21 CFR 522.1156 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act, this approval for use in nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning November 7, 1997, because the application contains substantial evidence of the effectiveness of the drug involved and any 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 of the application and conducted or sponsored by the applicant.

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 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. New § 522.1156 is added to read as follows:

§ 522.1156 Imidocarb dipropionate solution.

(a) *Specifications*. Each milliliter of injectable solution contains 120 milligrams of imidocarb.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 6.6 milligrams imidocarb per kilogram (3 milligrams per pound) of body weight.

(ii) *Indications for use*. Treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(iii) *Limitations*. Use subcutaneously or intramuscularly. Not for intravenous use. Repeat the dose after 2 weeks for a total of two treatments. Imidocarb is a cholinesterase inhibitor. Do not use simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: December 15, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33486 Filed 12–22–97; 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; Salinomycin, Bacitracin Zinc, and Roxarsone

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 two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved salinomycin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency.

EFFECTIVE DATE: December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200–209 and 200–215 that provide for combining approved salinomycin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler feeds containing salinomycin 40 to 60 grams per ton (g/t), bacitracin zinc 10 to 50 g/t, and roxarsone 34.1 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, increased rate of weight gain, and improved feed efficiency.

Alpharma Inc.'s ANADA 200–209 provides for using approved SACOX® (Hoechst-Roussel Vet's salinomycin ANADA 200–075), ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223), and 3–NITRO® (Alpharma Inc.'s roxarsone NADA 7–891) Type A medicated articles to make the combination drug Type C medicated feeds. Alpharma Inc.'s ANADA 200–215 provides for using approved BIO-COX® (Hoffmann-LaRoche, Inc.'s salinomycin NADA 128–686), ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223), and 3–NITRO® (Alpharma Inc.'s roxarsone NADA 7–891) Type A medicated articles to make the combination drug Type C medicated feeds.

Alpharma Inc.'s ANADA 200–209 is approved as a generic copy of Hoechst-Roussel Vet's ANADA 200–143. Alpharma Inc.'s ANADA 200–215 is approved as a generic copy of Hoffmann-LaRoche, Inc.'s NADA 139–190. The ANADA's are approved as of December 23, 1997, and the regulations are amended in 21 CFR 558.550(b)(1)(ix)(*c*) to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

This approval is for use of three single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, 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 form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of salinomycin, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds as provided in ANADA's 200–209 and 200–215 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 each of these applications 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 25.33 that these actions are of a type that do 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.

§ 558.550 [Amended]

2. Section 558.550 *Salinomycin* is amended in paragraph (b)(1)(ix)(*c*) by removing ''No. 000004'' and adding in its place ''Nos. 000004 and 046573''.

Dated: October 30, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33370 Filed 12–22–97; 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; Semduramicin and Roxarsone

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 Pfizer, Inc. The NADA provides for using approved single ingredient Type A medicated articles to make combination drug Type C medicated broiler chicken feeds containing semduramicin and roxarsone used for prevention of coccidiosis.

EFFECTIVE DATE: December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–066, which provides for combining approved Type A medicated articles containing Aviax™ (semduramicin sodium) (22.7 grams per pound (g/lb.)) and 3-Nitro (roxarsone) (45.4, 90, and 227 g/lb.) to make combination drug Type C medicated broiler chicken feeds containing 22.7 grams per ton of semduramicin and 45.4 grams per ton of roxarsone. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/ E. mitis*, *E. necatrix*, and *E. tenella* including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone. The NADA is approved as of December 23, 1997, and the regulations are amended by adding 21 CFR 558.555(b)(4) 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)(ii) of the Federal Food, Drug, and Cosmetic Act the act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years marketing exclusivity beginning December 23, 1997, because the application contains substantial evidence of the effectiveness of the drug involved, any 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.

This approval is for use of approved Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, 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 FDA form 1900 is required for making a Type B or Type C medicated feed as in this application. Under section 512(m) of the act, as amended by the Animal Drug Availability Act of 1996 (Pub L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of semduramicin and roxarsone Type A medicated articles to make Type C medicated feeds as provided in NADA 141–066 requires a feed mill license rather than an approved FDA Form 1900.

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 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 558.555 is amended by adding paragraph (b)(4) to read as follows:

§ 558.555 Semduramicin.

* * * * *

(b) * * *

(4) *Amount.* Semduramicin 22.7 grams with roxarsone 45.4 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati/E. mitis, E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone.

(ii) *Limitations.* Feed continuously as sole ration. Withdraw 5 days before slaughter. For broiler chickens only. Do not feed to laying hens. Use as sole source of organic arsenic. Roxarsone as provided by 046573, semduramicin as provided by 000069 in § 510.600(c) of this chapter.

Dated: December 15, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33376 Filed 12–22–97; 8:45 am]

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