

FR 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996 and effective September 16, 1996, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

AWP CA D Hayward, CA [Revised]

Harward Air Terminal, CA
(Lat. 37°39'34"N, long. 122°07'21" W)

San Francisco International Airport, CA
(Lat. 37°37'09"N, long. 122°22'30" W)

Metropolitan Oakland International Airport, CA

(Lat. 37°43'17"N, long. 122°13'15" W)

That airspace extending upward from the surface to but not including 1,500 feet MSL within a 5.6-mile radius of the Hayward Air Terminal excluding that portion within the San Francisco International Airport, CA, Class B airspace area and the Metropolitan Oakland International Airport, CA, Class C airspace area. This Class D airspace area is effective during the specific dates and times established by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Los Angeles, California, on September 13, 1996.

Leonard A. Mobley,
*Acting Manager, Air Traffic Division,
Western-Pacific Region.*

[FR Doc. 96–25415 Filed 10–7–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for an additional container size for the firm's oxytetracycline hydrochloride (OTC HCl) soluble powder. The drug product is administered orally in drinking water for either control or control and treatment of certain diseases of chickens, turkeys, swine, cattle, and sheep. In addition, the regulations are amended to specify the withdrawal period for use of medicated drinking water made from the subject sponsor's drug and to add certain warning statements required on the labeling.

EFFECTIVE DATE: October 8, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506–0457, is the sponsor of ANADA 200–146, which provides for use of OTC HCl soluble powder in drinking water for either control or control and treatment of certain diseases of chickens, turkeys, swine, cattle, and sheep in accordance with § 520.1660d (21 CFR 520.1660d). The firm has filed a supplement to the ANADA that provides for the drug product in a 5-pound (lb) pail in addition to the previously approved 2-lb pail. The supplemental ANADA is approved as of August 15, 1996, and the regulations are amended in § 520.1660d to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the regulations are amended to reflect the appropriate withdrawal times for the subject drug product. The withdrawal times were inadvertently omitted in the final rule which announced the original approval (61 FR 2914, January 30, 1996).

In addition, § 520.1660d(e)(1)(iv)(C) is revised by adding required warning statements against use of the drug product in the drinking water of calves to be processed for veal or female dairy cattle 20 months of age or older.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1660d is amended by revising paragraph (a)(7), the sixth sentence in paragraphs (e)(1)(ii)(A)(3), (e)(1)(ii)(B)(3), and (e)(1)(ii)(C)(3), the third sentence in paragraph (e)(1)(iii)(C), and by adding four sentences at the end of paragraph (e)(1)(iv)(C) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (pails: 2 and 5 lb).

* * * * *

(e) * * *

(1) * * *

(ii) * * *

(A) * * *

(3) * * * Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 017144, 057561, and 059130 in § 510.600(c) of this chapter. * * *

(B) * * *

(3) * * * Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 017144, 057561, and 059130 in § 510.600(c) of this chapter. * * *

(C) * * *

(3) * * * Withdraw 5 days prior to slaughter those products sponsored by Nos. 000069, 017144, 057561, and 059130 in § 510.600(c) of this chapter. * * *

(iii) * * *

(C) * * * Administer up to 14 days; do not use for more than 14 consecutive days; withdraw 5 days prior to slaughter those products sponsored by Nos. 000069 and 059130. * * *

(iv) * * *

(C) * * * A withdrawal period has not been established for this product in pre-maturing calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

* * * * *

Dated: September 13, 1996.

Robert C. Livingston,

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

[FR Doc. 96-25811 Filed 10-7-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 934

[ND-033-FOR]

North Dakota Abandoned Mine Land Reclamation Plan

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

ACTION: Final rule; approval of amendment.

SUMMARY: Office of Surface Mining Reclamation and Enforcement (OSM) is approving a proposed amendment to the North Dakota abandoned mine land reclamation (AMLR) plan (hereinafter, the "North Dakota plan") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). North Dakota proposed revisions to and the addition of provisions pertaining to contractor eligibility, procurement procedures, contract procedures, contract and procurement policies, and the State agency structural organization. The amendment was intended to revise the North Dakota plan to meet the

requirements of the corresponding Federal regulations and be consistent with SMCRA, and to improve operational efficiency.

