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Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

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, Division of Wyeth. The supplemental NADA adds an age precaution to labeling for moxidectin gel used for the control of various species of internal parasites in horses and ponies.

DATES: This rule is effective August 27, 2003.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; tel: 301-827-7543; e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141-087 for QUEST (moxidectin) 2.0% Equine Oral Gel used for the control of various species of internal parasites in horses and ponies. The supplemental NADA adds a precaution to labeling that the product is for oral use in horses and ponies 6 months of age and older. The supplemental NADA is approved as of May 29, 2003, and the regulations are amended in 21 CFR 520.1452 to reflect the approval and to reflect 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 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(d)(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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Section 520.1452 is amended by revising paragraphs (a), (d)(3), and by adding paragraph (c) to read as follows:

§ 520.1452 Moxidectin gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (2 percent) moxidectin.

* * * * *

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

(d) * * *

(3) *Limitations.* For oral use in horses and ponies 6 months of age and older. Not for use in horses and ponies intended for food.

Dated: August 13, 2003.

Steven D. Vaughn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin and Praziquantel Gel

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 new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The NADA provides for use of a moxidectin and praziquantel oral gel for the treatment and control of various species of internal parasites in horses and ponies.

DATES: This rule is effective August 27, 2003.

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; e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141-216 for QUEST PLUS (moxidectin 2.0%/praziquantel 12.5%) Gel for the treatment and control of various species of internal parasites in horses and ponies. The NADA is approved as of May 14, 2003, and part 520 (21 CFR part 520) is amended by adding new § 520.1453 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 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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,