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:

§ 520.1484 Neomycin sulfate soluble powder.

* * * * *

(c) * * *

(3) * * * Discontinue treatment prior to slaughter as follows: For sponsor 059130—cattle and goats, 30 days; swine and sheep, 20 days; for sponsors 000009, 000069, 050604—cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.

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 556.430 is revised to read as follows:

§ 556.430 Neomycin.

A tolerance of 7.2 parts per million (ppm) is established for residues of parent neomycin (marker residue) in uncooked edible kidney (target tissue), 7.2 ppm in fat, 3.6 ppm in liver, 1.2 ppm in muscle of cattle, swine, sheep, and goats. A tolerance of 0.15 ppm is established for neomycin in milk.

Dated: May 31, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–15724 Filed 6–19–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 17, 19, 70, 170, 194, 197, and 250

[T.D. ATF–379; Re Notice Nos. 634, 649, 748, and 758]

RIN 1512–AA20

Taxpaid Distilled Spirits Used in Manufacturing Products Unfit for Beverage Use (73R–24P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule amends and recodifies the regulations on taxpaid distilled spirits used to manufacture nonbeverage products. The regulations formerly in 27 CFR part 197 (Drawback on Distilled Spirits Used in Manufacturing Nonbeverage Products) are recodified as a new part, designated 27 CFR part 17. In conjunction with the recodification, a number of changes to the drawback regulations have been made. Further, the regulations formerly in 27 CFR part 170, subpart U (Manufacture and Sale of Certain Compounds, Preparations, and Products Containing Alcohol) have been distributed between 27 CFR part 19 and the new part 17; and conforming amendments have been made in 27 CFR parts 70, 194, and 250. Significant changes from prior regulations are discussed below under **SUPPLEMENTARY INFORMATION.**

EFFECTIVE DATE: This Treasury decision is effective on August 19, 1996.

FOR FURTHER INFORMATION CONTACT: Steve Simon, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Washington, DC 20226; (202) 927–8210.

SUPPLEMENTARY INFORMATION:

Notices of Proposed Rulemaking

On July 29, 1987, ATF published Notice No. 634 in the Federal Register (52 FR 28286). That notice proposed the recodification of regulations concerning nonbeverage drawback, including changes from the former regulations (27 CFR part 197). Public comment was requested concerning the proposed changes. A 90-day comment period was provided, which ended on October 27, 1987. In response to Notice No. 634, ATF received four written public comments. In addition, some review comments were received from ATF personnel after the publication of Notice No. 634.

On December 8, 1987, ATF solicited additional public comments regarding the nonbeverage drawback regulations. On that date, ATF published Notice No. 649 (52 FR 46628), which requested comments specifically relating to drawback on nonbeverage products brought into the U.S. from Puerto Rico or the Virgin Islands. In conjunction, the comment period for Notice No. 634 was extended until January 8, 1988. No additional comments concerning Notice No. 634 were received pursuant to that extension.

On August 31, 1992, ATF decided to republish the proposed recodification and amendment of 27 CFR part 197. Notice No. 748 was published in the Federal Register (57 FR 39536). Because more than 4 years had elapsed since the end of the previous comment periods, the proposed regulations were republished in their entirety, with some additional changes, so that anyone else who wished to comment on them would have an opportunity to do so.

Notice No. 748 prescribed a 30-day comment period, which was scheduled to end on September 30, 1992. On September 14, 1992, ATF was asked to extend this comment period for an additional 90 days. ATF partially granted this request. On October 1, 1992, Notice No. 758 (57 FR 45357) extended the comment period for Notice No. 748 by an additional 30 days, until October 30, 1992. The full 90-day extension (as requested) was not granted, because most of the same regulatory issues had been previously aired for public comment during a sufficient length of time. Subsequent to the official ending of the comment period, comments that were received while it was still practicable to consider them were given consideration.

In response to Notices No. 748 and 758, comments were received by letter, telephone, and personal visit from a total of twelve persons representing eleven entities (nine industry members and two industry groups). These comments are discussed carefully below, following the discussion of comments submitted previously under Notice No. 634.

Public Comments on Notice No. 634

Comments relating to Notice No. 634 were received from four correspondents:

1. One commenter proposed that § 17.183 be liberalized to allow manufacturers to sell or transport byproducts from which alcohol may be recovered, without removing the alcohol or adding an appropriate substance to prevent the recovery of residual alcohol. The commenter was concerned particularly about economic loss from an inability to process ''spent'' vanilla beans for food use applications.

ATF did not adopt this comment, because potable alcohol recovered from a nonbeverage manufacturer's byproduct would have been previously subject to drawback; thus less than 10% of the tax would remain paid. The possible recovery of such potable alcohol by unknown persons would present an unacceptable jeopardy to the revenue. Subject to formula approval and/or approval of an alternative procedure under § 17.3, ATF could allow byproducts containing recoverable alcohol to be subjected to additional processing, on the manufacturer's premises, for food use applications.

The basis for § 17.183 in this final rule is ATF Ruling 81–8, 1981–4 QB 24. That ruling provided a liberalized procedure for the disposition of spent vanilla beans, whereby they could be treated with any substance that the manufacturer deemed adequate to make