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Robert Goldner,

Acting Deputy Assistant Secretary for Aviation and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Neomycin Sulfate

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 Pharmacia & Upjohn Co. The supplemental NADA provides for use of neomycin sulfate Type A medicated articles to make Type B and C medicated feeds for cattle, swine, sheep, and goats, and medicated milk replacers for calves, piglets, lambs, and goat kids.

EFFECTIVE DATE: December 17, 1999.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA 140–976 that provides for use of neomycin sulfate Type A medicated articles to make Type B and C medicated feeds for cattle, swine, sheep, and goats, and medicated milk replacers for calves, piglets, lambs, and goat kids, for treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin. The products were the subject of a National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group review of the product's effectiveness (DESI 11–315V). The results of the NAS/NRC review and FDA's conclusions based on that review were published in the **Federal Register** of January 19, 1971 (36 FR 837). The sponsor filed a supplemental NADA that reflects compliance with the results of the NAS/NRC review and FDA's conclusions based on that review. The supplement is approved as of November 3, 1999, and 21 CFR 558.364 is added to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, 21 CFR 558.4 is amended in the ''Category II'' table in paragraph (d) to add an entry for neomycin sulfate.

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.

FDA has determined under 21 CFR 25.33(a)(3) 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 558

Animal drugs, Animal feeds.

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 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: 21 U.S.C. 360b, 371.

2. Section 558.4 is amended in the ''Category II'' table in paragraph (d) by adding an entry alphabetically for neomycin sulfate to read as follows:

§ 558.4 Medicated feed applications.

* * * * *

(d) * * *

Category II

Drug	Assay limits percent[1] type A	Type B maximum (100x)	Assay limits percent[1] type B/C[2]
* * * * * * *			
Neomycin sulfate	80–120	100 g/lb (22.0%)	70–125
* * * * * * *			

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

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3. Section 558.364 is added to subpart B to read as follows:

§ 558.364 Neomycin sulfate.

(a) *Approvals.* Type A medicated article: 325 grams per pound to 000009 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.430 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* Neomycin sulfate is used as follows:

Neomycin Sulfate	Combination	Indications for Use	Limitations	Sponsor
(1) 400 to 1,600 grams per ton (g/t) of dry type C feed.		Cattle, swine, sheep, and goats. For treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin.	To provide 10 milligrams (mg) of neomycin sulfate per pound of body weight per day for a maximum of 14 days. The concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in dry feeds only. Not for use in liquid feed supplements.	000009

Neomycin Sulfate	Combination	Indications for Use	Limitations	Sponsor
(2) 400 to 2,000 g/t of type C milk replacer.		Do.	To provide 10 mg of neomycin sulfate per pound of body weight per day for a maximum of 14 days. Amount consumed will vary depending on animal's consumption and weight. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in milk replacers only.	000009

Dated: December 1, 1999.

Andrew J. Beaulieu,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 99–32426 Filed 12–16–99; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN–142–FOR]

Surface Coal Mining and Reclamation Operations On Federal Lands; State-Federal Cooperative Agreements; Indiana

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

ACTION: Final rule.

SUMMARY: The Governor of the State of Indiana and the Secretary of the Department of the Interior (Secretary) are entering into a cooperative agreement between the Department of the Interior and the State of Indiana. This agreement will allow Indiana, under the permanent regulatory program, to regulate surface coal mining and reclamation operations on Federal lands in Indiana. Section 523(c) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA) authorizes the cooperative agreement.

EFFECTIVE DATE: January 18, 2000.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204–1521. Telephone (317) 226–6700. Internet: INFOMAIL@indgw.osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

The Secretary conditionally approved the Indiana program effective on July 29, 1982. On August 19, 1983, the program was fully approved. You can find background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the July 26, 1982, **Federal Register** (47 FR 32107). You can find later actions on the Indiana program at 30 CFR 914.10, 914.15, and 914.16.

II. Submission of the Cooperative Agreement

By letter dated March 10, 1998 (Administrative Record No. IND–1598), Indiana submitted a request for a State-Federal cooperative agreement under 30 CFR 745.11.

We announced receipt of the amendment in the February 8, 1999, **Federal Register** (64 FR 6150). In the same document, we opened the public comment period and provided an opportunity for a public hearing on the adequacy of the cooperative agreement. The public comment period closed on April 9, 1999. Because no one requested a public hearing or meeting, we did not hold one.