Dated: April 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–9427 Filed 4–8–98; 8:45 am]

BILLING CODE 4160–01–F

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 Med-Pharmex, Inc. The ANADA provides for use of neomycin sulfate soluble powder in water or milk as a drench or in drinking water for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats.

EFFECTIVE DATE: April 9, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–235 that provides for use of neomycin sulfate soluble powder in water or milk as a drench or in drinking water for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats.

Med-Pharmex, Inc.'s ANADA 200–235 is approved as a copy of Upjohn's NADA 11–315. The ANADA is approved as of March 9, 1998, and the regulations are amended in § 520.1484 (21 CFR 520.1484) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the regulation incorrectly indicates that Phoenix Scientific, Inc., has an approved neomycin sulfate soluble powder product. At this time, the regulation is amended by removing the sponsor for Phoenix Scientific, Inc., in § 520.1484(b) and by revising paragraph (c)(3).

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, 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 25.33(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.

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.

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, 046573, 050604, and 051259 in § 510.600(c) of this chapter.

(c) * * *

(3) * * * Discontinue treatment prior to slaughter as follows: Cattle (not for use in veal calves), 1 day; sheep, 2 days; swine and goats, 3 days.

Dated: March 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–9428 Filed 4–8–98; 8:45 am]

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DEPARTMENT OF STATE

[Public Notice 2784]

22 CFR Part 121

Amendments to the International Traffic in Arms Regulations

AGENCY: Bureau of Political-Military Affairs, State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic in Arms Regulations (ITAR) by removing from the U.S. Munitions List (USML), for transfer to the Department of Commerce's Commerce Control List (CCL), certain items when they are included in a commercial communications satellite licensed by the Department of Commerce. In all other cases, these items will continue to be controlled on the USML, subject to State Department licensing.

EFFECTIVE DATE: April 9, 1998.

FOR FURTHER INFORMATION CONTACT: William J. Lowell, Director, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (703) 812–2564 or FAX (703) 875–6647.

SUPPLEMENTARY INFORMATION: On October 26, 1996, the Department published an amendment to the ITAR to remove commercial communications satellites from the USML for transfer to licensing jurisdiction by the Department of Commerce. That amendment also covered certain USML items specified in Category XV(f) when they were included in a commercial comsat launch. In all other cases, however, these items remained on the USML. Recently, the Department, in consultation with the Departments of Commerce and Defense, has decided to elaborate the earlier amendment to include satellite fuel and certain additional USML items that may be included with a commercial communications satellite licensed by the Department of Commerce.

In carrying out this decision, the Note following Category XV(f)(9), describing those USML items that may be included in a Commerce licensed commercial communications satellite, is amended.

This amendment involves a foreign affairs function of the United States and, thus, is excluded from the procedures of Executive Order 12866 (58 FR 51735) and 9 U.S.C. 533 and 554, but has been reviewed internally by the Department to ensure consistency with the purposes thereof.

In accordance with 5 U.S.C. 808, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (the ''Act''), the Department of State has found for foreign policy reasons that notice and public procedure under section 251 of the Act is impracticable and contrary to the public interest. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory