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]

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; 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.

[FR Doc. 97–29649 Filed 11-10-97; 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 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

36.3 g/t with bacitracin zinc 10 g/t and roxarsone 30 to 45.4 g/t is used as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur, and for improved feed efficiency and improved pigmentation.

Alpharma Inc.'s ANADA 200–214 provides for combining approved AMPROL HI–E® (Merck Research Laboratories' amprolium and ethopabate NADA 13–461), 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 200–214 is approved as a generic copy of Hoffmann-LaRoche, Inc.'s NADA 105–758. The ANADA is approved as of November 12, 1997, and the regulations are amended 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 the table in paragraph (d)(1)(iii) in the entry for ''Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017% to 0.005%)'' under ''Limitations'' by removing ''No. 000004'' both times it appears and adding in their place ''Nos. 000004 and 046573'', and under ''Sponsor'' by removing ''000004'' and adding in its place ''000004, 046573''.

Dated: October 22, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–29653 Filed 11-10-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 946

[VA–106–FOR]

Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; correction.

SUMMARY: This document corrects and explains an OSM decision on a provision of a proposed amendment submitted by the State of Virginia as a modification to its permanent regulatory program (hereinafter referred to as the Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). OSM published its decision on the provision in a September 17, 1997, final rule **Federal Register** document. The provision concerns an exemption from the requirement to conduct mitigation measures to prevent or lessen the impact of subsidence damage, when planned subsidence mining methods are used, when the structure owners deny the permittee access to implement the measures to minimize material damage.

DATES: Effective: November 12, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Robert A. Penn, Director, Big Stone Gap Field Office, Office of Surface Mining Reclamation and Enforcement, 1941 Neeley Road, Suite 201, Compartment 116, Big Stone Gap, Virginia 24219, Telephone: (540) 523–4303.

SUPPLEMENTARY INFORMATION: By letter dated May 21, 1996 (Administrative Record No. VA–882), Virginia submitted amendments to the Virginia program concerning subsidence damage. The amendments are intended to make the Virginia program consistent with the Federal regulations as amended on March 31, 1995 (60 FR 16722). Virginia stated that the proposed amendments implement the standards of the Federal Energy Policy Act of 1992, and sections 45.1–243 and 45.1–258 of the Code of Virginia.

On September 17, 1997, OSM approved, with certain exceptions, the amendment submitted by Virginia (62 FR 48758). This document revises and explains one of OSM's decisions.

Subsidence Control

In the September 17, 1997, final rule, **Federal Register** document, OSM stated that it was approving, for longwall mining permittees, Virginia's proposed language at 480–03–19.817.121(a)(2)(iii) concerning an exemption from the requirement to conduct mitigation measures to minimize material damage from subsidence. The exemption would apply when the structure owners deny the permittee access to implement the measures to minimize material damage. (See Finding No. 5 of the September 17, 1997, final rule, 62 FR 48760.

In that finding, OSM excluded room and pillar retreat mining from qualifying for the proposed exemption. Upon further consideration of Virginia's proposed provision at 480–03–19.817.121(a)(2)(iii), OSM is changing is previous finding and decision. The rational for the revised decision is discussed below. The following finding replaces the preamble discussion for that part of Finding 5 that concerns amendments to subsection (a) of 480–03–19.817.121, in the final rule (62 FR 48758, second and third columns on page 48760).

5. § 480–03–13.817.121 Subsidence Control

Subsection (a) concerning measures to prevent or minimize damage is amended by adding new language (at new subsection (a)(2)) to provide that planned subsidence must include measures to minimize material damage to protected structures, except if the permittee has written consent of the structure owners, the costs of such measures exceed the anticipated costs of repair (unless the anticipated damage would constitute a threat to health or safety), or the structure owners deny the permittee access to implement the measures to minimize material damage and the permittee provides written evidence of good faith efforts to obtain access.

The proposed language is substantively identical to and no less effective than the counterpart Federal language at 30 CFR 817.121(a)(2) with one exception. 30 CFR 817.121(a)(2) contains no counterpart to the proposed language that provides an exception to the requirement to include measures to minimize material damage to protected