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]

BILLING CODE 4160–01–F

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
II. Submission of the Proposed Amendment
III. Director's Findings
IV. Summary and Disposition of Comments
V. Director's Decision
VI. Procedural Determinations

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.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the amendment.

Revisions not specifically discussed below concern nonsubstantive wording changes, or revised cross-references and paragraph notations to reflect organizational changes resulting from this amendment.

Revisions to Indiana's Rules That Are Substantively Identical to the Corresponding Provisions of the Federal Regulations

The proposed State rules discussed below contain language that is the same as or similar to the corresponding sections of the Federal regulations. Differences between the proposed State rules and the Federal regulations are nonsubstantive.

Topic	State rules	Federal counterpart regulation
Reclamation plans—surface mining	310 IAC 12–3–46(a)	30 CFR 780.18(a).
Estimate of reclamation cost—surface mining	310 IAC 12–3–46(b)(2)	30 CFR 780.18(b)(2).
Final surface configuration plan—surface mining	310 IAC 12–3–46(b)(3)	30 CFR 780.18(b)(3).
Soil removal/replacement plan—surface mining	310 IAC 12–3–46(b)(4)	30 CFR 780.18(b)(4).
Revegetation plan—surface mining	310 IAC 12–3–46(b)(5)	30 CFR 780.18(b)(5).
Soil testing plan—surface mining	310 IAC 12–3–46(b)(5)(g)	30 CFR 780.18(b)(5)(vii).
Reclamation plan—underground mining	310 IAC 12–3–80(a)	30 CFR 784.13(a).
Estimate of reclamation cost—underground mining	310 IAC 12–3–80(b)(2)	30 CFR 784.13(b)(2).
Final surface configuration plan—underground mining	310 IAC 12–3–80(b)(3)	30 CFR 784.13(b)(3).
Soil removal/replacement plan—underground mining	310 IAC 12–3–80(b)(4)	30 CFR 784.13(b)(4).
Revegetation plan—underground mining	310 IAC 12–3–80(b)(5)	30 CFR 784.13(b)(5).
Public availability of information	310 IAC 12–3–110(f)	30 CFR 773.13(d)(3)(iii).
Information disclosure procedures	310 IAC 12–3–110(g)	30 CFR 773.13(d)(3).
Stream buffer zones—surface mining	310 IAC 12–5–32(a)	30 CFR 816.57(a).
Marking of stream buffer zones—surface mining	310 IAC 12–5–32(b)	30 CFR 816.57(b).
Stream buffer zones—underground mining	310 IAC 12–5–97(a)	30 CFR 817.57(a).
Marking of stream buffer zones—underground mining	310 IAC 12–5–97(b)	30 CFR 817.57(b).

Because the above revisions are identical in meaning to the corresponding Federal regulations, the Director finds that Indiana's rules are no less effective than the Federal regulations.

IV. Summary and Disposition of Comments

Public Comments

OSM solicited public comments on the amendment, but none were received.

Federal Agency Comments

Pursuant to 30 CFR 732.17(h)(11)(i), OSM solicited comments on the amendment from various Federal agencies with an actual or potential interest in the Indiana program (Administrative Record No. IND–1600). On April 17, 1998, the U.S. Fish and Wildlife Service (FWS) responded to OSM's request (Administrative Record No. IND–1604). The FWS commented that 310 IAC 12–5–32(a)(1) and (a)(2) referred to underground mining activities when they should in fact be referring to surface mining activities. OSM notified Indiana of these concerns by letter dated April 20, 1998 (Administrative Record No. IND–1603). Indiana responded to OSM's concerns by electronic mail dated May 15, 1998 (Administrative Record No. IND–1608), stating that the editorial errors at 12–5–32(a)(1) and (a)(2) would be corrected. The FWS also commented that the addition of intermittent streams to the 100-foot disturbance buffer constraint at 310 IAC 12–5–32(a) and 310 IAC 12–5–97(a) is a ''major improvement for protection of water quality and aquatic resources.'' Finally, the FWS commented that compliance with State or Federal water quality standards as required by 310 IAC 12–5–32(a)(1) and 310 IAC 12–5–97(a)(1) should be consistent with the methodology used by the Indiana Department of Environmental Management in its reviews under Section 401 of the Clean Water Act. Indiana's regulations at 310 IAC 12–5–32(a)(1) and 310 12–5–97(a)(1) are substantially identical to the Federal regulations at 30 CFR 816.57(a)(1) and 30 CFR 817.57(a)(1), and therefore are not inconsistent with the Federal requirements. The methodology used to ensure compliance is not at issue in this rulemaking. However, a copy of the FWS comments were given to Indiana for its consideration.

