

FDC Date	State	City	Airport	FDC Number	Subject
01/24/06 ...	IL	Flora	Flora Muni	6/0825	LOC/DME RWY 21, ORIG-A.
01/24/06 ...	CA	Burbank	Bob Hope	6/0848	VOR RWY 8, AMDT 10D.
01/25/06 ...	IA	Muscatine	Muscatine Muni	6/0803	GPS RWY 24, AMDT 2A.
01/25/06 ...	IA	Muscatine	Muscatine Muni	6/0807	GPS RWY 6, ORIG-A.
01/25/06 ...	OR	Klamath Falls	Klamath Falls	6/0925	ILS RWY 32, AMDT 19C.

[FR Doc. 06-1118 Filed 2-8-06; 8:45 am]

BILLING CODE 4910-13-P

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 HealthCare LLC, Animal Health Division. The supplemental NADA provides for the use of flavored, chewable praziquantel/pyrantel pamoate/febantel tablets for the removal of several species of internal parasites in dogs.

DATES: This rule is effective February 9, 2006.

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: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141-007 that provides for use of DRONTAL PLUS (praziquantel/pyrantel pamoate/febantel) Taste Tabs for Dogs for the removal of several species of internal parasites in dogs. The supplemental NADA is approved as of January 12, 2006, 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 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 12, 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 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.

§ 520.1872 [Amended]

■ 2. Revise paragraph (a) introductory text in § 520.1872 by adding "or chewable tablet" after "tablet".

Dated: February 1, 2006.

Steven D. Vaughn,

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

[FR Doc. 06-1205 Filed 2-8-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2003P-0564]

Microbiology Devices; Reclassification of Hepatitis A Virus Serological Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify hepatitis A virus (HAV) serological assays from class III (premarket approval) into class II (special controls). FDA is taking this action after reviewing a reclassification petition submitted by Beckman Coulter, Inc. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays" that will serve as the class II special control for these devices.

DATES: This rule is effective March 13, 2006.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-0496.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act (SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and