

FDC DATE	STATE	CITY	AIRPORT	FDC NUMBER	SUBJECT
09/08/03	MD	INDIAN HEAD .....	MARYLAND .....	3/8693	VOR-A, ORIG-A.
09/06/03	MD	INDIAN HEAD .....	MARYLAND .....	3/8692	RNAV (GPS) RWY 36, ORIG.
09/06/03	PA	PITTSBURGH .....	PITTSBURGH INTL .....	3/8453	RNAV (GPS) RWY 10C, AMDT 2.
09/08/03	VA	TANGIER .....	TANGIER ISLAND .....	3/8516	VOR/DME OR GPS RWY 2, ORIG-B.
09/08/03	WV	PINEVILLE .....	KEE FIELD .....	3/8695	GPS RWY 26, ORIG-A.
09/06/03	WV	PINEVILLE .....	KEE FIELD .....	3/8694	GPS RWY 8, ORIG-A.
09/04/03	GA	ELBERTON .....	ELBERT CO-PATZ FIELD.	3/8354	VOR/DME OR GPS RWY 10, AMDT 2C; CORRECTION TO TL03-21.
09/12/03	AK	BETHEL .....	BETHEL .....	3/8912	VOR/DME-B, ORIG.
09/12/03	AK	BETHEL .....	BETHEL .....	3/8913	VOR RWY 18, AMDT 8B.
09/11/03	TX	HOUSTON .....	ELLINGTON FIELD .....	3/8976	RNAV (GPS) RWY 4, ORIG-A.
09/15/03	AK	BETHEL .....	BETHEL .....	3/9073	VOR/DME RWY 18, AMDT 1.
09/17/03	MA	HYANNIS .....	BARNSTABLE MUNI-BOARDMAN/ POLANDO FIELD.	3/9125 REPLACES 3/8768	VOR OR GPS RWY 6, AMDT 7C.
09/17/03	TX	LOCKHART .....	LOCKHART MUNI .....	3/9122	GPS RWY 36, ORIG-B.
09/11/03	CO	FORT COLLINS (LOVELAND).	FORT COLLINS-LOVELAND MUNI.	3/8900	NDB RWY 33, AMDT 4A.
09/11/03	CO	FORT COLLINS (LOVELAND).	FORT COLLINS-LOVELAND MUNI.	3/8901	ILS RWY 33, AMDT 5B.
09/11/03	PA	PITTSBURGH .....	PITTSBURGH INTL .....	3/8948	RNAV (GPS) Z RWY 28L, AMDT 2.
09/15/03	NY	ITHACA .....	ITHACA TOMPKINS REGIONAL.	3/9037	ILS RWY 32, AMDT 5.
09/18/03	PA	PHILADELPHIA .....	PHILADELPHIA .....	3/9160	NDB RWY 27L, AMDT 5B.

[FR Doc. 03-25054 Filed 10-2-03; 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 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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the oral use of praziquantel tablets for the removal and control of certain cestode parasites in dogs.

**DATES:** This rule is effective October 3, 2003.

**FOR FURTHER INFORMATION CONTACT:**

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terr., St. Joseph, MO 64503, filed ANADA 200-265 that provides for the use of Praziquantel Tablets for the removal and control of certain cestode parasites in dogs. Phoenix Scientific,

Inc.'s Praziquantel Tablets are approved as a generic copy of Bayer HealthCare LLC's DRONCIT (praziquantel) Canine Tablets approved under NADA 111-798. The ANADA is approved as of August 28, 2003, and the regulations are amended in 21 CFR 520.1870 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.

The agency 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.

■ 2. Section 520.1870 is amended by revising paragraphs (a), (b), and (c)(1) to read as follows:

#### § 520.1870 Praziquantel tablets.

(a) *Specifications.* Each tablet contains:

- (1) 34 milligrams (mg) praziquantel.
- (2) 11.5 or 23 mg praziquantel.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) No. 000859 for use of the product described in paragraph (a)(1) of this section, as in paragraph (c)(1) of this section; and for use of the product described in paragraph (a)(2) of this section, as in paragraph (c)(2) of this section.

(2) No. 059130 for use of the product described in paragraph (a)(1) of this section, as in paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii)(B) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 pounds (lb) and under, 1/2 tablet (17 mg); 6 to 10 lb, 1 tablet (34 mg); 11 to 15 lb, 1 1/2 tablets (51 mg); 16 to 30 lb, 2 tablets (68 mg); 31 to 45 lb, 3 tablets (102 mg); 46 to 60 lb, 4 tablets (136 mg); over 60 lb, 5 tablets maximum (170 mg). Administer directly by mouth or crumbled and in feed.