

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DNB

Display Date	3.18.99
Publication Date	3.17
Comments	C. WMB. D. J.

21 CFR Part 522

Implantation or Injectable 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 extended use of doramectin in cattle for persistent control of nematodes including *Haemonchus placei* for 14 days after treatment.

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

**FOR FURTHER INFORMATION CONTACT:** Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7575.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 141-061 that provides for subcutaneous and intramuscular use of Dectomax® (doramectin) 1 percent injectable solution in cattle to control infections and to protect from reinfection with *H. placei* for 14 days after treatment. The persistent use is in addition to the approved use in cattle for treatment and control of various gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* for 14 days, *Ostertagia ostertagi* for 21 days, and *Cooperia punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

Supplemental NADA 141-061 is approved as of February 1, 1999, and the regulations are amended in 21 CFR 522.770(d)(1)(ii) to reflect the 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 data and information submitted to support approval of the 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 February 1, 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 supplemental application and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin injection to control infections and to protect cattle from reinfection with *H. placei* for 14 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.

### **List of Subjects in 21 CFR Part 522**

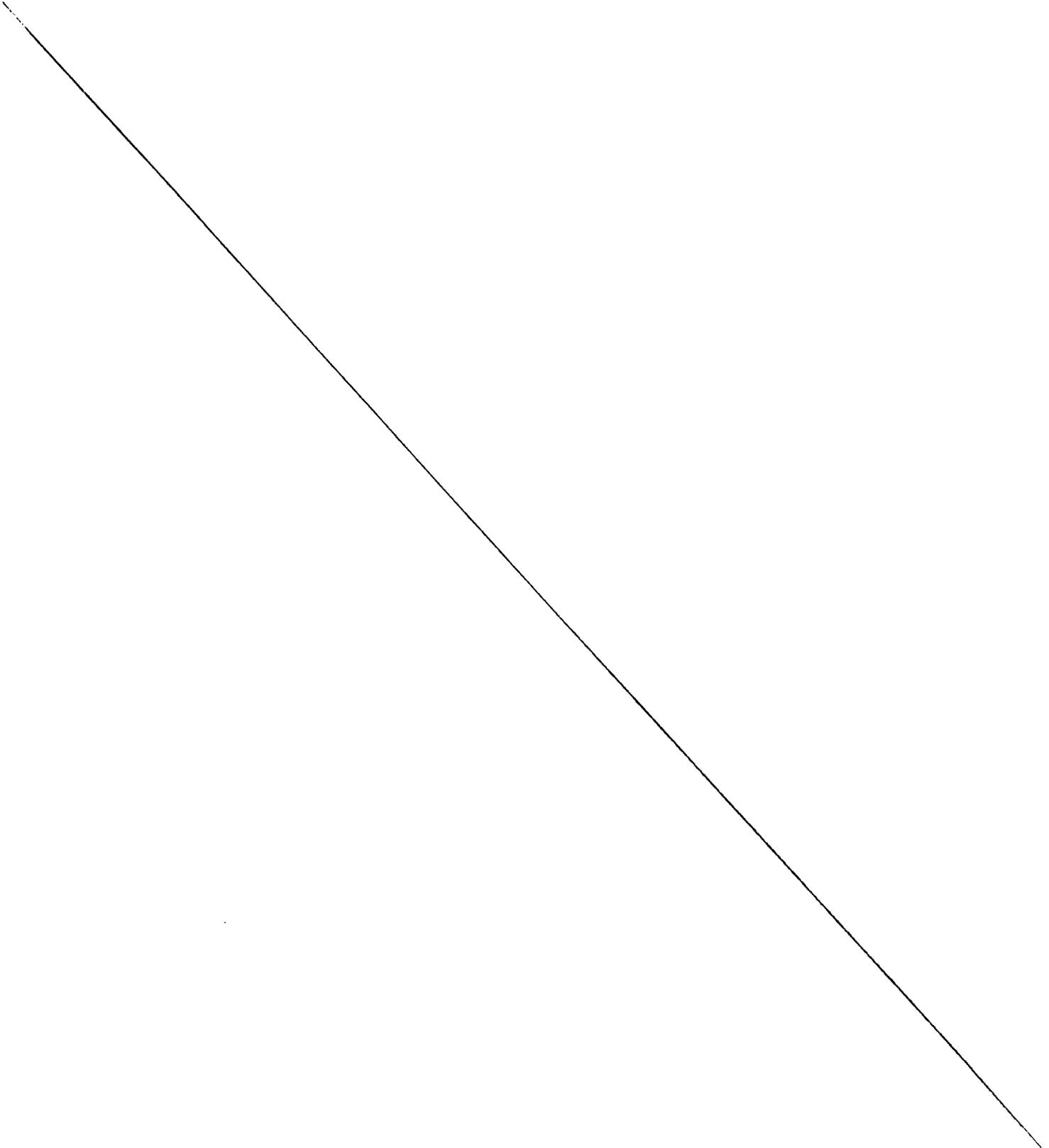
Animal drugs.

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 522 is amended as follows:

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 522 continues to read as follows:

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



§ 522.770 [Amended]

cdh

2. Section 522.770 *Doramectin* is amended in paragraph (d)(1)(ii) by adding after “*Cooperia onchophora*” the phrase “and *Haemonchus placei*”.

Dated: Feb 26, 1999

February 26, 1999

Margaret Ann Miller

Margaret Ann Miller  
Acting Director  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

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

**BILLING CODE 4160-01-F**

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