

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

\* \* \* \* \*

2. A new center heading and new § 12.145 are added to read as follows:

**Steel Products**

**§ 12.145 Entry or admission of certain steel products.**

In any case in which a steel import license number is required to be obtained under regulations promulgated by the U.S. Department of Commerce, that license number must be included:

(a) On the entry summary, Customs Form 7501, or on an electronic equivalent, at the time of filing, in the case of merchandise entered, or withdrawn from warehouse for consumption, in the customs territory of the United States; or

(b) On Customs Form 214, at the time of filing under Part 146 of this chapter, in the case of merchandise admitted into a foreign trade zone.

**Robert C. Bonner,**

*Commissioner of Customs.*

Approved: February 25, 2003.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

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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; Laidlomycin and 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 new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for the use of approved, single-ingredient Type A medicated articles containing

laidlomycin and chlortetracycline to formulate two-way combination drug Type C medicated feeds for cattle fed in confinement for slaughter.

**DATES:** This rule is effective March 21, 2003.

**FOR FURTHER INFORMATION CONTACT:** Eric S. Dubbin, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: edubbin@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-201 for use of CATTLYST (laidlomycin propionate potassium) and AUREOMYCIN (chlortetracycline) Type A medicated articles to formulate two-way combination drug Type C medicated feeds for cattle fed in confinement for slaughter. The NADA is approved as of December 18, 2002, and the regulations are amended in 21 CFR 558.128 and 558.305 to reflect the approval and a current format. 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 21 CFR 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 558.128 *Chlortetracycline* is amended in paragraph (e)(6) by redesignating paragraphs (e)(6)(vii) through (e)(6)(xii) as paragraphs (e)(6)(viii) through (e)(6)(xiii); and by adding new paragraph (e)(6)(vii) to read as follows:

**§ 558.128 Chlortetracycline.**

\* \* \* \* \*

(e) \* \* \*

(6) \* \* \*

(vii) Laidlomycin in accordance with § 558.305.

\* \* \* \* \*

3. Section 558.305 is amended by:

- a. Revising the section heading;
- b. Redesignating paragraph (b) as paragraph (c);
- c. Adding new paragraphs (b) and (c)(3); and
- d. Revising paragraphs (a) and (d) to read as follows:

**§ 558.305 Laidlomycin.**

(a) *Specifications.* Type A medicated articles containing 50 grams laidlomycin propionate potassium per pound.

(b) *Approvals.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Special considerations.*

\* \* \* \* \*

(3) Labeling for all Type B feeds (liquid and dry) and Type C feeds containing laidlomycin shall bear the following statements:

(i) Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium.

(ii) The safety of laidlomycin propionate potassium in unapproved species has not been established.

(iii) Not for use in animals intended for breeding.

(d) *Conditions of use.* It is used in cattle being fed in confinement for slaughter as follows:

Laidlomycin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 5		For improved feed efficiency and increased rate of weight gain.	Feed continuously in a Type C feed at a rate of 30 to 75 mg/head/day.	046573

Laidlomycin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(2) 5	Chlortetracycline 10 mg/lb body weight	For improved feed efficiency and increased rate of weight gain; and for treatment of bacterial enteritis caused by <i>Echerichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	046573
(3) 5	Chlortetracycline 350 mg/head/day	For improved feed efficiency and increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	046573
(4) 5 to 10		For improved feed efficiency.	Feed continuously in a Type C feed at a rate of 30 to 150 milligrams/head/day.	046573
(5) 5 to 10	Chlortetracycline 10 mg/pound body weight	For improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline.	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	046573
(6) 5 to 10	Chlortetracycline 350 mg/head/day	For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	046573

Dated: February 25, 2003.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[CA 088-FON; FRL-7470-6]

#### Finding of Failure To Submit State Implementation Plan Revisions for Particulate Matter, California—San Joaquin Valley

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is taking final action to find that California failed to make a

Clean Air Act (CAA or Act) state implementation plan (SIP) submittal for particulate matter of ten microns or less (PM-10) required for the San Joaquin Valley PM-10 nonattainment area (the San Joaquin Valley or the Valley). Under the Act, for serious areas failing to attain the PM-10 National Ambient Air Quality Standards (NAAQS) by the required attainment date, states are required to submit within 12 months after the applicable attainment date, plan revisions which provide for attainment of the PM-10 NAAQS, and from the date of such submission until attainment, for an annual reduction of PM-10 or PM-10 precursor emissions within the area of not less than 5 percent of the amount of such emissions as reported in the most recent inventory prepared for the area (5% attainment plan). The San Joaquin Valley is a serious PM-10 nonattainment area that failed to meet its attainment date of

December 31, 2001. Thus, the 5% PM-10 attainment plan was due on December 31, 2002 but has not yet been submitted.

This action triggers the 18-month clock for mandatory application of sanctions and the 2-year clock for a federal implementation plan (FIP) under the Act. This action is consistent with the CAA mechanism for assuring SIP submissions.

**EFFECTIVE DATE:** This action is effective as of March 7, 2003.

**FOR FURTHER INFORMATION CONTACT:** Doris Lo, U. S. Environmental Protection Agency, Region 9, Air Division (AIR-2), 75 Hawthorne Street, San Francisco, CA 94105-3901, Telephone: (415) 972-3959; [lo.doris@epa.gov](mailto:lo.doris@epa.gov).

**SUPPLEMENTARY INFORMATION:**