

Compliance (HFD-310), Office of Compliance”.

Dated: August 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-18224 Filed 8-10-04; 8:45 am]

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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, technical amendment.

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 Agri Laboratories, Ltd. The supplemental ANADA provides for a new packet size and strength of oxytetracycline hydrochloride soluble powder used to make medicated drinking water.

DATES: This rule is effective August 11, 2004.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed a supplement to ANADA 200-066 that provides for use of AGRIMYCIN 166 (oxytetracycline hydrochloride) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a new packet size and strength of oxytetracycline hydrochloride soluble powder used to make medicated drinking water. The supplemental application is approved as of July 13, 2004, and the regulations are amended in 21 CFR 520.1660d 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 Subject 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.

§ 520.1660d [Amended]

■ 2. Section 520.1660d is amended in paragraph (a)(6) by adding “Each 2.73 grams of powder contains 1 gram of OTC HCl (packet: 9.87 oz).” after the last sentence.

Dated: July 30, 2004.

Steven D. Vaughn,

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

[FR Doc. 04-18361 Filed 8-10-04; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY-216-FOR]

Kentucky Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving, with certain exceptions, an amendment to the Kentucky regulatory program (the “Kentucky program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Kentucky proposed revisions to the Kentucky Administrative Regulations (KAR) pertaining to water replacement, subsidence, bonding, definitions, hydrology, and permits. Kentucky revised its program to be consistent with the corresponding Federal regulations.

DATES: Effective August 11, 2004.

FOR FURTHER INFORMATION CONTACT:

William J. Kovacic, Telephone: (859) 260-8400. Internet address: bkovacic@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Kentucky Program
- II. Submission of the Proposed Amendment
- III. OSM’s Findings
- IV. Summary and Disposition of Comments
- V. OSM’s Decision
- VI. Procedural Determinations

I. Background on the Kentucky 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 by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act”; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Kentucky program on May 18, 1982. You can find background information on the Kentucky program, including the Secretary’s findings, the disposition of comments, and conditions of approval in the May 18, 1982, **Federal Register** (47 FR 21404). You can also find later actions concerning Kentucky’s program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16 and 917.17.

II. Submission of the Proposed Amendment

By letter dated July 30, 1997 (administrative record no. KY-1410), Kentucky sent us, the Office of Surface Mining Reclamation and Enforcement (OSM), a proposed amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) The amendment revises 405 KAR at Sections 8:001, 8:030, 8:040, 16:001, 16:060, 16:090, 16:100, 16:160,