

CFR 520.1484(c)(3) and now for ANADA 200-113 in § 520.1485(d)(3).

No additional effectiveness or safety studies were required for this approval. Therefore, a freedom of information summary is not required. A summary of data and information submitted to support the original ANADA approval 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(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 520.1485 is amended by revising the last sentence of paragraph (d)(3) to read as follows:

§ 520.1485 Neomycin sulfate oral solution.

* * * * *

(d) * * *

(3) * * * Discontinue treatment prior to slaughter as follows: For sponsor 059130: 30 days for cattle and goats, and 20 days for swine and sheep; for sponsors 000009 and 050604: 1 day for cattle, 2 days for sheep, and 3 days for swine and goats.

Dated: October 10, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 97-29654 Filed 11-10-97; 8:45 am]

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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; Medicated Feed Applications; Lasalocid; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the correct assay limits for lasalocid in Type A medicated articles. Although a supplement to the new animal drug application (NADA) was approved, the regulations had not been previously amended to reflect that approval. At this time the regulations are amended to reflect the current assay limits in the approved NADA.

EFFECTIVE DATE: November 12, 1997.

FOR FURTHER INFORMATION CONTACT: Mary G. Leadbetter, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1662.

SUPPLEMENTARY INFORMATION: FDA is amending the regulation concerning use of animal drugs in medicated feeds in § 558.4(d) (21 CFR 558.4(d)) to reflect that the assay limit for lasalocid Type A medicated articles is 95 to 115 percent of the labeled amount. Although the original approval for NADA 96-298 Hoffmann-LaRoche, Inc., provided for a 10 percent overage (an assay limit of 100 to 120 percent), a supplemental approval dated August 25, 1992, revised that overage to 5 percent (95 to 115 percent). The regulation in § 558.4(d) is amended in the table entitled "Category I," in the entry for "Lasalocid," accordingly.

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.

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d), in the table entitled "Category I," in the entry for "Lasalocid," in the second column by removing "100-120" and adding in its place "95-115".

Dated: October 21, 1997.

Robert C. Livingston,

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; Amprolium Plus Ethopabate With 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 an abbreviated new animal drug application (ANADA) filed by Alpharma Inc. The ANADA provides for using approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used as an aid in the prevention of coccidiosis and improved feed efficiency or improved feed efficiency and improved pigmentation.

EFFECTIVE DATE: November 12, 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, filed ANADA 200-214 that provides for combining approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler feeds. The Type C medicated feed containing amprolium 113.5 grams per ton (g/t) plus ethopabate 36.3 g/t with bacitracin zinc 10 to 50 g/t and roxarsone 15.4 to 45.4 g/t is used 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 for improved feed efficiency. The Type C medicated feed containing amprolium 113.5 g/t plus ethopabate