Environmental Protection Agency (EPA)

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to obtain the written concurrence of the EPA with respect to those provisions of the program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Indiana proposed to make in this amendment pertain to air or water quality standards. Therefore, OSM did not request the EPA's concurrence.

Pursuant to 30 CFR 732.17(h)(11)(i), OSM solicited comments on the amendment from the EPA (Administrative Record No. IND–1600). The EPA did not respond to OSM's request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Pursuant to 30 CFR 732.17(h)(4), OSM is required to solicit comments on amendments which may have an effect on historic properties from the SHPO and ACHP. OSM solicited comments on the amendment from the SHPO and ACHP (Administrative Record No. IND–1600). Neither the SHPO nor ACHP responded to OSM's request.

V. Director's Decision

Based on the above findings, the Director approves the amendment as submitted by Indiana on March 6, 1998.

The Director approves the rules as proposed by Indiana with the provision that they be fully promulgated in identical form to the rules submitted to and reviewed by OSM and the public.

The Federal regulations at 30 CFR Part 914, codifying decisions concerning the Indiana program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into

conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Unfunded Mandates

OSM has determined and certifies pursuant to the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of $100 million or more in any given year on local, state, or tribal governments or private entities.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 9, 1998.

Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

For the reasons set out in the preamble, 30 CFR part 914 is amended as set forth below:

PART 914—INDIANA

1. The authority citation for part 914 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 914.15 is amended in the table by adding a new entry in chronological order by ''Date of final publication'' to read as follows:

§ 914.15 Approval of Indiana regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	*
March 6, 1998	July 24, 1998	310 IAC 12–3–46(a), (b)(2) through (b)(5); 12–3–80(a), (b)(2) through (b)(5); 12–3–110 (f), (g); 12–5–32(a), (b); 12–5–97(a), (b).

[FR Doc. 98–19791 Filed 7–23–98; 8:45 am]

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DEPARTMENT OF THE TREASURY

Federal Law Enforcement Training Center

31 CFR Part 700

Regulations Governing Conduct in Federal Law Enforcement Training Center (FLECT) Buildings and on the Grounds in Glynco, Georgia, Artesia, New Mexico, the FLETC Washington Office, and Any Other Temporary Site the FLETC May Occupy

AGENCY: Federal Law Enforcement Training Center (FLETC).

ACTION: Final rule.

SUMMARY: This final rule amends the regulations governing conduct in Federal Law Enforcement Training Center (FLETC) buildings and grounds. The existing regulations apply only to the FLETC buildings and grounds in Glynco, Georgia. This final rule modifies the existing regulations to include the FLETC Artesia facility in New Mexico, the FLETC Washington Office, and any other temporary site the FLETC may occupy.

EFFECTIVE DATES: July 24, 1998.

FOR FURTHER INFORMATION CONTACT: Stephen M. Bodolay, 912–267–2441.

SUPPLEMENTARY INFORMATION: The Federal Law Enforcement Training Center (FLETC) facility in Artesia, New Mexico, the FLETC Washington Office, and any other temporary site the FLETC may occupy are included in 31 CFR 700. Section 301 of Title 5, United States Code, and Treasury Order 140–01 (September 20, 1994) authorize the Director, FLETC, to make all needful rules and regulations governing conduct in FLETC's buildings and on its grounds. This final rule prohibits discrimination or harassment of other persons on the property, requires compliance with instructions of uniformed security officers, prohibits the taking of photographs of students without their consent, restricts the smoking of cigarettes, cigars and pipes, and requires that bicycles be equipped with appropriate safety devices.