

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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Certifier	L. CLAWSON
	DDM

Oral Dosage Form New Animal Drugs; Moxidectin Gel; 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 two supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADAs provide for oral use of moxidectin gel or moxidectin and praziquantel gel in horses and ponies for the treatment and control of two additional species of small strongyles.

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

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, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141-087 for QUEST (moxidectin 2.0%) Gel and to NADA 141-216 for QUEST Plus (moxidectin 2.0%/praziquantel 12.5%) Gel. Both products are used for the treatment and control of various species of internal parasites in horses and ponies. The supplements provide for the addition of two new species of adult small strongyles to product labeling. The supplemental NADAs are approved
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as of November 23, 2005, and 21 CFR 520.1452 and 520.1453 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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)), these approvals qualify for 3 years of marketing exclusivity beginning November 23, 2005. Exclusivity applies only to the effectiveness claim for adult *Cylicocyclus radiatus* and *Petrovinema poculatus* for which new data were required.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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.

§ 520.1452 [Amended]

■ 2. Section 520.1452 is amended in paragraph (d)(2) as follows:

a. By removing “and *C. nassatus*,” and adding in its place “*C. nassatus*, and *C. radiatus*,” and

b. By removing “and *Gyalocephalus capitatus*,” and adding in its place “*Gyalocephalus capitatus*; and *Petrovinema poculatus*,”.

§ 520.1453 [Amended]

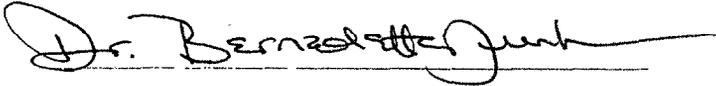
■ 3. Section 520.1453 is amended in paragraph (d)(2) as follows:

a. By removing “and *C. nassatus*,” and adding in its place “*C. nassatus*, and *C. radiatus*,” and

b. By removing "and *Gyalocephalus capitatus*;" and adding in its place "*Gyalocephalus capitatus*; and *Petrovinema poculatus*;"

Dated: 12/8/05

December 8, 2005.



Bernadette A. Dunham,
Deputy Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

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

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