

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Moxidectin Solution

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 Fort Dodge Animal Health. The supplemental NADA provides for use of an injectable moxidectin solution in cattle for the treatment and control of an additional three species of internal parasites and an additional three life stages of previously-approved internal parasites.

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

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141-220 that provides for use of CYDECTIN (moxidectin) Injectable Solution for Beef and Nonlactating Dairy Cattle for the treatment and control of an additional three species of internal parasites and an additional three life stages of previously-approved internal parasites. The NADA is approved as of January 10, 2006, and the regulations are amended in 21 CFR 522.1450 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 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 supplemental approval qualifies for 3 years of marketing exclusivity beginning January 10, 2006.

FDA 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 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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.

- 2. Revise paragraph (d)(2) in § 522.1450 to read as follows:

§ 522.1450 Moxidectin solution.

* * * * *

(d) * * *

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei* (adults), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia spatulata* (adults), *Cooperia surnabada* (adults and fourth-stage larvae), *Nematodirus helvetianus* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); lice: *Linognathus vituli* and *Solenopotes capillatus*; for protection of cattle from reinfection with *D. viviparus* and

O. radiatum for 42 days after treatment, with *H. placei* for 35 days after treatment, and with *O. ostertagi* and *T. axei* for 14 days after treatment.

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Dated: February 3, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S