

# Rules and Regulations

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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 and Bacitracin Methylene Disalicylate

**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 new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved, single-ingredient amprolium and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds used for the development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency in replacement chickens.

**DATES:** This rule is effective April 19, 2001.

#### FOR FURTHER INFORMATION CONTACT:

Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-156 that provides for use of Amprol® (25 percent amprolium) and BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound bacitracin methylene disalicylate) Type A medicated articles to make combination Type C medicated feeds containing 36.3 to 113.5 grams per ton (g/ton) amprolium and 4 to 50 g/ton bacitracin methylene disalicylate for use in replacement chickens. The Type C medicated feeds are used for the development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency in replacement chickens. The NADA is approved as of February 12, 2001, and 21 CFR 558.55 is 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 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)(2) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### 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.

2. Section 558.55 is amended in the table in paragraph (d)(2) by alphabetically adding an item under entry (i) to read as follows:

#### § 558.55 Amprolium.

*	*	*	*	*
(d)	*	*	*	*
(2)	*	*	*	*

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).				
*	*	*	*	*
Bacitracin methylene disalicylate 4 to 50.	Replacement chickens; development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency.	Feed according to subtable in item (i); bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573	
*	*	*	*	*

\* \* \* \* \*

Dated: April 9, 2001.

**Stephen F. Sundlof,***Director, Center for Veterinary Medicine.*

[FR Doc. 01-9651 Filed 4-18-01; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF TRANSPORTATION****Coast Guard****33 CFR Part 117****[CGD07-01-027]****Drawbridge Operation Regulations;  
Brorein Street Bridge, across the  
Hillsborough River, Tampa, FL****AGENCY:** Coast Guard, DOT.**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Brorein Street Bridge across the Hillsborough River, mile 0.16, Tampa, Florida. This deviation allows the drawbridge to remain closed to navigation for five days. This temporary deviation is required to allow the bridge owner to safely complete repairs to the bridge.

**DATES:** This deviation is effective from April 30, 2001 to May 4, 2001.

**FOR FURTHER INFORMATION CONTACT:** Mr. Barry Dragon, Chief, Operations Section, Seventh Coast Guard District, Bridge Section at (305) 415-6743.

**SUPPLEMENTARY INFORMATION:** The Brorein Street Bridge across the Hillsborough River at Tampa, has a vertical clearance of 15 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 80 feet. On March 23, 2001, Acutec, Inc., acting as an agent for the drawbridge owner, requested a deviation from the current operating regulation in 33 CFR 117.291(a) which requires the drawbridge to open on signal if at least two hours notice is given. This temporary deviation was requested to

allow the bridge owner to safely disassemble the span lock system in a critical time sensitive manner.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR 117.291(a) for the purpose of repair completion of the drawbridge. Under this deviation, the Brorein Street Bridge need not open from 7 a.m. April 30, 2001 until 12 p.m. May 4, 2001.

Dated: April 4, 2001.

**Greg E. Shapley,***Chief, Bridge Administration, Seventh Coast Guard District.*

[FR Doc. 01-9711 Filed 4-18-01; 8:45 am]

BILLING CODE 4910-15-P

**ENVIRONMENTAL PROTECTION  
AGENCY****40 CFR Part 52****[CA 241-0274a; FRL-6954-8]****Revisions to the California State  
Implementation Plan, Bay Area Air  
Quality Management District and  
Imperial County Air Pollution Control  
District****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve revisions to the Bay Area Air Quality Management District and the Imperial County Air Pollution Control District portions of the California State Implementation Plan (SIP). These revisions concern the adoption of rules for volatile organic compound (VOC) source categories for the Bay Area Air Quality Management District (BAAQMD) and the Imperial County Air Pollution Control District (ICAPCD). We are approving these local rules under the Clean Air Act as amended in 1990 (CAA or the Act).

**DATES:** This rule is effective on June 18, 2001 without further notice, unless EPA receives adverse comments by May 21, 2001. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** to notify the public that this rule will not take effect.

**ADDRESSES:** Mail comments to Andy Steckel, Rulemaking Office Chief (AIR-4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

You can inspect copies of the submitted SIP revisions and EPA's technical support documents (TSDs) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revisions at the following locations:

Environmental Protection Agency, Air Docket (6102), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington DC 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95812

Bay Area Air Quality Management District, 939 Ellis Street, San Francisco, CA 94109

Imperial County Air Pollution Control District, 150 South Ninth Street, El Centro, CA 92243

**FOR FURTHER INFORMATION CONTACT:** Julie A. Rose, Rulemaking Office (AIR-4), U.S. Environmental Protection Agency, Region IX, (415) 744-1184.

**SUPPLEMENTARY INFORMATION:** Throughout this document, "we," "us" and "our" refer to EPA.

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**I. The State's Submittal****A. What Rules Did the State Submit?**

Table 1 lists the rules we are approving with the dates that they were adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1.—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
BAAQMD .....	8-40	Aeration of Contaminated Soil and Removal of Underground Storage Tanks .....	12-15-99	03-28-00
ICAPCD .....	426	Cutback Asphalt and Emulsified Paving Materials .....	09-14-99	05-26-00