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]
BILLING CODE 4190–29–P

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.,