List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 529

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 parts 510 and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''Rhone-Poulenc Chemicals, Ltd.,'' and in the table in paragraph (c)(2) by numerically adding an entry for ''059258'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK	059258
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
059258	Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK.
* * *	* * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 529 continues to read as follows:

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

4. Section 529.1186 is amended by revising paragraph (b) to read as follows:

§ 529.1186 Isoflurane.

* * * * *

(b) *Sponsors.* See Nos. 000074, 010019, 012164, and 059258 in § 510.600(c) of this chapter.

* * * * *

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3983 Filed 2–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Difloxacin Tablets

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 new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for oral use of difloxacin tablets for management of diseases in dogs associated with bacteria susceptible to difloxacin.

EFFECTIVE DATE: February 18, 1998.

FOR FURTHER INFORMATION CONTACT: Tania D. Woerner, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products, 800 Fifth St. NW., P.O. Box 518, Fort Dodge, IA 50501, filed NADA 141–096 that provides for oral use of Dicural® (difloxacin) tablets for management of diseases in dogs associated with bacteria susceptible to difloxacin. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of November 20, 1997, and the regulations are amended by adding new § 520.645 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iv) of the Federal Food, Drug, and Cosmetic Act

(the act), this approval, which is solely for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning November 20, 1997, because the applicant has elected to waive section 512(c)(2)(F)(i) of the act.

FDA has determined under 21 CFR 25.33(d) 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 the 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 520.645 is added to read as follows:

§ 520.645 Difloxacin.

(a) *Specifications.* Each tablet contains 11.4, 45.4, or 136 milligrams (mg) of difloxacin hydrochloride.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 5 to 10 mg per kilogram (2.3 to 4.6 mg/pound) of body weight.

(ii) *Indications for use.* For management of diseases in dogs associated with bacteria susceptible to difloxacin.

(iii) *Limitations.* Use once a day for 2 to 3 days beyond cessation of clinical signs of disease up to a maximum of 30 days. Federal law prohibits the extra-label use of this drug in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: January 21, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3984 Filed 2–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 936

[SPATS No. OK–023–FOR]

Oklahoma Abandoned Mine Land Reclamation Plan

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Oklahoma abandoned mine land reclamation plan (hereinafter referred to as the ''Oklahoma plan'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment is intended to revise the Oklahoma plan to allow the State to assume responsibility for administering an emergency response reclamation program in Oklahoma on behalf of OSM.

EFFECTIVE DATE: February 18, 1998.

FOR FURTHER INFORMATION CONTACT: Michael C. Wolfrom, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135–6547, Telephone: (918) 581–6430.

SUPPLEMENTARY INFORMATION:

I. Background on the Oklahoma Plan

On January 21, 1982, the Secretary of the Interior approved the Oklahoma plan. Background information on the Oklahoma plan, including the Secretary's findings, the disposition of comments, and the approval of the plan can be found in the January 21, 1982, **Federal Register** (46 FR 2989). Subsequent actions concerning the Oklahoma plan and amendments to the plan can be found at 30 CFR 936.25.

II. Submission of the Proposed Amendment

Section 410 of SMCRA authorizes the Secretary to use funds under the abandoned mine land reclamation (AMLR) program to abate or control emergency situations in which adverse effects of past coal mining pose an immediate danger to the public health, safety, or general welfare. On September 29, 1982, (47 FR 42729) OSM invited States to amend their AMLR plans for the purpose of undertaking emergency reclamation programs on behalf of OSM. States would have to demonstrate that they have the statutory authority to undertake emergencies, the technical capability to design and supervise the emergency work, and the administrative mechanisms to quickly respond to emergencies either directly or through contracts.

Under the provisions of 30 CFR 884.15, any State may submit proposed amendments to its approved AMLR plan. If the proposed amendments change the scope or major policies followed by the State in the conduct of its AMLR program, OSM must follow the procedures set out in 30 CFR 884.14 in reviewing and approving or disapproving the proposed amendments.

The proposed assumption of the AMLR emergency program on behalf of OSM is a major addition to the Oklahoma AMLR plan. Therefore, to assume the emergency program, Oklahoma must either revise the Oklahoma plan to include conducting the AMLR emergency program, or demonstrate that its plan currently includes provisions for assuming and conducting the emergency program.

By letter dated November 3, 1997 (Administrative Record No. OAML–77), Oklahoma submitted a proposed amendment to its plan pursuant to SMCRA. Oklahoma submitted the proposed amendment on its own initiative. The amendment was intended to demonstrate Oklahoma's capability to effectively perform the AMLR emergency program on behalf of OSM. A brief description of the amendment is presented below.

A. The proposed amendment would allow Oklahoma to assume the administration of the AMLR emergency program in Oklahoma on behalf of OSM. In its formal submittal, Oklahoma stated that in 1982, as part of its approved State Abandoned Mine Land Program, the Oklahoma Conservation Commission (OCC) incorporated the necessary language to assume responsibility of the AMLR emergency program at a later date. The following information, taken from the approved Oklahoma plan, was included in Oklahoma's formal submission to OSM to verify that the authority already exists for the OCC to assume AMLR emergency program responsibilities:

1. A letter from the Governor that designates the OCC as the agency responsible for the Abandoned Mine Land Reclamation Program in Oklahoma.

2. A legal opinion from the Attorney General that the OCC has the power to