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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Praziquantel, Pyrantel Pamoate, and Febantel Tablets

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 Bayer Corp., Agriculture Division, Animal Health. The supplemental NADA provides for use of a larger size of praziquantel/pyrantel pamoate/febantel tablet for the removal of several species of internal parasites in dogs.

DATES: This rule is effective April 28, 2003.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141-007 that provides for use of a larger size of DRONTAL PLUS (praziquantel/pyrantel pamoate/febantel) Tablets for the removal of several species of internal parasites in dogs. The supplemental NADA is approved as of February 10, 2003, and the regulations are amended in 21 CFR 520.1872 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.

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 520.1872 is amended by adding new paragraph (a)(3), and by revising the table in paragraph (c)(1)(i) to read as follows:

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

(a) * * *

(3) Tablet No. 3: 136 milligrams (mg) praziquantel, 136 mg pyrantel base, and 680.4 mg febantel.

* * * * *

(c) * * *

(1) * * *

(i) * * *

Weight of animal		Number of tablets per dose		
Kilograms	Pounds	Tablet no. 1	Tablet no. 2	Tablet no. 3
0.9 to 1.8	2 to 4	1/2		
2.3 to 3.2	5 to 7	1		
3.6 to 5.4	8 to 12	1 1/2		
5.9 to 8.2	13 to 18	2		
8.6 to 11.4	19 to 25	2 1/2		
11.8 to 13.6	26 to 30		1	
14.1 to 20.0	31 to 44		1 1/2	
20.4 to 27.2	45 to 60		2	
27.7 to 40.9	61 to 90			1
41.3 to 54.5	91 to 120			1 1/2
				2