Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	* *	* *	*	*
(xii)	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day.	046573
*	* *	* *	*	*
(xviii) 1440	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	021930 017800

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Dated: November 8, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–30783 Filed 12–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Salinomycin and Tylosin Phosphate

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 Elanco Animal Health. The NADA provides for use of approved, single-ingredient salinomycin and tylosin phosphate Type A medicated articles to make two-way combination Type C medicated feeds used as an aid in the prevention of coccidiosis, and for increased rate of weight gain and improved feed efficiency in broiler chickens.

DATES: This rule is effective December 5, 2002.

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, e-mail: *candres@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–198 that provides for use of BIO–COX (30 or 60 grams per pound (g/lb) salinomycin activity) and TYLAN (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make two-way combination Type C medicated broiler chicken feeds. The combination Type C medicated feeds contain 40 to 60 g/ton salinomycin and 4 to 50 g/ton tylosin phosphate and are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of September 4, 2002, and the regulations in 21 CFR 558.550 and 558.625 are being 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 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 558.550 is amended by adding paragraph (d)(1)(xxii) to read as follows:

§ 558.550 Salinomycin.

* * * * *

(d) * * *

(1) * * *

(xxii) *Amount per ton.* Salinomycin, 40 to 60 grams; plus tylosin, 4 to 50 grams.

(A) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin as provided by 046573; tylosin phosphate as provided by 000986 in § 510.600(c) of this chapter.

* * * * *

3. Section 558.625 is amended by adding paragraph (f)(2)(viii) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(2) * * *

(viii) Salinomycin as in § 558.550.

Dated: November 21, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–30784 Filed 12–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Decoquinate

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 the use of decoquinate Type A medicated articles to make Type C medicated feeds for cattle, sheep, and goats at a broader range of concentrations for the prevention of coccidiosis.

DATES: This rule is effective December 5, 2002.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 39–417 that provides for use of DECCOX (decoquinate) Type A medicated articles to make Type C medicated feeds for cattle, sheep, and goats at a broader range of concentrations for the prevention of coccidiosis caused by various *Eimeria* species. The NADA is approved as of September 4, 2002, and the regulations are amended in 21 CFR 558.195 to reflect the approval. Section 558.195 is also revised to reflect a current format.

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)(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.

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 558.195 is revised to read as follows:

§ 558.195 Decoquinate.

(a) *Specifications.* Type A medicated article containing 6 percent decoquinate.

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

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Special considerations.* (1) Bentonite should not be used in decoquinate feeds.

(2) Type A medicated articles may be used to manufacture dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraphs (e)(2) and (e)(3) of this section.

(3) Type C cattle feeds may be manufactured from decoquinate liquid Type B feeds having a pH between 5.0 to 6.5 and containing a suspending agent to maintain a viscosity of not less than 500 centipoises.

(e) *Conditions of use.* It is used as follows:

(1)*Chickens.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2		Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*,*E. acervulina*, *E. maxima*, and *E. brunetti*.	Do not feed to laying chickens.	046573
(ii) 27.2	Bacitracin methylene disalicylate 4 to 50	Broiler chickens: As in paragraph (e)(1)(i) of this section; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.	046573
(iii) 27.2	Bacitracin zinc 10 to 50	Broiler chickens: As in paragraph (e)(1)(ii) of this section.	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter.	046573
(iv) 27.2	Bacitracin zinc 12 to 50 plus roxarsone 11 to 45	Broiler chickens: As in paragraph (e)(1)(ii) of this section.	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic. Bacitracin zinc and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.	046573