

by the Office of Management and Budget under that Executive order, as it is not deemed "significant" thereunder.

Regulatory Flexibility Act

As Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this final rule correction will not have a significant economic impact on a substantial number of small entities because it primarily affects Federal executive branch employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this correcting amendment does not contain information collection requirements that require the approval of the Office of Management and Budget.

List of Subjects in 5 CFR Part 2640

Conflict of interests, Government employees.

Approved: April 23, 1997.

Stephen D. Potts,

Director, Office of Government Ethics.

Accordingly, for the reasons set forth in the preamble, the Office of Government Ethics is correcting 5 CFR part 2640 as follows:

PART 2640—[CORRECTED]

1. The authority citation for part 2640 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); 18 U.S.C. 208; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2640.203(a)(2) [Corrected]

2. Section 2640.203(a)(2) is corrected by removing the word "vested" from between the words "a" and "pension".

[FR Doc. 97-11026 Filed 4-28-97; 8:45 am]

BILLING CODE 6345-01-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Sulfadimethoxine 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 Phoenix Scientific, Inc. The ANADA provides for use of sulfadimethoxine injection in cattle for treatment of certain bacterial infections.

EFFECTIVE DATE: April 29, 1997.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center For Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-177, which provides for intravenous use of sulfadimethoxine injection in cattle for treatment of bovine respiratory disease (shipping fever complex), bacterial pneumonia, calf diphtheria, and foot-rot.

Approval of Phoenix's ANADA 200-177 for sulfadimethoxine injection is as a generic copy of Pfizer's NADA 41-245 for Albon® (sulfadimethoxine) Injection 40 percent. The ANADA is approved as of March 13, 1997, and the regulations are amended by adding new 21 CFR 522.2220(a)(2)(iii) 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 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 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2220 is amended by adding new paragraph (a)(2)(iii) to read as follows:

§ 522.2220 Sulfadimethoxine injection.

(a) * * *

(2) * * *

(iii) See No. 059130 for use as in paragraph (a)(3)(iii) of this section.

* * * * *

Dated: April 8, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97-10979 Filed 4-28-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Decoquinat

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 new animal drug application (NADA) filed by Rhone-Poulenc, Inc. The supplemental NADA provides for certain revisions in the Type C medicated feed fed for prevention of coccidiosis in cattle, sheep, and goats.

EFFECTIVE DATE: April 29, 1997.

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: Rhone-Poulenc, Inc., P.O. Box 125, Black Horse Lane, Monmouth Junction, NJ 08810, filed supplemental NADA 39-417, which provides for use of 6 percent decoquinat Type A medicated article to make 0.06 to 0.6 percent decoquinat Type B feeds to make 0.0015 to 0.059 percent decoquinat Type C medicated feed for cattle, sheep, and goats for prevention of coccidiosis. The supplemental NADA is approved as of

March 7, 1997, and the regulations are amended in 21 CFR 558.195(c) and (d) to reflect the approval.

The supplemental NADA does not contain added safety or effectiveness data. Therefore, a freedom of information (FOI) summary for the supplemental approval is not required. An FOI summary for the currently approved 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. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.195 is amended by adding new paragraph (c)(2) and in the table in paragraph (d) a new entry for "13.6 to 535.7 (0.0015 to 0.059 pct)" to read as follows:

§ 558.195 Decoquinatone.

* * * * *

(c) * * *

(2) Type A medicated articles containing 6 percent decoquinatone may be used to make dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraph (d) of this section.

(d) * * *

Decoquinatone in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
13.6 to 535.7 (0.0015 to 0.059 pct)		Cattle: prevention of coccidiosis in ruminating and nonruminating calves (including veal calves) and cattle caused by <i>Eimeria bovis</i> and <i>E. zurnii</i> .	Feed Type C feed (including dry milk replacer) to provide 22.7 mg per 100 lb body weight (0.5 mg per kg) per day. May be prepared from dry Type B feed containing 0.06 to 0.6 pct decoquinatone or liquid Type B feed containing 0.0125 to 0.05 pct decoquinatone. The liquid Type B feed must have pH 5.0 to 6.5 and contain a suspending agent to maintain a viscosity of not less than 500 centipoises. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food.	011526
		Young sheep: prevention of coccidiosis caused by <i>Eimeria ovinoidalis</i> , <i>E. parva</i> , <i>E. bakuensis</i> , <i>E. crandallis</i> .	do	do
		Young goats: prevention of coccidiosis caused by <i>Eimeria christenseni</i> , <i>E. ninakohlyakimovae</i> .	do	do
*	*	*	*	*

Dated: April 8, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 97-10986 Filed 4-28-97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 904

[SPATS No. AR-027-FOR]

Arkansas Regulatory Program and 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 Arkansas regulatory program and abandoned mine land reclamation plan (hereinafter referred to as the "Arkansas program") under the Surface Mining Control and Reclamation Act of 1997 (SMCRA). Arkansas proposed revisions to and additions of rules pertaining to termination of jurisdiction, permit fees, minimum required permit application information, remaining ownership an control, permit approval or denial, small operator assistance, bond and insurance, water replacement, subsidence damage repair/compensation, performance standards, inspections, and abandoned mine land reclamation requirements.