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.

(ii) *Indications for use*—(A) For removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(B) For removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

(iii) *Limitations*—(A) If labeled only for use as in paragraph (c)(1)(ii)(A) of this section: Not intended for use in puppies less than 4 weeks of age. Consult your veterinarian before administering tablets to weak or debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(B) If labeled for use as in paragraph (c)(1)(ii)(B) of this section: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

Dated: September 15, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–25090 Filed 10–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 120

[Public Notice 4505]

RIN 1400–AB86

Bureau of Political-Military Affairs; Amendment to the International Traffic in Arms Regulations

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic in Arms Regulations (ITAR) implementing section 38 of the Arms Export Control Act (AECA) (22 U.S.C. 2778), which governs the import and export of defense articles and defense services. The rule reflects the change in the Directorate of Defense Trade Controls whereby two individuals will now hold the separate positions of Deputy Assistant Secretary of State for Defense Trade Controls and Managing Director of Defense Trade Controls.

EFFECTIVE DATE: August 11, 2003.

FOR FURTHER INFORMATION CONTACT: Robert W. Maggi, Managing Director of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (202) 663–2700 or Michael T. Dixon, Office of Defense Trade Controls Management (202) 663–2798, FAX (202) 261–8199.

SUPPLEMENTARY INFORMATION: Effective August 11, 2003, the Department of State will have two individuals hold the separate positions of Deputy Assistant Secretary for Defense Trade Controls (DAS—Defense Trade Controls) and Managing Director of Defense Trade Controls (MD—Defense Trade Controls). Section 120.1(b)(2) is amended to reflect this change.

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1996. It will not have substantial direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this rule does not have sufficient federalism implications to warrant application of the consultation provisions of Executive Orders 12372 and 13123.

List of Subjects in 22 CFR Part 120

Arms and munitions, Classified information, Exports.

■ Accordingly, for the reasons set forth above, title 22, chapter I, subchapter M, part 120, is being amended as follows:

PART 120—PURPOSE AND DEFINITIONS

■ 1. The authority citation for Part 120 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2794; E.O. 11958, 42 FR 4311, 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658; Pub. L. 105–261, 112 Stat. 1920.

■ 2. Section 120.1(b)(2) is revised to read as follows:

§ 120.1 General authorities and eligibility.

* * * * *

(b) * * *

(1) * * *

(2) In the Bureau of Political-Military Affairs, there is a Deputy Assistant Secretary for Defense Trade Controls (DAS—Defense Trade Controls) and a Managing Director of Defense Trade Controls (MD—Defense Trade Controls). The DAS—Defense Trade Controls and the MD—Defense Trade Controls are responsible for exercising the authorities conferred under this subchapter. The DAS—Defense Trade Controls is responsible for oversight of the defense trade controls function. The MD—Defense Trade Controls is responsible for the Directorate of Defense Trade Controls, which oversees the subordinate offices described in paragraph (b)(2)(i) of this section.

* * * * *

Dated: September 12, 2003.

John R. Bolton,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 03–25169 Filed 10–2–03; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–249–FOR]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving a proposed amendment to the Ohio regulatory program (the ''Ohio program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Ohio proposed revisions to its Ohio Administrative Code (OAC) to incorporate a variety of changes related to the certification of blasters. The amendment is intended to facilitate the certification of blasters in the State's non-coal regulatory program as well as to upgrade the coal surface mining blaster certification program.

EFFECTIVE DATE: October 3, 2003.

FOR FURTHER INFORMATION CONTACT: George Rieger, Program Manager, Oversight and Inspection Office, Telephone: 412–937–2153, Internet address: *grieger@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders