Rockville, MD 20855, 301–827–7543, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141–208 that provides for veterinary prescription use in dogs of ADVANTAGE DUO (imidacloprid and ivermectin) Topical Solution for the prevention of heartworm disease caused by *D. immitis* and treatment of flea infestations (*C. felis*). The NADA is approved as of September 27, 2002, and the regulations are amended by adding 21 CFR 524.1140 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 qualifies for 3 years of marketing exclusivity beginning September 27, 2002.

The agency has determined under 21 CFR 25.33(d)(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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1140 is added to read as follows:

§ 524.1140 Imidacloprid and ivermectin.

(a) *Specifications.* The product is available in unit applicator tubes containing 0.4, 1.0, 2.5, or 4.0 milliliters (mL). Each mL of solution contains 100 milligrams (mg) imidacloprid and 800 micrograms (µg) ivermectin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of Use in Dogs*—(1) *Amount.* The recommended minimum dosage is 4.5 mg/pound (lb) (10 mg/kilogram (kg)) of imidacloprid and 36.4 µg/lb (80 µg/kg) of ivermectin, topically once a month.

(2) *Indications for Use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*; kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 17, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–32442 Filed 12–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice 4236]

RIN 1400–AB61

Bureau of Political-Military Affairs; Amendments to the International Traffic in Arms Regulation: Canadian Exemption

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule clarifies the Canadian Exemption at the International Traffic in Arms Regulations (ITAR) as to how the Department of State will identify Canadian Crown Corporations as authorized end-users.

EFFECTIVE DATE: December 26, 2002.

FOR FURTHER INFORMATION CONTACT: David C. Trimble, Director, Compliance Division, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (202) 663–2700.

SUPPLEMENTARY INFORMATION: On February 16, 2001, the Department of State published a final rule amending the Canadian Exemption (22 CFR 126.5) of the ITAR (66 FR 10575). Authorized end-users included Canadian Federal or Provincial governmental authorities acting in an official capacity or a ''Canadian-registered person.'' The term ''Canadian-registered person'' encompassed any Canadian national (including Canadian business entities organized under the laws of Canada), dual national, and permanent resident registered in Canada in accordance with the Canadian Defence Production Act, and such other Canadian Crown Corporations as may be identified by the Department of State. This final rule amends section 126.5(b) of the ITAR by adding ''Canadian Crown Corporations identified by the Department of State in a list of such persons publicly available through the Internet Website of the Office of Defense Trade Controls and by other means.''

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1966. It will not have substantial direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant application of Executive Orders 12372 and 13123. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, Canadian Exemption, 12th Floor, SA–1, Washington, D.C. 20522–0112. Such persons must be so registered with the Department of State's Office of Defense Trade Controls (DTC) pursuant to the registration requirements of section 38 of the Arms Export Control Act.

List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Part 126, is being amended as follows:

PART 126—GENERAL POLICIES AND PROVISIONS

1. The authority citation for part 126 continues to reads as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778,

2780, 2791, and 2797); 22 U.S.C. 2778; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p.79; 22 U.S.C. 2658; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205, 3 CFR 1994 Comp., p 899.

2. Section 126.5(b) introductory text is revised to read as follows:

§ 126.5 Canadian exemptions.

(a) * * *

(b) *Permanent and temporary export of defense articles.* Except for the defense articles and related technical data, and defense services identified in paragraphs (b)(1) through (b)(20) of this section, for exports that transit third countries, and provided the requirements of this subchapter are met, (to include 22 CFR 120.1 (c) and (d), parts 122 and 123 (except insofar as exemption from licensing requirements is herein authorized) and § 126.1, and the requirement to obtain non-transfer and use assurances for all significant military equipment), District Director of Customs and postmasters shall permit, when for end-use in Canada by Canadian Federal or Provincial governmental authorities acting in an official capacity or by a Canadian-registered person or return to the United States, the permanent and temporary export to Canada without a license of defense articles and related technical data identified in 22 CFR 121.1, except as described in paragraphs (b)(1) through (20) of this section, and the defense services and technical data described in paragraph (c) of this section. For purposes of this section, ''Canadian-registered person'' is any Canadian national (including Canadian business entities organized under the laws of Canada), dual national, and permanent resident registered in Canada in accordance with the Canadian Defense Production Act, and such other Canadian Crown Corporations identified by the Department of State in a list of such persons publicly available through the Internet Website of the Office of Defense Trade Controls and by other means. The defense articles, related technical data, and defense services identified in 22 CFR 121.1 continuing to require a license are:

* * * * *

Dated: October 28, 2002.

John R. Bolton,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 02–32424 Filed 12–24–02; 8:45 am]

BILLING CODE 4710–25–U

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 200

Employee Responsibilities and Conduct

AGENCY: Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: USAID is amending its regulations governing the responsibilities and conduct of USAID employees.

DATES: This rule becomes effective December 26, 2002.

FOR FURTHER INFORMATION CONTACT: Dennis Diamond, Attorney, Office of General Counsel, Ethics and Administration, USAID, telephone 202–712–4456; telefax (202) 216–3055; email *ddiamond@usaid.gov.*

SUPPLEMENTARY INFORMATION:

A. Explanation of Changes

The regulations governing the responsibilities and conduct of employees previously codified as part 10 of this title prescribed jointly by the Department of State, the Agency for International Development, and the U.S. Information Agency have been repealed.

The Agency for International Development is amending Part 200 to delete the reference to part 10 of this title and to reference the Office of Government Ethics' government-wide Standards of Ethical Conduct of the Executive Branch, 5 CFR part 2635.

B. Regulatory Analysis

1. *Executive Order 12866.* USAID has determined that this regulation is not a significant regulatory action as defined in Executive Order 12866 and, accordingly, this regulation has not been reviewed by the Office of Management and Budget.

2. *Regulatory Flexibility Act.* It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a Regulatory Flexibility Analysis is not required.

3. *Executive Order 13132.* This regulation will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

4. *Unfunded Mandates Reform Act of 1995.* This regulation will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

5. *Small Business Regulatory Enforcement Fairness Act of 1996.* This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Act. 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic or export markets.

7. *Executive Order 12988—Civil Justice Reform.* USAID has conducted the reviews required by section 3 of Executive Order 12988 and has determined that, this rule meets the applicable standards in section 3 to mitigate litigation, eliminate ambiguity and reduce burden.

8. *Paperwork Reduction Act.* This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Accordingly, 22 CFR part 200 is revised to read as follows:

PART 200—EMPLOYEE RESPONSIBILITIES AND CONDUCT

Cross-References: The regulations governing the responsibilities and conduct of employees of the Agency for International Development are codified as part 2635 of title 5, prescribed by the Office of Government Ethics.

Dated: December 18, 2002.

Arnold Haiman,

Designated Agency Ethics Official, Office of General Counsel.

[FR Doc. 02–32423 Filed 12–24–02; 8:45 am]

BILLING CODE 6116–01–P