DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 4-26-06
Publication Date 4-27-06
Certifier

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid and Chlortetracycline

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 approval of a new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for use of approved single-ingredient Type A medicated articles containing lasalocid and chlortetracycline to formulate two-way, combination drug Type B and Type C medicated feeds for pasture cattle and cattle fed in confinement for slaughter.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *eric.dubbin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, Fort Lee, NJ 07024, filed NADA 141–250 for use of BOVATEC (lasalocid sodium) and AUREOMYCIN (chlortetracycline) Type A medicated articles to formulate two-way, combination drug Type B and Type C medicated feeds for pasture cattle and cattle fed in confinement for slaughter. The NADA is approved as of March 31, 2006, and the regulations are amended in §§ 558.128 and 558.311 (21 CFR 558.128 and 558.311) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

cv063

2006-141-250

NFR 7

In addition, § 558.128 is amended to reflect an approved concentration for single-ingredient chlortetracycline Type C medicated cattle feed which, in error, was omitted from the final rule announcing its approval (67 FR 43248, June 27, 2002). Also, FDA has found that the April 1, 2005, edition of parts 500 to 599 of title 21 of the Code of Federal Regulations (CFR) does not accurately reflect several special considerations regarding use for lasalocid. These special considerations were inadvertently deleted as a publication error. At this time, the regulations are being amended in § 558.311 to correct this error. Furthermore, § 558.311 is amended to codify an approved label statement warning against the use of medicated feeds containing lasalocid in calves to be processed for veal. These actions are being taken to improve the accuracy of the regulations.

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 Division of Dockets Management (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. Amend § 558.128 as follows:

a. In the table in paragraph (e)(4), redesignate paragraphs (e)(4)(v) through (e)(4)(viii) as paragraphs (e)(4)(vi) through (e)(4)(ix);

b. In the table in paragraph (e)(4), add new paragraph (e)(4)(v) to read as follows;

c. Redesignate paragraphs (e)(6)(viii) through (e)(6)(xiii) as paragraphs (e)(6)(ix) through (e)(6)(xiv); and

d. Add new paragraph (e)(6)(viii).

The additions read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Indications for use	Limitations	Sponsor
* * * * * * *			
(v) 500 to 4,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Hand feed continuously for not more than 5 days to provide 10 mg/lb body weight per day.	046573.
* * * * * * *			

* * * * *

(6) * * *

(viii) Lasalocid in accordance with § 558.311.

* * * * *

■ 3. In § 558.311, add paragraphs (d)(5), (d)(6), and (d)(7); and in the table in paragraph (e)(1) add paragraphs (xx) through (xxiii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(d) * * *

(5) Required label statements:

(i) For liquid Type B feed (cattle and sheep): Mix thoroughly with grain and/or roughage prior to feeding. Feeding undiluted, mixing errors, or inadequate mixing (recirculation or agitation) may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(ii) For Type A articles or Type B feeds (cattle and sheep): Feeding undiluted or mixing errors may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(iii) For Type A articles, Type B or Type C feeds (cattle): A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(6) Lasalocid Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle and sheep feed only.

(7) Each use in a free-choice Type C cattle feed as in paragraphs (e)(1)(xii) and (e)(1)(xviii) of this section must be the subject of an approved NADA or supplemental NADA as provided in § 510.455 of this chapter.

(e)(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xx) 10 to 30.	Chlortetracycline 25 to 100.	1. Cattle fed in confinement for slaughter: For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
		2. Cattle under 700 pounds fed in confinement for slaughter: For improved feed efficiency; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
(xxi) 10 to 30.	Chlortetracycline 500 to 2000.	Cattle fed in confinement for slaughter: For improved feed efficiency; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
(xxii) 25 to 30.	Chlortetracycline 25 to 42.2.	1. Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
		2. Cattle under 700 pounds fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
(xxiii) 25 to 30.	Chlortetracycline 500 to 1200.	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
(xxiv) 30 to 181.8.	Chlortetracycline 25 to 2800.	1. Beef cattle under 700 pounds: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Hand feed continuously at a rate of 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day.	046573
		2. Beef cattle up to 800 pounds: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Hand feed continuously at a rate of 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day.	046573
(xxv) 30 to 181.8.	Chlortetracycline 500 to 4000.	Cattle up to 800 pounds: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day.	046573
(xxvi) 30 to 600.	Chlortetracycline 25 to 700.	1. Pasture cattle (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Hand feed continuously at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	046573

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		2. Pasture cattle under 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Hand feed continuously at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	046573
(xxvii) 30 to 600.	Chlortetracycline 25 to 1100.	Pasture cattle over 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): For increased rate of weight gain; and for control of control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.	Hand feed continuously at a rate of 0.5 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	046573
(xxiii) 30 to 600.	Chlortetracycline 500 to 4000.	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline.	Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	046573

* * * * * * *

* * * * *

Dated: 4/17/06
April 17, 2006.

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

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

BILLING CODE 4160–01–S