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)(1)(xxviii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

(xxviii) *Amount per ton.* Monensin, 90 to 110 grams, plus tylosin phosphate, 4 to 50 grams.

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

(*b*) *Limitations.* Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. As monensin sodium and tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter.

* * * * *

§ 558.625 [Amended]

3. Section 558.625 *Tylosin* is amended in paragraph (a) by removing ''rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857,'' and by adding in its place ''5630 Fishers Lane, rm. 1061, Rockville, MD 20852,'' and by redesignating paragraph (f)(2)(v)(*e*) as paragraph (f)(1)(vi)(*e*).

Dated: August 23, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–22572 Filed 9–1–00; 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 Bambermycins

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 monensin and bambermycins Type A medicated articles to make two-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in growing turkeys.

DATES: This rule is effective September 5, 2000.

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 & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140–955 that provides for use of Coban® (45 or 60 grams per pound (g/lb) of monensin as monensin sodium) and Flavomycin® (2, 4, or 10 g/lb of bambermycins activity) Type A medicated articles to make combination Type C medicated feeds. The combination Type C medicated feeds containing 54 to 90 g/ton monensin and 1 to 2 g/ton bambermycins and are used for prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*; and for improved feed efficiency in growing turkeys. The combination Type C medicated feeds containing 54 to 90 g/ton monensin and 2 g/ton bambermycins and are used for prevention of coccidiosis caused by *E. adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*; and for increased rate of weight gain and improved feed efficiency in growing turkeys. The NADA is approved as of June 28, 2000, and the regulations in 21 CFR 558.95 and 558.355 are amended 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.

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 558.95 is amended by redesignating paragraphs (d)(5)(iii) and (d)(5)(iv) as (d)(5)(iv) and (d)(5)(v), and by adding new paragraph (d)(5)(iii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(5) * * *

(iii) Monensin as in § 558.355.

* * * * *

3. Section 558.355 is amended by adding paragraphs (f)(2)(v) and (f)(2)(vi) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(v) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 1 to 2 grams.

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

(*b*) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 012799 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 2 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. 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. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 012799 in § 510.600(c) of this chapter.

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Dated: August 23, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–22570 Filed 9–1–00; 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; Monensin, Bacitracin Methylene Disalicylate, and Roxarsone

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 use of approved, single-ingredient monensin, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make three-way combination drug Type C medicated feed used as an aid in the prevention of coccidiosis, as an aid in the prevention and control of necrotic enteritis, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

DATES: This rule is effective September 5, 2000.

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: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–138 that provides for use of Coban® (45 or 60 grams per pound (g/lb) of monensin as monensin sodium), BMD (10, 25, 30, 40, 50, 60, or 75 g/lb BMD), and 3–Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make combination Type C medicated feeds for replacement chickens intended for use as caged layers. The Type C medicated feeds contain 90 to 110 g/ton monensin, 50 or 100 to 200 g/ton BMD, and 22.7 to 45.4 g/ton roxarsone and are used as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the prevention (at 50 g/ton BMD) or control (at 100 to 200 g/ton BMD) of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of June 28, 2000, and 21 CFR 558.355 is amended to reflect the approval. The basis for 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.

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 558.355 is amended by redesignating paragraphs (f)(4)(ii) and (f)(4)(iii) as paragraphs (f)(4)(i)(*a*) and (f)(4)(i)(*b*), and by adding new paragraphs (f)(4)(ii) and (f)(4)(iii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(4) * * *

(ii) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 50 grams; plus roxarsone, 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 100 to 200 grams; plus roxarsone, 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* 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). Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as