[FR Doc. E8–1012 Filed 1–23–08; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Clindamycin

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 Novopharm Ltd. The ANADA provides for the veterinary prescription use of clindamycin hydrochloride oral capsules in dogs for the treatment of various infections due to susceptible bacterial pathogens.

DATES: This rule is effective January 24, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9808, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Novopharm Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9, filed ANADA 200–383 that provides for the veterinary prescription use of CLINDAROBE (clindamycin hydrochloride) Capsules in dogs for the treatment of various infections due to susceptible bacterial pathogens. Novopharm Ltd.'s CLINDAROBE Capsules is approved as a generic copy of Pharmacia & Upjohn Co.'s ANTIROBE Capsules, approved under NADA 120–161. The ANADA is approved as of December 19, 2007, and 21 CFR 520.446 is amended to reflect the approval.

In addition, Novopharm Ltd. has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 Division of Dockets Management (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 the 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 alphabetically adding a new entry for ''Novopharm Ltd.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''043806'' 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
* * *	* *
Novopharm Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9	043806
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
043806	Novopharm Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9
* *	* * *

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.

■ 4. In § 520.446, add paragraphs (a)(3) and (b)(3) to read as follows:

§ 520.446 Clindamycin capsules and tablets.

(a) * * *

(3) Each capsule contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.

(b) * * *

(3) No. 043806 for use of tablets described in paragraph (a)(3) of this section.

* * * * *

Dated: January 14, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–1199 Filed 1–23–08; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 51

RIN 1400–AC28

[Public Notice: 6071]

Passports; Correction

AGENCY: Department of State.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the revised Passport rule published in the **Federal Register** on November 19, 2007, 72 FR 64930.

DATES: Effective on February 1, 2008.

FOR FURTHER INFORMATION CONTACT: Consuelo Pachon, Office of Legal Affairs and Law Enforcement Liaison, Bureau of Consular Affairs, 2100 Pennsylvania Avenue, NW., Suite 3000, Washington, DC., telephone number 202–663–2431.

Background

The rule reorganizes, restructures, and updates the passport regulations in order to make them easier for users to access the information, to better reflect current practice and changes in