''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

July 9, 1996 (61 FR 35949), FDA provided for approval of five supplemental NADA's to reflect compliance with the results of the NAS/NRC DESI review of the products and FDA's conclusions based on that study. In that document, FDA failed to reflect that Hoffmann-La Roche is the sponsor of the product codified in § 558.128(d)(2) (see 53 FR 31316, August 18, 1988). The sponsor was the subject of a change of sponsor from American Cyanamid published in the **Federal Register** of April 24, 1996 (61 FR 18081). At this time, the paragraph is amended to reflect the correct sponsor.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of human food safety data and information submitted to support approval of this supplement 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.

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 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 entry (xi) in the column ''Limitations'' by adding after the existing text the sentence ''For sponsor 000004 zero withdrawal time.'', in entry (xii) for indication 1., in the column ''Limitations'' by adding after the phrase ''for sponsor 048573;'' the phrase ''zero withdrawal for sponsor 000004;'', in entry (xvii) for indication 1., in the column ''Limitations'' by adding after the existing text the sentence ''For sponsor 000004 zero withdrawal time.'', and in paragraph (d)(2) by adding after the number ''(2)'' the phrase ''For sponsor 000004:'' and removing the phrase ''discontinue use 4 days prior to slaughter''.

Dated: November 3, 1997.

Robert C. Livingston,

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

[FR Doc. 97–30405 Filed 11–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Office of Justice Programs

28 CFR Part 50

[OJP–1078]

RIN 1121–AA37

Young American Medals Program

AGENCY: Office of Justice Programs, Justice.

ACTION: Final rule.

SUMMARY: The United States Department of Justice, Office of Justice Programs (OJP), is publishing this final rule to implement the regulations for the Young American Medals Program as authorized by the Youth Medals Act. The final rule provides an outline of the program and criteria for the awarding of the Young American Medals for Bravery and Service.

DATES: This regulation is effective as of November 19, 1997.

FOR FURTHER INFORMATION CONTACT: Ellen Wesley at (202) 616–3558.

SUPPLEMENTARY INFORMATION: Congress authorized the Department of Justice to promulgate rules and regulations establishing medals under the Youth Medals Act, codified at 42 U.S.C, § 1921, *et seq.* The Act establishes two medals to be awarded under different criteria to persons eighteen years of age or younger at the time of the occurrence. The first, the Young American Medal for Bravery, 42 U.S.C. § 1921, is awarded to a person who has exhibited exceptional courage, extraordinary decisiveness, presence of mind, and unusual swiftness of action, regardless of his or her own personal safety. The second medal, the Young American Medal for Service, 42 U.S.C. § 1922, is awarded to a person who has displayed outstanding character and service.

The final rule sets forth eligibility criteria and application and presentation procedures for the medals. The Young American Medals Committee, part of the Office of the Attorney General, is authorized to issue regulations for the establishment of the two medals, and pursuant to that authority is issuing this final rule.

The interim rule with request for comments was published on September 19, 1996. No comments were received before November 18, 1996, the end of the comment period. Accordingly, the interim rule amending 28 CFR part 50 which was published at 61 FR 49259 on September 19, 1996, is adopted as a final rule without change.

Regulatory Flexibility Act

The Assistant Attorney General, Office of Justice Programs, in accordance with the Regulatory Flexibility Act (5 U.S.C. § 605(b)), has reviewed this final rule and, by approving it, certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The Assistant Attorney General, Office of Justice Program determined that the: (1) Final rule provides the outline of a program governing the award of medals to individuals for bravery or service; and (2) the award of such medals imposes no requirements on small businesses or on small entities.

Paperwork Reduction Act

No information requirements are contained in this final rule.

Executive Order 12866

This final rule has been reviewed in accordance with Executive Order 12866, § 1(b), Principles of Regulation. The Office of Justice Programs has determined that this Final Rule is not a ''significant regulatory action'' under Executive Order 12866 § 3(f), Regulatory Planning and Review, and accordingly this Final Rule has not been reviewed by OMB.

Executive Order 12612

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private section, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were