

Dated: April 3, 1998.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

[FR Doc. 98-9427 Filed 4-8-98; 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 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

Change, Room 200, SA-6, Washington, D.C. 20520-0602.

List of Subjects in 22 CFR Part 121

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Part 121 is amended as follows:

PART 121—THE UNITED STATES MUNITIONS LIST

1. The authority citation for part 121 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); E.O. 11958, 42 FR 4311; 3 CFR 1977 comp. p. 79; 22 U.S.C. 2658.

2. In § 121.1 Category XV, the note following paragraph (f)(9) is revised to read as follows:

§ 121.1 General. The United States Munitions List.

* * * * *

Category XV—Spacecraft Systems and Associated Equipment

* * * * *

(b) * * *

(9) * * *

Note: Commercial communications satellites are subject to commerce licensing jurisdiction even if they include the individual munitions list systems, components, or parts identified in Category XV(f) of the United States Munitions List (USML). In all other cases, these Category XV(f) systems, components, or parts remain on the USML except that satellite fuel, ground support equipment, test equipment, payload adapter/interface hardware, replacement parts for the preceding items and non-embedded, solid propellant orbit transfer engines ("kick motors") are subject to Commerce licensing jurisdiction (and not controlled on the USML) when they are to be utilized for the specific commercial communications satellite launch, provided the solid propellant "kick motor" being utilized is not specifically designed or modified for military use or capable of being restarted after achievement of mission orbit (such orbit transfer engines are always controlled under Category IV of the USML). Technical data (as defined in § 120.10 of this subchapter, the International Traffic in Arms Regulations (ITAR) and defense services (as defined in § 120.9 of this subchapter related to the systems, components, or parts referred to in category XV(f) of the USML are always controlled under the USML, even when the satellite itself is licensed by the Department of Commerce.

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Dated: March 13, 1998.

John D. Holm,

Acting Under Secretary of State for Arms Control and International Security Affairs and Director, U.S. Arms Control and Disarmament Agency, Department of State.
[FR Doc. 98-9278 Filed 4-8-98; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 203

Announcement of Public Workshop on Final Regulations Implementing Outer Continental Shelf (OCS) Deep Water Royalty Relief Act

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of Workshop.

SUMMARY: MMS issued final regulations implementing Public Law 104-58, Outer Continental Shelf (OCS) Deepwater Royalty Relief Act and guidelines on January 16, 1998 on the procedure lease owners' use to apply for deep water royalty relief and for end-of-life royalty relief. This notice announces a workshop to illustrate the application requirements, explain the relief qualification systems, and answer evaluation and implementation questions.

DATES: MMS will hold the workshop Wednesday, June 10, 1998, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: The workshop will be held at the Gulf of Mexico Regional Office, 1201 Elmwood Park Blvd., Elmwood Towers Bldg., Room 111, New Orleans, LA 70123.

FOR FURTHER INFORMATION CONTACT: Marshall Rose, Chief, Economics Division, MMS at (703) 787-1538, or Mike Melancon, Gulf of Mexico Regional Supervisor, Production and Development, MMS at (504) 736-2675.

SUPPLEMENTARY INFORMATION: Owners of leases that pre-date November 28, 1995 and are located in water 200 meters or deeper in the Central or Western Gulf of Mexico may request suspension of royalties by submitting a complete application. The final rule and guidelines specify the contents and format for such an application along with the criteria for, and conditions of, approval (63 FR 2605, January 16, 1998).

Part of the submission involves use of a computer model developed by MMS. Applicants use this model to organize their data and demonstrate that royalty relief can make their otherwise uneconomic field or expansion project

economic. MMS has issued a revised version of this computer model (RSVP 2.0) that uses more widely available Windows-based spreadsheets. This workshop will show interested parties how to use the model, how to best support the values they input to the model, and how MMS has dealt with selected issues raised in early applications. In conjunction with the workshop, MMS will also issue documentation for the revised RSVP model and review technical corrections including new price assumptions for the deep water guidelines.

Owners of producing leases anywhere on the Outer Continental Shelf may qualify for reduced royalty rates. The final rule and guidelines on end-of-life royalty relief describe the conditions under which leases qualify for this relief. This system replaces and significantly simplifies the net revenue share relief system previously available to leases nearing the end of their economic life. This workshop will show how interested parties may determine whether their leases qualify for, and how royalty would be determined under, end-of-life relief.

MMS encourages all interested parties to attend the workshop and participate in the discussions. It should be especially valuable for those who will be responsible for preparing applications for their companies. Question and answer periods will be part of each session.

There is no registration fee for this workshop. However, to assess the probable number of participants, MMS requests participants to register with Mary Carter by calling (504) 736-2675 or FAX (504) 736-1738 before June 5, 1998. Seating is limited and will be on a first-come-first-seated basis.

Preliminary Agenda

- Welcome and Introduction.
- Review of the Deep Water Relief Evaluation Process.
- Use of the Resource Module of RSVP.
- Use of the Viability Module of RSVP.
- Evaluation Issues (e.g., price, sunk costs, joint costs, multi-lease fields) with Deep Water Applications.
- Process Issues (e.g., redetermination, tolling, field naming, dissemination of decisions) with Deep Water Applications.
- Structure and Qualification for End-of-Life Relief.

Dated: April 1, 1998.

E.P. Danenberger,

Chief, Engineering and Operations Division.
[FR Doc. 98-9285 Filed 4-8-98; 8:45 am]

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