DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Bacitracin Methylene Disalicylate Soluble

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 soluble bacitracin methylene disalicylate (BMD) powder to make a medicated drinking water for replacement chickens as an aid in the prevention and control of necrotic enteritis.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., Fort Lee, NJ 07024, filed supplemental NADA 65–470 that provides for use of BMD® Soluble (BMD soluble powder) to make a medicated drinking water for replacement chickens. Medicated drinking water containing the equivalent of 100 milligrams (mg) of bacitracin per gallon is used as an aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to BMD. Medicated drinking water containing the equivalent of 200 to 400 mg of bacitracin per gallon is used as an aid in the control of necrotic enteritis caused by *C. perfringens* susceptible to BMD. The supplemental NADA is approved as of February 2, 1999, and the regulations in § 520.154a (21 CFR 520.154a) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the specifications paragraph is revised to reflect that the 200 grams per pound concentration has been previously approved for use in all species as in § 520.154a(d).

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)(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.

List of Subjects in 21 CFR Part 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.154a [Amended]

2. Section 520.154a *Soluble bacitracin methylene disalicylate* is amended in paragraph (a) by removing the phrase ''paragraphs (d)(3) and (d)(4)'' and by adding in its place the phrase ''paragraph (d)'', and in paragraph (d)(2) by removing the heading ''Broiler chickens'' and by adding in its place ''Broiler and replacement chickens''.

Dated: February 26, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–6458 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Lasalocid

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 Roche Vitamins, Inc. The supplemental NADA provides for use of a lower concentration lasalocid Type A medicated article to make a Type C rabbit feed used for prevention of coccidiosis and to provide for a tolerance for drug residues in rabbits.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298, filed supplemental NADA 96–298 that provides for use of Bovatec® (15 percent lasalocid) in addition to previously approved use of Avatec® (20 percent lasalocid) Type A medicated articles to make 113 grams per ton lasalocid Type C rabbit feeds used for prevention of coccidiosis caused by *Eimeria stiedae*. The supplemental NADA is approved as of February 5, 1999, and the regulations are amended in 21 CFR 558.311(b)(4) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

At this time, the human food safety data originally submitted in public master file 5042 for use of lasalocid in rabbits was reevaluated and a tolerance for drug residues in edible rabbit tissues is established in 21 CFR 556.347. Also, that section is revised 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 supplemental 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.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

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 parts 556 and 558 are amended as follows:

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

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

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

2. Section 556.347 is revised to read as follows:

§ 556.347 Lasalocid.

(a) [Reserved]

(b) *Tolerances*—(1) *Chickens*. A tolerance is established for lasalocid residues of 0.3 part per million (ppm) parent lasalocid (marker residue) in skin with adhering fat (target tissue).

(2) *Cattle*. A tolerance is established for lasalocid residues of 0.7 ppm parent lasalocid (marker residue) in liver (target tissue).

(3) *Sheep*. A tolerance for residues of lasalocid is not needed.

(4) *Rabbits*. A tolerance is established for lasalocid residues of 0.7 ppm parent lasalocid (marker residue) in liver (target tissue).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

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

4. Section 558.311 is amended by revising paragraph (b)(4) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(4) 15 percent activity to No. 063238 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2) and (e)(3) of this section.

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Dated: February 23, 1999.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–6461 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Monensin and Virginiamycin

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, a Division of Eli Lilly and Co. The NADA provides for combining approved monensin and virginiamycin Type A medicated articles to make combination drug Type C medicated growing turkey feeds used for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: March 17, 1999.

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: Elanco Animal Health, a Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–110 that provides for combining approved monensin and virginiamycin Type A medicated articles to make combination drug Type C medicated growing turkey feeds containing 54 to 90 grams per ton (g/t) monensin and 10 to 20 g/t virginiamycin. The Type C medicated growing turkey feed is used for the prevention of coccidiosis caused by *Eimeria meleagrimitis*, *E. adenoeides*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of January 29, 1999, and the regulations are amended in 21 CFR 558.355 to reflect the approval.

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.

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 558.355 is amended by adding paragraph (f)(2)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(iv) *Amount per ton*. Monensin, 54 to 90 grams, with virginiamycin, 10 to 20 grams.

(a) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations*. For growing turkeys only. Feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses, mature turkeys, and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Virginiamycin as provided by No. 000069 in § 510.600(c) of this chapter.

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Dated: February 26, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–6460 Filed 3–16–99; 8:45 am]

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