List of Subjects

21 CFR Part 510

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

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 parts 510 and 522 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 removing the entry for ''American Veterinary Products, Inc.,'' and by alphabetically adding an entry for ''Veterinary Research Associates, Inc.,'' and in the table in paragraph (c)(2) by removing the entry for ''045984'' and by numerically adding an entry for ''064408'' 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
* * *	* * * *
Veterinary Research Associates, Inc., 20 Old Dock Rd., Yaphank, NY 11980	064408
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
064408	Veterinary Research Associates, Inc., 20 Old Dock Rd., Yaphank, NY 11980
* * *	* * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1222a [Amended]

4. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing the phrase ''045984, 059130, and 061690'' and adding in its place ''059130, 061690, and 064408''.

Dated: October 29, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–31574 Filed 11–25–98; 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; Chlortetracycline, Salinomycin, 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 chlortetracycline, salinomycin, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and as an aid in the reduction of mortality due to *Escherichia coli* infections.

EFFECTIVE DATE: November 27, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20852, 301–827–0209.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200–259 and 200–260 that provide for combining approved ChlorMax™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline), Sacox® or Bio-Cox® (30 or 60 g/lb salinomycin sodium), and 3–Nitro® (10, 20, or 50 percent roxarsone) Type A medicated articles to make Type C medicated broiler feeds containing chlortetracycline 500 grams per ton (g/t), salinomycin 40 to 60 g/t, and roxarsone 45.4 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone, and as an aid in the reduction of mortality due to *E.*

coli infections susceptible to such treatment.

Alpharma Inc.'s ANADA 200–259 is approved as a generic copy of Hoechst-Roussel's ANADA 200–091. Alpharma Inc.'s ANADA 200–260 is approved as a generic copy of Roche Vitamins, Inc.'s NADA 140–867. Alpharma Inc.'s ANADA's 200–259 and 200–260 are approved as of September 21, 1998, and 21 CFR 558.550(a)(3) is added and paragraph (d)(1)(xv) is amended to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

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)(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 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 558.550 is amended by revising paragraph (a) and the last sentence in paragraph (d)(1)(xv)(*c*) to read as follows:

§ 558.550 Salinomycin.

(a) *Approvals.* Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass) as follows:

(1) To 063238 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) To 012799 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), and (d)(3)(i) through (d)(3)(iii) of this section.

(3) To 046573 for use as in paragraph (d)(1)(xv) of this section.

* * * * *

(d) * * *

(1) * * *

(xv) * * *

(*c*) * * * Chlortetracycline as provided by Nos. 046573 and 063238 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

* * * * *

Dated: November 12, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–31575 Filed 11–25–98; 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; Chlortetracycline

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 Roche Vitamins, Inc. The supplemental NADA provides for a zero-day withdrawal period for use of 500 grams per ton (g/t) chlortetracycline (CTC) Type C medicated chicken feeds.

EFFECTIVE DATE: November 27, 1998.

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: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298, filed supplemental NADA 48–761 that provides for use of Aureomycin® (CTC) Type A medicated articles to make 500 g/t CTC Type C chicken feeds. The 500 g/t CTC Type C chicken feeds are used for 5 days for reduction of mortality due to CTC susceptible *Escherichia coli* infections. The supplement provides for reducing the 24-hour withdrawal period to a zero-day slaughter withdrawal period. The supplemental NADA is approved as of October 26, 1998, and the regulations in 21 CFR 558.128(d)(1)(viii) are amended 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 supplemental 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)(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.

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.

§ 558.128 [Amended]

2. Section 558.128 *Chlortetracycline* is amended in the table in paragraph (d)(1) in the entry for ''(viii) 500 g/ton'' under the column ''Limitations'' by removing the phrase ''; withdraw 24 h prior to slaughter''.

Dated: November 16, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–31572 Filed 11–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 98N–0520]

Medical Devices; Establishment Registration and Device Listing for Manufacturers and Distributors of Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a direct final rule that appeared in the