DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

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 oral use pyrantel pamoate suspension as an anthelmintic to treat horses and ponies.

EFFECTIVE DATE: July 24, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–246 that provides for oral use of 50 milligrams per milliliter (mg/mL) pyrantel pamoate suspension in horses and ponies for removal and control of mature infections of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*), pinworms (*Oxyuris equi*), large roundworms (*Parascaris equorum*), and small strongyles.

Approval of ANADA 200–246 for Phoenix Scientific, Inc.'s pyrantel pamoate suspension is as a generic copy of NADA 91–739 for Pfizer, Inc.'s Strongid® T (pyrantel pamoate) suspension. The ANADA is approved as of June 18, 1998, and the regulations are amended in 21 CFR 520.2043(a)(2) 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 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(a) 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.

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 520.2043 is amended by revising paragraph (a)(2) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

(a) * * *

(2) *Sponsors.* See Nos. 000069 and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: July 15, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19713 Filed 7–23–98; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN–130–FOR; State Program Amendment No. 95–8]

Indiana Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving an amendment to the Indiana regulatory program (hereinafter referred to as the ''Indiana program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Indiana proposed revisions to its rules pertaining to permit application requirements for reclamation plans, public availability of information, and stream buffer zones. The amendment is intended to revise the Indiana program to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: July 24, 1998.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204–1521. Telephone: (317) 226–6700. Internet: agilmore@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Secretary of the Interior conditionally approved the Indiana program. Background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the July 26, 1982, **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 914.10, 914.15, and 914.16.

II. Submission of the Proposed Amendment

By letter dated March 6, 1998 (Administrative Record No. IND–1596), Indiana submitted a proposed amendment to its program pursuant to SMCRA. Indiana submitted the amendment at its own initiative.

OSM announced receipt of the amendment in the April 6, 1998 **Federal Register** (63 FR 16723), and in the same document opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. The public comment period closed on May 6, 1998. Because no one requested a public hearing or meeting, none was held.

During its review of the amendment, OSM identified concerns relating to technical errors at 310 IAC 12–3–80(a), reclamation plan requirements; 310 IAC 12–5–32(a)(1), water quality standards; and 310 IAC 12–5–32(a)(2), requirements for stream channel diversions. OSM notified Indiana of these concerns by letter dated April 20, 1998 (Administrative Record No. IND–1603).

By electronic mail dated May 15, 1998 (Administrative Record No. IND–1608), Indiana responded to OSM's concerns by stating that the editorial errors at 310 IAC 12–3–80(a), 12–5–32(a)(1), and 12–5–32(a)(2) would be corrected. Because no substantive revisions were made to the amendment, OSM did not reopen the public comment period.