types of liquid foods at temperatures not exceeding 70 °C (158 °F).

(2) Maximum thickness of the copolymer membrane is 0.007 inch (0.17 centimeter).

(3) Perfluorinated ion exchange membranes shall be maintained in a sanitary manner in accordance with current good manufacturing practice so as to prevent microbial adulteration of food.

(4) To assure their safe use, perfluorinated ionomer membranes shall be thoroughly cleaned prior to their first use in accordance with current good manufacturing practice.


L. Robert Lake,
Acting Director, Center for Food Safety and Applied Nutrition.
[FR Doc. 94–7883 Filed 4–1–94; 8:45 am]
BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bambermycins

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 new animal drug application (NADA) filed by Hoechst-Roussel Agri-Vet Co. The NADA provides for expanding the use of currently approved bambermycins-containing Type A medicated articles to make Type C medicated feeds for increased rate of weight gain in pasture cattle.


FOR FURTHER INFORMATION CONTACT: Warner J. Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., Rt. 202–206 North, P.O. Box 2500, Somerville, NJ 08876–1258, has filed NADA 141–034. The NADA provides for expanding the use of currently approved 2–4–, and 10–gram-per-pound bambermycins-containing Type A medicated articles to make Type C medicated feeds for increased rate of weight gain in pasture cattle (as in related NADA 44–759 which covers broiler chickens, growing-finishing swine, growing turkeys, and cattle fed in confinement for slaughter). The NADA is approved as of March 4, 1994, and the regulations are amended in §558.95(b) (21 CFR 558.95(b)) to reflect the approval.

As provided in 21 CFR 558.4(a) and (d), bambermycins are Category I drugs, which as the sole drug ingredient, do not require an approved Form FDA 1900 for making Type C medicated feeds as in approved NADA 141–034 and in §558.95, as amended herein.

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–2050), Food and Drug Administration, rm. 1–23, 12420 Parklaw Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning March 4, 1994, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) and, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the claim of increased rate of weight gain in pasture cattle for which the application is being approved.

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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:


2. Section 558.95 is amended by adding new paragraph (b)(4)(ii) to read as follows:

§558.95 Bambermycins.

* * * * *

(b) * * *

(4) * * *

(ii) Amount per ton. 4 to 20 grams.

(a) Indications for use. For increased rate of weight gain.

(b) Limitations. Feed continuously to pasture cattle (slaughtering, stocker, and feeder) at a rate of 10 to 20 milligrams of bambermycins per head per day in at least 1 pound and not more than 10 pounds of Type C medicated feed. Not for use in animals intended for breeding.

* * * * *


Richard H. Teske,
Acting Director, Center for Veterinary Medicine.
[FR Doc. 94–7884 Filed 4–1–94; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF STATE

Bureau of Political-Military Affairs

22 CFR Part 126

[Public Notice 1972]

Amendment to the International Traffic in Arms Regulations Proscribed List

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to reflect that it is no longer the policy of the United States to deny licenses, other approvals, exports and imports of defense articles and defense services, destined for or originating in the following countries: Albania, Bulgaria, Cambodia, Estonia, Latvia, Lithuania and Romania. The regulations are also amended to add Haiti, as a result of the UN arms embargo against it, and to add Sudan. A new provision is added to reflect the qualified embargo of Angola which is set forth in Executive Order 12865 of September 26, 1993 and which is also implemented by the UNITA (Angola) Sanctions Regulations published by the
Office of Foreign Assets Control, Department of the Treasury on December 10, 1993 (58 FR 64904).


FOR FURTHER INFORMATION CONTACT: Andrew P. Church, Office of Export Control Policy, Bureau of Political-Military Affairs, Department of State (202) 647-4230.

SUPPLEMENTARY INFORMATION: The Department of State is amending the ITAR to reflect that it is no longer the policy of the United States to, pursuant to 22 CFR 126.1, deny licenses, other approvals, exports and imports of defense articles and defense services, destined for or originating in the following countries: Albania, Bulgaria, Cambodia, Estonia, Latvia, Lithuania and Romania. With respect to these countries, all requests for approval involving items covered by the U.S. Munitions List (22 CFR part 121) will be reviewed on a case-by-case basis.

With respect to Albania, Bulgaria, Estonia, Latvia, Lithuania and Romania, this action is taken in response to the great progress made by these countries in transforming themselves from authoritarian, one-party communist regimes to free market democracies. Cambodia is removed from the provisions of § 126.1(a) as a result of the installation of a new and democratically-elected government, and the end of multinational civil conflict that plagued the country for over a decade.

