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.,