available for public disclosure before making the documents available for inspection.

II. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum entitled ''FOAM ADD 10—A terminal no-rinse sanitizer—Manufactured by Rio Linda Chemical Corp.,'' dated June 10, 1994.

IV. Filing of Objections

Any person who will be adversely affected by this regulation may at any time on or before July 22, 1996 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.1010 is amended by adding new paragraphs (b)(46) and (c)(40) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(46) An aqueous solution of chlorine dioxide and related oxychloro species generated by acidification of an aqueous solution of sodium chlorite with a solution of sodium gluconate, citric acid, phosphoric acid, and sodium mono- and didodecylphenoxybenzenedisulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

* * * * *

(c) * * *

(40) The solution identified in paragraph (b)(46) of this section shall provide, when ready for use, at least 100 parts per million and not more than 200 parts per million of chlorine dioxide as determined by the method developed by Bio-cide International, Inc., entitled, ''Iodometric Method for the Determination of Available Chlorine Dioxide (50–250 ppm Available ClO_2),'' dated June 11, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this method are available from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC; at least 380 parts per million and not more than 760 parts per million of sodium gluconate; and at least 960 parts per million and not more than 1,920 parts per million of sodium mono- and didodecylphenoxybenzenedisulfonate. Other components listed under paragraph (b)(46) of this section shall be used in the minimum amount necessary to produce the intended effect.

* * * * *

Dated: June 7, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–15726 Filed 6–19–96; 8:45 am]

BILLING CODE 4160–01–F

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 Rhone Merieux, Inc. The ANADA provides for the use of a generic neomycin sulfate oral solution in drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis.

EFFECTIVE DATE: June 20, 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: Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210, filed ANADA 200–153, which provides for the use of neomycin sulfate oral solution in drinking water or in milk of cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial scours) caused by *Escherichia coli* susceptible to neomycin. ANADA 200–153 is approved as a generic copy of The Upjohn Co.'s NADA 11–035. The ANADA is approved as of May 8, 1996, and the regulations are amended in 21 CFR 520.1485(b) and (d)(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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 520.1485 is amended by revising paragraph (b) and the last sentence of paragraph (d)(3) to read as follows:

§ 520.1485 Neomycin sulfate oral solution.

* * * * *

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

* * * * *

(d) * * *

(3) * * * Discontinue treatment prior to slaughter as follows: For sponsors 000009 and 059130: 30 days for cattle and goats, and 20 days for swine and sheep; for sponsor 050604: 1 day for cattle (not for use in veal calves), 2 days for sheep, and 3 days for swine and goats.

Dated: June 10, 1996.

Shephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–15566 Filed 6–19–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 520 and 556

Animal Drugs, Feeds, and Related Products; 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 a supplemental new animal drug application (NADA) filed by The Upjohn Co. and two supplemental abbreviated new animal drug applications (ANADA's), one filed by Pfizer, Inc., and the other filed by Rhone Merieux, Inc. The applications provide for use of neomycin sulfate soluble powder in drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis. The supplements provide for revised preslaughter withdrawal times following use of the drug and revised tolerances for neomycin residues in edible tissues of treated animals.

EFFECTIVE DATE: June 20, 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, filed supplemental NADA 11–315; Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental ANADA 200–046; Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210, filed supplemental ANADA 200–050. The supplements provide for revised withdrawal times for use of neomycin sulfate soluble powder in drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial scours) caused by *Escherichia coli* susceptible to neomycin sulfate. The supplements are approved as of April 3, 1996, and § 520.1484(c)(3) (21 CFR 520.1484(c)(3)) is amended to reflect the approvals. The basis for approval is discussed in the freedom of information summary as indicated below. Also, the firms sponsored studies which provided data to support revised tolerances for residues of neomycin in the edible tissues of cattle, swine, sheep, and goats. Based on evaluation of the data as provided in the General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals Guidelines, tolerances of 1.2 parts per million (ppm) in muscle, 3.6 ppm in liver, and 7.2 ppm in kidney and fat, and withdrawal times of 1 day for cattle, 2 days for sheep, and 3 days for swine and goats, are established. The revised withdrawal times are provided in § 520.1484(c)(3). The revised tolerances for neomycin residues are established in amended 21 CFR 556.430.

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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals do not qualify for marketing exclusivity because the applications do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or new human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicants.

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 520

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 520 and 556 are 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 in paragraph (c)(3) by revising the last sentence to read as follows: