

(g) Replacing the fin spar, P/N's 205-032-899-all dash numbers, 205-030-846-all dash numbers, or 205-032-851-all dash numbers, with an airworthy fin spar that has been demonstrated to the FAA to satisfy the structural fatigue requirements of repeated high torque events and approved by the Manager, FAA, Rotorcraft Standards Staff, constitutes a terminating action for the requirements of this AD.

(h) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, FAA, Regulations Group, Rotorcraft Standards Staff. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, FAA, Regulations Group.

Note 4: Information concerning the existence of approved fin spar configurations and alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(i) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(j) This amendment becomes effective on January 11, 2000.

Issued in Fort Worth, Texas, on November 30, 1999.

Mark R. Schilling,

*Acting Manager, Rotorcraft Directorate,
Aircraft Certification Service.*

[FR Doc. 99-31675 Filed 12-6-99; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Trimethoprim and Sulfadiazine

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 Pharmacia & Upjohn Co. The ANADA provides for use of trimethoprim and sulfadiazine powder for control of bacterial infections of horses.

EFFECTIVE DATE: December 7, 1999.

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: Pharmacia & Upjohn Co., 7000 Portage Rd.,

Kalamazoo, MI 49001-0199, filed ANADA 200-244 that provides for use of Tucoprim® (trimethoprim and sulfadiazine) powder for control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses. ANADA 200-244 is approved as a generic copy of Macleod Pharmaceuticals, Inc.'s ANADA 200-033 Uniprim™ (trimethoprim and sulfadiazine) powder for horses. The ANADA is approved as of October 22, 1999, and the regulations in 21 CFR 520.2613 are amended to reflect the approval. The basis for 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)(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.

§ 520.2613 [Amended]

2. Section 520.2613 *Trimethoprim and sulfadiazine powder* is amended in paragraph (b) by adding the phrase "000009 and" before "058711".

Dated: November 29, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99-31571 Filed 12-6-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 918

[SPATS No. LA-018-FOR]

Louisiana Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving an amendment to the Louisiana regulatory program (Louisiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Louisiana proposed revisions to and additions of statutes concerning requirements for permit applications, eligibility requirements for the Small Operator Assistance Program (SOAP), and permit exemptions. Louisiana intends to revise the Louisiana program to be consistent with SMCRA and the Louisiana Surface Mining Regulations.

EFFECTIVE DATE: December 7, 1999.

FOR FURTHER INFORMATION CONTACT:

Michael C. Wolfrom, Director, Tulsa Field Office, Office of Surface Mining, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135-6548. Telephone: (918) 581-6430. Internet: mwolfrom@tokgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Louisiana 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 Louisiana Program

On October 10, 1980, the Secretary of the Interior approved the Louisiana program. You can find background information on the Louisiana program, including the Secretary's findings and the disposition of comments in the October 10, 1980, **Federal Register** (45 FR 67340). You can find later actions concerning the Louisiana program at 30 CFR 918.15 and 918.16.