§ 524.155 [Amended]

44. Section 524.155 *Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment* is amended in paragraph (a)(1) by removing ''011716'' and adding in its place ''000061''.

§ 524.900 [Amended]

45. Section 524.900 *Famphur* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 524.1240 [Amended]

46. Section 524.1240 *Levamisole* is amended in paragraph (b) by removing ''010042 and 011716'' and adding in its place ''000061 and 010042''.

§ 524.1443 [Amended]

47. Section 524.1443 *Miconazole nitrate cream; miconazole nitrate lotion; miconazole nitrate spray* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 524.1742 [Amended]

48. Section 524.1742 *N-(Mercaptomethyl) phthalimide S-(O,O-dimethyl phosphorodithioate) emulsifiable liquid* is amended in paragraph (b) by removing ''011536 and 011716'' and adding in its place ''000061 and 011536''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.175 [Amended]

50. Section 558.175 *Clopidol* is amended in paragraph (c)(1)(iii)(*b*) and (c)(1)(iv)(*b*) by removing ''011716'' and adding in its place ''000061''.

§ 558.195 [Amended]

51. Section 558.195 *Decoquinate* is amended in the table in paragraph (d), under the ''Limitations'' column by removing ''011716'' wherever it appears and adding in its place ''000061''.

§ 558.254 [Amended]

52. Section 558.254 *Famphur* is amended in paragraph (a) by removing ''011716'' and adding in its place ''000061''.

§ 558.311 [Amended]

53. Section 558.311 *Lasalocid* is amended in the table in paragraph (e)(1)(ii), under the ''Limitations'' column, 5th paragraph, by removing ''011716'' and adding in its place ''000061''.

§ 558.515 [Amended]

54. Section 558.515 *Robenidine hydrochloride* is amended in paragraph (d)(1)(vi)(*b*) by removing ''011716'' and adding in its place ''000061''.

Dated: November 3, 1997.

Robert C. Livingston,

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

[FR Doc. 97–30337 Filed 11–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Orbifloxacin Tablets

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 Schering-Plough Animal Health. The supplemental NADA provides for veterinary prescription use of orbifloxacin tablets for management of diseases in cats associated with bacteria susceptible to orbifloxacin.

EFFECTIVE DATE: NOVEMBER 19, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph J. Bertone, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1692.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, is sponsor of NADA 141–081 Orbax™ (orbifloxacin) tablets that provide for veterinary prescription use in dogs for management of diseases associated with bacteria susceptible to orbifloxacin. The sponsor filed a supplemental NADA providing for veterinary prescription use of orbifloxacin tablets for management of diseases in cats associated with bacteria susceptible to orbifloxacin. The supplemental NADA is approved as of September 18, 1997, and the regulations are amended in 21 CFR 520.1616 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Furthermore, certain limitations, although required in the labeling, are not required in the regulation. Those limitations are removed from the regulation at this time.

Also, the sponsor's address has been changed. At this time, the address in the list of sponsors of approved applications in 21 CFR 510.600(c)(1) and (c)(2) is amended to reflect the new address.

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, 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning September 18, 1997, because the supplemental application contains substantial evidence of the effectiveness of the drug involved or studies of target animal safety required for approval and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to use of orbifloxacin tablets for cats.

FDA 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 510

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

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 parts 510 and 520 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.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) in the entry for

''Schering-Plough Animal Health'' and in paragraph (c)(2) in the entry for ''000061'' by removing the current address and adding in its place the address ''1095 Morris Ave., Union, NJ 07083''.

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.

§ 520.1616 [Amended]

2. Section 520.1616 *Orbifloxacin tablets* is amended in the heading of paragraph (d)(1) and in paragraph (d)(1)(iii) by adding after the word ''dogs'' the phrase ''and cats'', and in paragraph (d)(1)(iii) by removing the phrase ''2.5 milligrams per kilogram of body weight'' and the second, third, and fourth sentences.

Dated: October 22, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–30411 Filed 11–18–97; 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; Amprolium Plus Ethopabate With Bacitracin Zinc

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 Alpharma Inc. The ANADA provides for using approved amprolium plus ethopabate and bacitracin zinc Type A medicated articles to make Type C medicated feeds used for prevention of coccidiosis in broiler and replacement chickens and improved feed efficiency in broiler chickens.

EFFECTIVE DATE: November 19, 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 200–205 that provides for combining approved amprolium plus ethopabate and bacitracin zinc Type A medicated articles to make Type C medicated feeds for broilers containing amprolium 113.5 grams per ton (g/t) plus ethopabate 36.3 g/t and bacitracin zinc 4 to 50 g/t. The Type C medicated feed is used: (1) As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima*, and *E. brunetti* is likely to occur in broiler chickens and replacement chickens where immunity to coccidiosis is not desired, and for increased rate of weight gain in broiler chickens raised in floor pens; (2) as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima*, and *E. brunetti* is likely to occur; and (3) for improved feed efficiency in broiler chickens.

Alpharma Inc.'s ANADA 200–205 is approved as a generic copy of Hoffmann-LaRoche, Inc.'s NADA 114–794. The ANADA is approved as of September 19, 1997, and the regulations are amended in the table in 21 CFR 558.58(d)(1)(iii) 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.

The agency has determined under 21 CFR 25.33 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.

§ 558.58 [Amended]

2. Section 558.58 *Amprolium and ethopabate* is amended in paragraph (d)(1)(iii) in the table in the entry for ''Bacitracin 4 to 50'' in the columns ''Limitations'' and ''Sponsor''by removing ''000004'' and adding in its place ''000004 and 046573''.

Dated: October 30, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–30409 Filed 11–18–97; 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; 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 Hoffmann-La Roche, Inc. The supplemental NADA provides for changing the withdrawal time to zero following certain uses of chlortetracycline (CTC) in Type C cattle feeds (including free-choice feeds).

EFFECTIVE DATE: November 19, 1997.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199, filed supplemental NADA 48–761 that provides for decreasing the withdrawal times for all National Academy of Sciences/National Research Council drug efficacy study implementation (NAS/NRC DESI) approved uses of CTC Type C medicated feeds (including free-choice feeds) for beef and nonlactating dairy cattle and for control of anaplasmosis and other claims to a zero withdrawal time. The supplemental NADA is approved as of September 23, 1997, and the regulations are amended in § 558.128(d)(1) and (d)(2) (21 CFR 558.128(d)(1) and (d)(2)) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, in the revision of § 558.128 published in the **Federal Register** of