Rules and Regulations

Federal Register
Vol. 68, No. 191
Thursday, October 2, 2003

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Dexamethasone Injection

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 Veterinary Laboratories, Inc. The ANADA provides for the use of dexamethasone injectable solution for the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses.

DATES: This rule is effective October 2, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215, filed ANADA 200–324 that provides for use of Dexamethasone Injection for the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses. Veterinary Laboratories' Dexamethasone Injection is approved as a generic copy of Schering-Plough Animal Health's AZIUM (dexamethasone) Solution 2 Mg., approved under NADA 012–559. The ANADA is approved as of August 19, 2003, and the regulations are amended in § 522.540 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 Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.540 is amended by revising paragraph (a) to read as follows:

§ 522.540 Dexamethasone injection.

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061 and 059130 for use as in paragraph (a)(3) of this section.

(ii) No. 000857 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use*—(i) *Amount.* The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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Dated: September 11, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–24928 Filed 10–1–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA–135–FOR]

Pennsylvania Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving a proposed amendment to the Pennsylvania regulatory program (the ''Pennsylvania program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Pennsylvania proposed revisions to its rules about surface and ground water monitoring and coal refuse disposal to satisfy required program amendments. Additionally, Pennsylvania submitted new rules concerning coal refuse disposal operations. Pennsylvania intended to revise its program to be consistent with the corresponding Federal regulations and SMCRA, clarify ambiguities, and provide additional safeguards. Finally, we are removing a regulatory program amendment where we required Pennsylvania to correct