

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.

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.

2. Section 520.1660d is amended by revising paragraph (a)(7), by removing paragraph (c), and by redesignating paragraphs (d) and (e) as paragraphs (c) and (d) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (pails: 2 and 5 lb), each 272.2 grams (9.6 oz) of powder contains 204.8 grams of OTC HCl, each 907.2 grams (2 lb) of powder contains 686 grams of OTC HCl, each 2.26 kilograms (5 lb) of powder contains 1,715 grams of OTC HCl.

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Dated: February 26, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 556, and 558

Animal Drugs, Feeds, and Related Products; Lincomycin

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 three supplemental new animal drug applications (NADA's) filed by Pharmacia & Upjohn Co. The supplemental NADA's provide new tolerances and withdrawal times for use of lincomycin, and codification of an acceptable daily intake (ADI).

EFFECTIVE DATE: March 18, 1999.

FOR FURTHER INFORMATION CONTACT:

William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7570.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed

supplemental NADA's 34-025, 97-505, and 111-636. NADA 34-025 provides for use of Lincocin® sterile solution and Lincomix® injectable (lincomycin hydrochloride) for dogs, cats, and swine. NADA 97-505 provides for use of Lincomix® 20/50 Type A medicated

articles and Lincomix® 10 Type B medicated feed (lincomycin hydrochloride) for swine and broiler chickens. NADA 111-636 provides for use of Lincomix® soluble powder (lincomycin hydrochloride) for swine and broiler chicken drinking water. The supplemental NADA's provide for establishing a zero withdrawal period for lincomycin oral products, establishing residue tolerances of 0.6 parts per million (ppm) in swine liver and 0.1 ppm in swine muscle, and establishing an ADI of 25 micrograms per kilogram of body weight per day. The supplemental NADA's are approved as of August 25, 1998, and the regulations in 21 CFR 520.1263c(d)(1)(i)(C), 556.360, and 558.325(c)(2)(ii)(b), (c)(2)(iii)(b), and (c)(2)(iv)(b) are amended to reflect the approval. The basis of approval is discussed in each freedom of information summary.

Since these approvals involve revised tolerances for residues of lincomycin in edible tissues of swine, § 556.360 is amended to reflect the revised tolerance for lincomycin residues in swine tissues.

In addition to revising the tolerance for lincomycin residues in swine tissues, FDA is further amending the tolerance regulation to codify the ADI for total residues of lincomycin. The ADI is the amount of total drug residue that can be safely consumed by humans every day.

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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), the supplemental approval for food-producing animals for Lincocin® sterile solution and Lincomix® injectable (NADA 34-025) qualifies for 3 years of marketing exclusivity beginning August 25, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new tolerance for lincomycin in swine liver for which the supplemental NADA was approved.

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.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 520, 556, and 558 are 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.

§ 520.1263c [Amended]

2. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (d)(1)(i)(C) by removing the last sentence.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.360 is revised to read as follows:

§ 556.360 Lincomycin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

(b) *Chickens*. A tolerance for residues of lincomycin in chickens is not required.

(c) *Swine*. Tolerances for lincomycin of 0.6 part per million in liver and 0.1 part per million in muscle are established.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.325 [Amended]

6. Section 558.325 *Lincomycin* is amended by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), in newly redesignated paragraph (d)(2)(ii)(b) by removing “; feed containing 100 grams per ton lincomycin hydrochloride should be withdrawn 6 days before slaughter”, and in newly redesignated paragraphs (d)(2)(iii)(b) and (d)(2)(iv)(b) by removing “; withdraw 6 days before slaughter”.

Dated: March 2, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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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; Ivermectin and Bacitracin Methylene Disalicylate

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 Merial Ltd. The NADA provides for use of ivermectin and bacitracin methylene disalicylate (BMD) Type A medicated articles to make Type B and Type C medicated swine feeds for use as antiparasitics, antibacterials, and growth promotants.

EFFECTIVE DATE: March 18, 1999.

FOR FURTHER INFORMATION CONTACT:

Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7575.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, filed NADA 141-097 that provides for use of Ivermectin® (ivermectin 0.6 percent) and BMD (BMD 30, 50, 60, and 75 grams(g) per pound) Type A medicated articles to make ivermectin and BMD Type B and Type C medicated swine feeds. The Type C medicated feeds contain 1.8 g of ivermectin and 10, 30, or 250 g of BMD per ton for feeding to growing and finishing swine, and pregnant sows. It is used for the treatment and control of gastrointestinal roundworms, kidneyworms, lungworms, and threadworm infections; lice and mange mite infestations; increased rate of weight gain and improved feed efficiency; and for the control of clostridial enteritis and swine dysentery. The NADA is approved as of February 3, 1999, and the regulations are amended in 21 CFR 558.76 and § 558.300 (21 CFR 558.300) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, the regulation concerning the limitations for use of ivermectin feeds in § 558.300(d) are editorially amended by removing “sole ration” and adding in its place “only feed”.

This NADA is for use of approved ivermectin and BMD Type A medicated articles to make Type B and Type C medicated swine feeds. Ivermectin is a category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved medicated feed application is required for making Type B or Type C medicated feeds as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by the requirement for feed mill licenses. Therefore, use of ivermectin and BMD Type A medicated articles to make Type B and Type C medicated feeds as in this NADA is limited to manufacture in a licensed feed mill.

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)(2) 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: 21 U.S.C. 360b, 371.

2. Section 558.76 is amended by adding paragraph (d)(3)(xx) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xx) Ivermectin as in § 558.300.

3. Section 558.300 is amended in paragraphs (d)(1)(ii), (d)(2)(ii), (d)(3)(ii), (d)(4)(ii), and (d)(5)(ii) by removing the phrase “sole ration” and adding in its place the phrase “only feed”, and by adding new paragraph (d)(6) to read as follows:

§ 558.300 Ivermectin.

* * * * *

(d) * * *

(6) *Amount per ton*. For weaned, growing-finishing pigs, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day), and 10 to 30 or 250 grams of bacitracin methylene disalicylate. For adult and breeding swine, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day), and 10 to 30 or 250 grams of bacitracin methylene disalicylate.

(i) *Indications for use*. For treatment and control of gastrointestinal