after the first month for which disability or blindness benefits are suspended because of such VR refusal.

§ 416.2217 [Amended]

13. Section 416.2217 is amended in the introductory text of the section by adding ''and (e)'' after ''section 1615(d).''

[FR Doc. 96–15407 Filed 6–18–96; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate Soluble Powder

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 Wade Jones Co., Inc. The ANADA provides for the use of a generic neomycin sulfate soluble powder in drinking water and milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis.

EFFECTIVE DATE: June 19, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Wade Jones Co., Inc., Hwy. 71 North, Lowell, AK 72745, filed ANADA 200–130, which provides for the use of neomycin sulfate soluble powder in drinking water and milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate. ANADA 200–130 is approved as a generic copy of the Upjohn Co.'s NADA 11–315. The ANADA is approved as of May 8, 1996, and the regulations are amended in 21 CFR 520.1484(b) and (c)(3) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1484 is amended by revising paragraph (b) and the last sentence of paragraph (c)(3) to read as follows:

§ 520.1484 Neomycin sulfate soluble powder.

* * * * *

(b) *Sponsors.* See Nos. 000009, 000069, 047864, 050604, and 059130 in § 510.600(c) of this chapter.

(c) * * *

(3) * * * Discontinue treatment prior to slaughter as follows: For sponsors 000009, 000069, 047864, and 050604—cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.

Dated: June 10, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–15466 Filed 6–18–96; 8:45 am]
BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 Pennfield Oil Co. The ANADA provides for the use of a generic oxytetracycline injection for beef cattle, non-lactating dairy cattle, and swine.

EFFECTIVE DATE: June 19, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed ANADA 200–154, which provides for use of 200 milligram per milliliter (mg/mL) oxytetracycline injection for intramuscular and intravenous use in beef cattle and non-lactating dairy cattle and intramuscular use in swine for control or treatment of diseases caused by oxytetracycline susceptible diseases. The drug is used in beef cattle and non-lactating dairy cattle for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresi*; leptospirosis caused by *Leptospira pomona*; and wound infections and metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. The drug is used in swine for the treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*; pneumonia caused by *P. multocida*; and leptospirosis caused by *L. pomona*; and in sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

ANADA 200–154 for Pennfield Oil Co.'s oxytetracycline injection is approved as a generic copy of Pfizer's NADA 113–232 Liquamycin® LA–200 (oxytetracycline) Injection. The ANADA is approved as of May 8, 1996, and the regulations are amended in 21 CFR 522.1660 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, 12420 Parklawn Dr.,

rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(l)(i) 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 522

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 522 is 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraphs (b) and (c)(2)(iii) by adding ''053389,'' after ''000069,''.

Dated: June 10, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–15465 Filed 6–18–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Spectinomycin Injection

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 The Upjohn Co. The ANADA provides for subcutaneous use of a generic spectinomycin sterile solution in turkey poults and newly-hatched chicks as an aid in the control of bacterial respiratory infections, airsacculitis, and mortality. The regulations are also amended to add a tolerance for spectinomycin residues in turkey tissues.

EFFECTIVE DATE: June 19, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Agricultural Division, Kalamazoo, MI 49001–0199, is the sponsor of ANADA 200–127 which provides for the use of a generic spectinomycin dihydrochloride pentahydrate sterile solution (500 milliliter (mL) vial; 100 milligrams of spectinomycin activity per mL). The generic drug product is administered subcutaneously to 1- to 3-day-old turkey poults as an aid in the control of chronic respiratory disease (CRD) and airsacculitis and 1- to 3-day-old chicks as an aid in the control of mortality and to lessen the severity of respiratory infections, caused by certain microbial species sensitive to spectinomycin.

Approval of ANADA 200–127 for The Upjohn Co.'s spectinomycin dihydrochloride pentahydrate sterile solution is as a generic copy of Rhone Merieux's (formerly Sanofi Animal Health) NADA 040–040 for Spectam® Injectable. The ANADA is approved as of May 9, 1996, and the regulations are amended in 21 CFR 522.2120 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Spectinomycin was originally approved based on the negligible tolerance concept. A negligible tolerance has been applied to animal drug residues when the supporting toxicological data are of subchronic (90-day) duration. The ''negligible tolerance'' concept is based on two precepts: (1) The residue present is at a level of insignificance and (2) the safety of the residue is supported by limited toxicological data. The upper level for a drug residue to qualify for ''negligible tolerance'' is considered customarily to be 0.1 part per million (ppm) residue in tissue. Therefore, the tolerance for spectinomycin residues in edible tissues is the same for all species in which the drug is approved. Accordingly, 21 CFR 556.600 is amended to apply the tolerance of 0.1 ppm to edible turkey tissues.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 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 to read 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2120 is amended by revising paragraph (b) and by amending paragraph (d)(4) by removing ''M. mileagridis'' and adding in its place ''M. meleagridis'' to read as follows:

§ 522.2120 Spectinomycin injection.

* * * * *

(b) *Sponsor.* In § 510.600 of this chapter, see Nos. 000033 and 050604 for conditions of use as in paragraph (d) of this section, and see No. 000009 for conditions of use as in paragraph (d)(2) and (d)(4) of this section.

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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: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. Section 556.600 is revised to read as follows:

§ 556.600 Spectinomycin.

A tolerance of 0.1 part per million is established for negligible residues of spectinomycin in the uncooked edible tissues of chickens and turkeys.

Dated: June 10, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–15567 Filed 6–18–96; 8:45 am]

BILLING CODE 4160–01–F