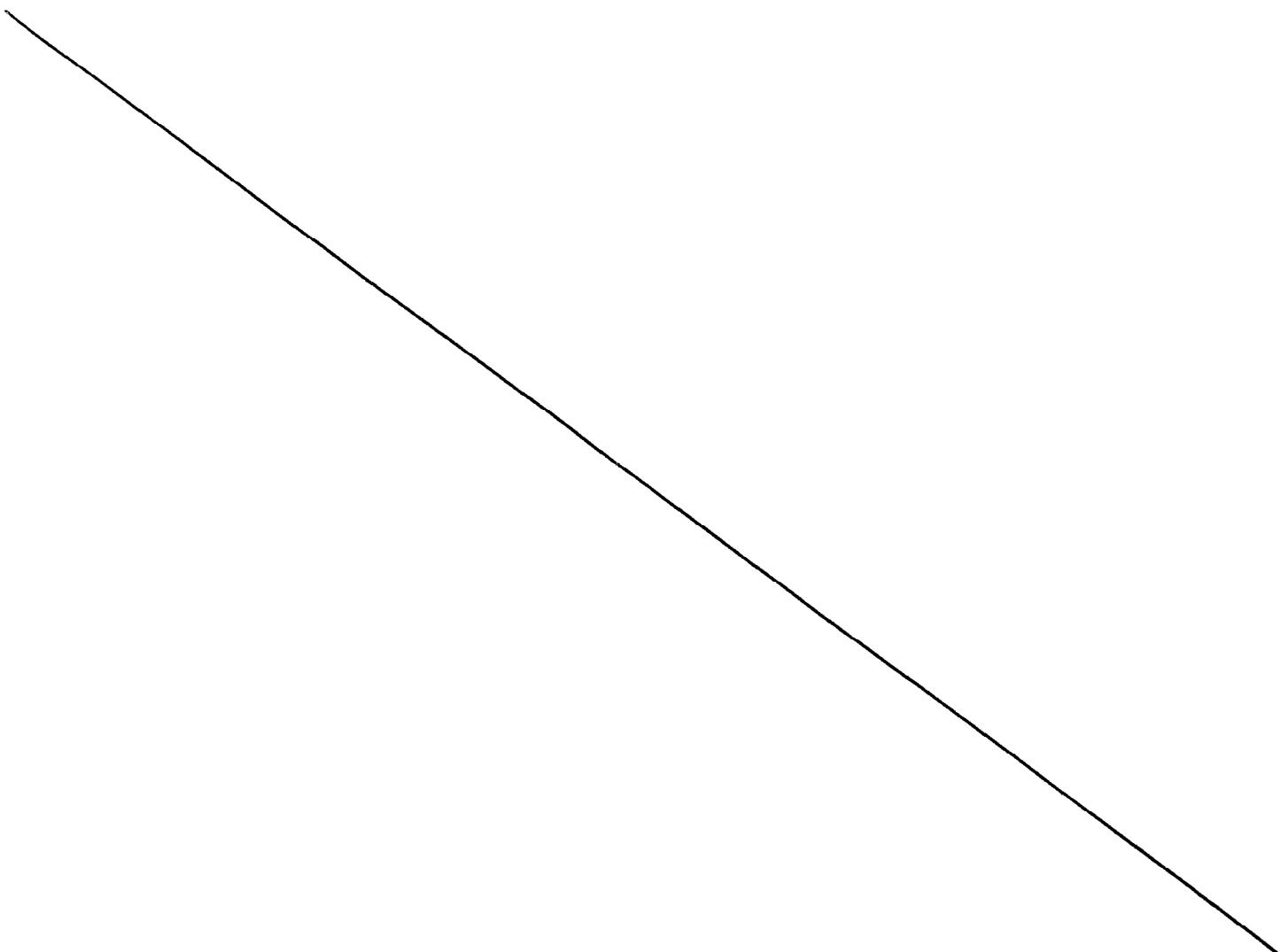
(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Administer topically as a single dose 0.5 mg (1 mL) per kilogram (1 mL per 22 pounds) body weight.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and fourth-stage larvae), *O. ostertagi* (inhibited fourth-stage larvae), *O. lyrata* (adults), *Haemonchus placei* (adults and fourth-stage larvae), *Trichostrongylus axei* (adults and fourth-stage larvae), *T. colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults and fourth-stage larvae), *C. punctata* (adults and fourth-stage larvae), *C. pectinata* (adults), *C. surnabada* (adults), *Bunostomum phlebotomum* (adults),

*Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); eyeworms: *Thelazia gulosa* (adults), *T. skrjabini* (adults); grubs: *Hypoderma bovis* and *H. lineatum*; sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, and *Solenopotes capillatus*; biting lice: *Damalinia bovis*; mange mites: *Chorioptes bovis* and *Sarcoptes scabiei*; horn flies: *Haematobia irritans*; and to control infections and to protect from reinfection with *C. oncophora*, *D. viviparus*, *O. ostertagi*, and *O. radiatum* for 28 days; and with *C. punctata*, and *H. placei* for 35 days after treatment.

(3) *Limitations*. Do not slaughter cattle within 45 days of latest treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.



Dated: July 28, 2004  
July 28, 2004.

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