Section 126.1(a) is amended to add Haiti as a result of the UN arms embargo against it, and § 126.1(d) is amended to add Sudan, which was designated by the Secretary of State on August 12, 1993 as a country which has repeatedly provided support for acts of international terrorism.

A § 126.1(f) is added to reflect the qualified embargo of Angola which is set forth in Executive Order 12895 of September 26, 1993 and which is also implemented by the UNITA (Angola) Sanctions Regulations published by the Office of Foreign Assets Control, Department of the Treasury, at 58 FR 64904.

This amendment involves a foreign affairs function of the United States and this is excluded from the major rule procedures of Executive Order 12291 (46 FR 31393) and the procedures of 5 U.S.C. 553 and 554. This final rule does not contain a new or amended requirement subject to the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

List of Subjects in 22 CFR Part 128

Arms and munitions, Exports.

Accordingly, for the reasons set forth in the preamble, and under the authority of section 38 of the Arms Export Control Act (22 U.S.C. 2778) and Executive Order 11958, as amended, 22 CFR subchapter M is amended as follows:

PART 128—GENERAL POLICIES AND PROVISIONS

1. The authority citation for part 128 continues to read as follows:

Authority: Sec. 38, sec. 42, Arms Export Control Act, 50 Stat. 744 (22 U.S.C. 2778, 2780); E.O. 11958, 42 FR 4311, E.O. 11322, 32 FR 119; 22 U.S.C. 2658, unless otherwise noted.

2. Section 126.1 is amended by revising paragraphs (a) and (d), and by adding paragraph (f) as follows:

§ 128.1 Prohibited exports and sales to certain countries.

(a) General. It is the policy of the United States to deny licenses, other approvals, exports and imports of defense articles and defense services, destined for or originating in certain countries. This policy applies to Armenia, Azerbaijan, Belarus, Cuba, Georgia, Iran, Iraq, Kazakhstan, Kyrgyzstan, Libya, Moldova, Mongolia, North Korea, Russia, South Africa, Syria, Tajikistan, Turkmenistan, Ukraine, Uzbekistan and Vietnam. This policy also applies to countries with respect to which the United States maintains an arms embargo (e.g., Burma, China, Haiti, Liberia, Somalia, Sudan, the former Yugoslavia, and Zaire) or whenever an export would not otherwise be in furtherance of world peace and the security and foreign policy of the United States.

Comprehensive arms embargoes are normally the subject of a State Department notice published in the Federal Register. The exemptions provided in the regulations in this subchapter, except §§ 123.17 and 125.4(b)(13) of this subchapter, do not apply with respect to articles originating in or for export to any proscribed country or areas.

(d) Terrorism. Exports to countries which the Secretary of State has determined to have repeatedly provided support for acts of international terrorism are contrary to the foreign policy of the United States and are thus subject to the policy specified in paragraph (a) of this section and the requirements of section 40 of the Arms Export Control Act (22 U.S.C. 2780) and the Omnibus Diplomatic Security and Anti-Terrorism Act of 1986 (22 U.S.C. 4801, note). The countries in this category are: Cuba, Iran, Iraq, Libya, North Korea, Sudan and Syria. The same countries are identified pursuant to section 6(j) of the Export Administration Act, as amended (50 U.S.C. App. 2405(j)).


Date: March 23, 1994.

Lynda E. Davis,
Under Secretary for International Security Affairs.
[FR Doc. 94-6112 Filed 4-1-94; 8:45 am]
BILLING CODE 4710-25-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[FRL-4857-9]

Approval of Tennessee's Petition To Relax the Federal Reid Vapor Pressure Volatility Standard From 7.8 psi to 9.0 psi

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: In this document EPA is approving as a direct final rule Tennessee's petition to relax the Reid Vapor Pressure Standard (RVP) applicable to gasoline introduced into commerce from June 1 to September 15 in the former Knox County ozone nonattainment area from 7.8 pounds per square inch (psi) to 9.0 psi. Knox County, Tennessee has met the requirements for redesignation from nonattainment to attainment status contained in section 107(d)(4)(E) of the Clean Air Act. Tennessee's petition is based on evidence that the Knox County area does not need the 7.8 psi standard to maintain ozone attainment. EPA believes that further imposition of the 7.8 psi volatility standard would impose needless costs in light of Tennessee's attainment of the National Ambient Air Quality Standard. This action is being taken without prior proposal because EPA believes that this final rulemaking is noncontroversial, for the reasons...