

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 Schering-Plough Animal Health Corp. The NADA provides for use of a subcutaneous ear implant containing zeranol in pasture cattle for increased rate of weight gain. FDA is also amending the regulations to add the acceptable daily intake (ADI) for total residues of zeranol.

DATES: This rule is effective February 14, 2002.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: dbenz@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, filed NADA 141-192 for RALGRO LA (zeranol), a subcutaneous ear implant containing 138 milligrams (mg) zeranol. The implants are used for increased rate of weight gain for up to 210 days in pasture cattle (slaughter, stocker, and feeder steers, and heifers). The application is approved as of November 1, 2001, and the regulations are amended in § 522.2680 (21 CFR 522.2680) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 522.2680 is also being amended to reflect a current format for regulations pertaining to cattle ear implants. This action is being taken to improve the clarity and readability of the regulations. In addition, the regulations are amended in 21 CFR 556.760 by adding the previously established ADI for total residues of zeranol, and editorially, to reflect current format.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning November 1,

2001, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.2680 is amended by revising paragraphs (a), (d)(1)(i), (d)(2)(i), (d)(3)(i), and (d)(3)(ii), and by adding paragraph (d)(4) to read as follows:

§ 522.2680 Zeranol.

(a) *Specifications.* Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

* * * * *

(d) *Conditions of use*—(1) *Beef cattle*—(i) *Amount.* 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.

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(2) *Feedlot lambs*—(i) *Amount.* 12 mg zeranol (one implant consisting of 1

pellet containing 12 mg zeranol) per implant dose.

* * * * *

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

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(4) *Pasture cattle (slaughter, stocker, feeder steers, and heifers)*—(i) *Amount.* 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.760 is amended by redesignating paragraphs (a) and (b) as paragraphs (b)(1), and (b)(2), respectively, by revising newly redesignated paragraph (b)(1), and by adding paragraph (a) to read as follows:

§ 556.760 Zeranol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of zeranol is 0.00125 milligrams per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle.* Tolerances for residues of zeranol in edible tissues are not needed.

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Dated: February 1, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02-3681 Filed 2-13-02; 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; Bacitracin Methylene Disalicylate and Zoalene

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 supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provides for using approved single-ingredient bacitracin methylene disalicylate and zoalene Type A medicated articles to make two-way combination drug Type C medicated feeds used for the management of necrotic enteritis and coccidiosis in replacement and broiler chickens.

DATES: This rule is effective February 14, 2002.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7580, e-mail: svaughn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 141-085 that provides for combining approved BMD (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate) and ZOAMIX (113.5 g/lb zoalene) Type A medicated articles to make two-way combination drug Type C medicated chicken feeds containing 50 or 100 to 200 g/ton bacitracin methylene disalicylate and 36.3 to 113.5 or 113.5 g/ton zoalene. The combination Type C feeds containing 50 g/ton bacitracin methylene disalicylate and 36.3 to 113.5 g/ton zoalene are used as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the development of active immunity to coccidiosis in replacement chickens. The combination Type C feeds containing 100 to 200 g/ton bacitracin methylene disalicylate and 36.3 to 113.5 g/ton zoalene are used as an aid in the control of necrotic

enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the development of active immunity to coccidiosis in replacement chickens. The combination Type C feeds containing 50 g/ton bacitracin methylene disalicylate and 113.5 g/ton zoalene are used as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the prevention and control of coccidiosis in broiler chickens. The combination Type C feeds containing 100 to 200 g/ton bacitracin methylene disalicylate and 113.5 g/ton zoalene are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin and for the prevention and control of coccidiosis in broiler chickens. The supplemental NADA is approved as of November 30, 2001, and the regulations are amended in 21 CFR 558.680 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.

FDA 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 558.680 is amended by redesignating paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d), respectively; by adding new paragraph (a); by revising newly redesignated paragraph (b); and in the table in paragraph (d)(1) by adding in item (i) after the entry for "Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50" the entries for "Bacitracin methylene disalicylate 50" and "Bacitracin methylene disalicylate 100 to 200", and by adding in item (ii) after the entry for "Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%)" the entries for "Bacitracin methylene disalicylate 50" and "Bacitracin methylene disalicylate 100 to 200" to read as follows:

§ 558.680 Zoalene.

(a) *Specifications.* Type A medicated article containing 25 percent zoalene.

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

* * * * *

(d) * * *

(1) * * *

| Zoalene in grams/ton | Combination in grams/ton | Indications for use | Limitations |
|--------------------------------|--------------------------------------|---|--|
| * * * | * * * | * * * | * * * |
| (i) 36.3-113.5 (0.004-0.0125%) | Bacitracin methylene disalicylate 50 | Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | Feed continuously as sole ration as in subtable in this item (i); grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter. |

| Zoalene in grams/ton | Combination in grams/ton | Indications for use | Limitations |
|----------------------|--|--|--|
| | Bacitracin methylene disalicylate 100 to 200 | Replacement chickens; development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | Feed continuously as sole ration as in subtable in this item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter. |
| (ii) 113.5 (0.0125%) | Bacitracin methylene disalicylate 50 | Broiler chickens; prevention and control of coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter. |
| | Bacitracin methylene disalicylate 100 to 200 | Broiler chickens; prevention and control of coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter. |

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Dated: February 1, 2002.
Claire M. Lathers,
 Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

33 CFR Part 402

[Docket No. SLSDC 2002-11529]

RIN 2135-AA14

Tariff of Tolls

AGENCY: Saint Lawrence Seaway Development Corporation, DOT.

ACTION: Final rule.

SUMMARY: The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Tariff of Tolls in their respective jurisdictions. The Tariff sets forth the level of tolls assessed on all commodities and vessels transiting the

facilities operated by the SLSDC and the SLSMC. The SLSDC is revising its regulations to reflect the fees and charges charged by the SLSMC in Canada starting in the 2002 navigation season, which are effective only in Canada.

DATES: This rule is effective on March 18, 2002.

FOR FURTHER INFORMATION CONTACT: Marc C. Owen, Chief Counsel, Saint Lawrence Seaway Development Corporation, 400 Seventh Street, SW, Washington, DC 20590, (202) 366-6823.

SUPPLEMENTARY INFORMATION: The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Tariff of Tolls in their respective jurisdictions. (The Tariff is called the Schedule of Fees and Charges in Canada.) The amendments are described in the following summary.

The Tariff sets forth the level of tolls assessed on all commodities and vessels transiting the facilities operated by the SLSDC and the SLSMC. The SLSDC is revising § 402.8, "Schedule of tolls", to reflect the fees and charges charged by the SLSMC in Canada starting in the 2002 navigation season. The changes

affect the tolls for commercial vessels and are applicable only in Canada as the collection of the U.S. portion of tolls for commercial vessels is waived by law (33 U.S.C. 988a(a)).

Regulatory Evaluation

This regulation involves a foreign affairs function of the United States and therefore Executive Order 12866 does not apply. This regulation has also been evaluated under the Department of Transportation's Regulatory Policies and Procedures and the regulation is not considered significant under those procedures and its economic impact is expected to be so minimal that a full economic evaluation is not warranted.

Regulatory Flexibility Act Determination

The Saint Lawrence Seaway Development Corporation certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The St. Lawrence Seaway Tariff of Tolls primarily relates to commercial users of the Seaway, the vast majority of whom are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels.