DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 520 and 556

New Animal Drugs; Moxidectin

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 oral use of moxidectin solution in sheep for the treatment and control of a variety of 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.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141–247 for CYDECTIN (moxidectin) Oral Drench for Sheep, used for the treatment and control of various internal parasites in sheep. The NADA is approved as of November 30, 2005, and the regulations are amended in part 520 (21 CFR part 520) by adding § 520.1454 and in part 556 (21 CFR part 556) by revising § 556.426 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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NFR1

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 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc–2), this approval qualifies for 7 years of exclusive marketing rights beginning November 30, 2005, because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

FDA has determined under 21 CFR 25.33(d)(4) 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

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 parts 520 and 556 are 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.

§ 520.1451 [Amended]

■ 2. Section 520.1451 is amended by revising the section heading to read "Moxidectin tablets."

■ 3. Add § 520.1454 to read as follows:

§ 520.1454 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 1 milligram (mg) moxidectin.

(b) *Sponsor.* See No. 000856 in § 510.600 of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

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

(e) *Conditions of use in sheep*—(1) *Amount.* Administer 1 mL per 11 pounds body weight (1 mL per 5 kilograms) by mouth.

(2) *Indications for use.* For the treatment and control of the adult and L4 larval stages of *Haemonchus contortus, Teladorsagia circumcincta, T. trifurcata, Trichostrongylus axei, T. colubriformis, T. vitrinus, Cooperia curticei, C. oncophora, Oesophagostomum columbianum, O. venulosum, Nematodirus battus, N. filicollis,* and *N. spathiger.*

(3) *Limitations.* Sheep must not be slaughtered for human consumption within 7 days of treatment. Because a withholding time in milk has not been established for this product, do not use in female sheep providing milk for human consumption.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 4. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 5. Section 556.426 is amended by adding paragraph (b)(2) and revising paragraph (c) to read as follows:

§ 556.426 Moxidectin.

* * * * *

(b) * * *

(2) *Sheep*—(i) *Fat (the target tissue).* The tolerance for parent moxidectin (the marker residue) is 900 parts per billion (ppb).

(ii) *Liver.* The tolerance for parent moxidectin (the marker residue) is 200 ppb.

(iii) *Muscle*. The tolerance for parent moxidectin (the marker residue) is 50 ppb.

(c) *Related conditions of use*. See §§ 520.1454 and 522.1450 of this chapter.

Dated: 12/12/05
December 12, 2005.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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