EFFECTIVE DATE: October 8, 1996.

FOR FURTHER INFORMATION CONTACT:

Guy Padgett, Telephone: (307) 261-6550, Internet address: GPADGETT@CWYGW.OSMRE.GOV.

SUPPLEMENTARY INFORMATION:

I. Background on the North Dakota Plan

On December 23, 1981, the Secretary of the Interior approved the North Dakota plan. General background information on the North Dakota plan, including the Secretary's findings and the disposition of comments, can be found in the December 23, 1981, Federal Register (46 FR 62253). Subsequent actions concerning North Dakota's plan and plan amendments can be found at 934.25.

II. Proposed Amendment

By letter dated September 20, 1995, North Dakota submitted a proposed amendment to its plan (administrative record No. ND-X-02) pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). North Dakota submitted the proposed amendment in response to a September 26, 1994, letter (administrative record No. ND-X-01) that OSM sent to North Dakota in accordance with 30 CFR 884.15(b), and at its own initiative. The provisions of the North Dakota plan that North Dakota proposed to revise or add were: North Dakota Century Code (NDCC) 38-14.2-03(14), bidder eligibility for abandoned mine land (AML) contracts; procurement procedures; contract procedures; contract and procurement policies 2-02-81(5) and 2-01-81(5); and the North Dakota Public Service Commission (PSC) organizational chart.

OSM announced receipt of the proposed amendment in the October 16, 1995, Federal Register (60 FR 53564), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (administrative record No. ND-X-05). Because no one requested a public hearing or meeting, none was held. The public comment period ended on November 15, 1995.

During its review of the amendment, OSM identified concerns relating to the provisions at NDCC 38-14.2-03(14), bidder eligibility, and section IV.C.5 of the North Dakota PSC procurement procedures, non-competitive negotiation. OSM notified North Dakota of the concerns by letter dated December 7, 1995 (administrative record

No. ND-X-04). North Dakota responded in a letter dated April 30, 1996, by submitting additional explanatory information (administrative record No. ND-X-09). North Dakota proposed additional explanatory information for NDCC 38-14.2-03(14), contractor responsibility, and procurement procedure section IV.C.5., sole-source procurement.

Based upon the additional explanatory information for the proposed plan amendment submitted by North Dakota, OSM reopened the public comment period in the May 21, 1996, Federal Register (61 FR 25425, administrative record No. ND-X-18). Because no one requested a public hearing or meeting, none was held. The public comment period closed on June 20, 1996.

III. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 884.14 and 884.15, finds that the proposed plan amendment submitted by North Dakota on September 20, 1995, and as supplemented with additional explanatory information on April 30, 1996, meets the requirements of the corresponding Federal regulations and is consistent with SMCRA. Thus, the Director approves the proposed amendment.

1. Nonsubstantive Revisions to North Dakota's Plan Provisions

North Dakota proposed revisions to the following previously-approved plan provisions that are nonsubstantive in nature and consist of minor editorial and recodification changes (corresponding Federal regulation provisions are listed in parentheses):

North Dakota PSC Procurement Procedures (30 CFR 884.13(d)(3)), title and table of contents, and North Dakota PSC Contract Procedures (30 CFR 884.13(d)(3)), title and table of contents.

Because the proposed revisions to these previously-approved plan provisions are nonsubstantive in nature, the Director finds that they meet the requirements of the Federal regulations. The Director approves the proposed revisions to these plan provisions.

2. NDCC 38-14.2-03(14), Bidder Eligibility for Abandoned Mine Land Contracts

North Dakota proposed to add NDCC 38-14.2-03(14) to require that:

Every successful bidder for an AML contract must be eligible based on available information concerning Federal and State failure-to-abate cessation orders, unabated Federal and State imminent harm cessation