DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate Oral Solution

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 an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for the oral use of neomycin sulfate solution for the treatment and control of colibacillosis in cattle, swine, sheep, and goats.

DATES: This rule is effective September 5, 2000.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–289 that provides for the oral use of neomycin sulfate solution for the treatment and control of colibacillosis in cattle, swine, sheep, and goats. Med-Pharmex's ANADA 200–289 NEORAL® (neomycin sulfate) Oral Solution is approved as a generic copy of Pharmacia & Upjohn's NADA 011–315 NEOMIX® 325 Soluble Powder. The application is approved as of July 3, 2000, and the regulations in 21 CFR 520.1485 are 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 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 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.

§ 520.1485 [Amended]

2. Section 520.1485 *Neomycin sulfate oral solution* is amended in paragraph (b) by adding in numerical order after ''000009,'' the entry ''051259,''.

Dated: August 23, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–22571 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 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 monensin 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, for increased rate of weight gain, and improved feed efficiency in broiler chickens. Technical corrections are also being made.

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 141–164 that provides for use of Coban® (44, 45, or 60 grams per pound (g/lb) of monensin activity as monensin sodium) and Tylan® (10 g/lb of tylosin phosphate) Type A medicated articles to make combination Type C medicated broiler chicken feeds. The combination Type C medicated feeds contain 90 to 110 g/ton monensin and 4 to 50 g/ton tylosin phosphate and are used as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, for increased rate of weight gain, and improved feed efficiency in broiler chickens. The NADA is approved as of July 3, 2000, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, 21 CFR 558.625 is being revised by updating the address for Dockets Management Branch in paragraph (a) and by moving paragraph (f)(1)(vi)(*e*) to precede paragraph (f)(2), correcting a sequence error in the format of this paragraph.

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 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.

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§ 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.

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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