Dated: December 19, 2002.

David M. Mason,

Chairman, Federal Election Commission.

[FR Doc. 02–32452 Filed 12–24–02; 8:45 am]

BILLING CODE 6715–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Clindamycin Liquid; Change of Sponsor's Address

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 Delmarva Laboratories, Inc., and a change of this sponsor's address. The ANADA provides for oral use of clindamycin hydrochloride liquid in dogs and cats for the treatment of various bacterial infections.

DATES: This rule is effective December 26, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113, filed ANADA 200–291 for CLINSOL (clindamycin hydrochloride) Liquid. The application provides for oral use of clindamycin hydrochloride liquid in dogs and cats for the treatment of various bacterial infections. Delmarva Laboratories' CLINSOL Liquid is approved as a generic copy of Pharmacia & Upjohn's ANTIROBE Aquadrops Liquid, approved under NADA 135–940. ANADA 200–291 is approved as of August 26, 2002, and the regulations are amended in 21 CFR 520.447 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Delmarva Laboratories, Inc., has informed FDA of a change of address to 1500 Huguenot Rd., suite 106, Midlothian, VA 23113. Accordingly, the agency is amending the regulations in 21 CFR 510.600 to reflect the change of sponsor address.

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA 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.

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 congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Delmarva Laboratories, Inc.'' and in the table in paragraph (c)(2) by revising the entry for ''059079'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* *
Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113	059079

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
059079	Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113
* *	* * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.447 [Amended]

4. Section 520.447 *Clindamycin liquid* is amended in paragraph (b)(2) by removing ''No.'' and by adding in its place ''Nos. 059079 and''.

Dated: December 17, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–32440 Filed 12–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Imidacloprid and Ivermectin

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 Bayer Corp., Agriculture Division, Animal Health. The NADA provides for veterinary prescription use in dogs of an imidacloprid and ivermectin topical solution for the prevention of heartworm disease caused by *Dirofilaria immitis* and treatment of flea infestations (*Ctenocephalides felis*).

DATES: This rule is effective December 26, 2002.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl.,

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,