

[FR Doc. E8-1012 Filed 1-23-08; 8:45 am]
BILLING CODE 4910-13-P

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 CLINDAROB (clindamycin hydrochloride) Capsules in dogs for the treatment of various infections due to susceptible bacterial pathogens. Novopharm Ltd.'s CLINDAROB 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

statutory authority, and to remove outdated provisions.

Need for Correction

The final passport rule published on November 19, 2007 erroneously labels two sentences in the rule contained in 22 CFR 51.21(b) and (c) as a "Note." This correction deletes the labels "Note" and corrects the numbering of the two provisions.

Correction

■ The final passport rule published on November 19, 2007 (72 FR 64930) is corrected as follows:

■ 1. On page 64933, 22 CFR part 51.21 is corrected by making the following correcting amendments:

PART 51—PASSPORTS

Section 51.21(b) and (c) is revised to read as follows:

§ 51.21 Execution of passport application.

* * * * *

(b) *Application by mail—persons in the United States.* (1) A person in the United States who previously has been issued a passport valid for 10 years in his or her own name may apply for a new passport by filling out, signing and mailing an application on the form prescribed by the Department if:

(i) The most recently issued previous passport was issued when the applicant was 16 years of age or older;

(ii) The application is made not more than 15 years following the issue date of the previous passport, except as provided in paragraph (e) of this section; and

(iii) The most recently issued previous passport of the same type is submitted with the new application.

(2) The applicant must also provide photographs as prescribed by the Department and pay the applicable fees prescribed in the Schedule of Fees for Consular Services (22 CFR 22.1).

(c) *Application by mail—persons abroad.* (1) A person in a foreign country where the Department has authorized a post to receive passport applications by mail who previously has been issued a passport valid for 10 years in his or her own name may apply for a new passport in that country by filling out, signing and mailing an application on the form prescribed by the Department if:

(i) The most recently issued previous passport was issued when the applicant was 16 years of age or older;

(ii) The application is made not more than 15 years following the issue date of the previous passport, except as provided in paragraph (e) of this section; and

(iii) The most recently issued previous passport of the same type is submitted with the new application.

(2) The applicant must also provide photographs as prescribed by the Department and pay the applicable fees prescribed in the Schedule of Fees for Consular Services (22 CFR 22.1).

* * * * *

Dated: January 18, 2008.

Ann Barrett,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. E8-1205 Filed 1-23-08; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG-2007-0169]

RIN 1625-AA00

Safety Zone: Trent River Between New Bern and James City, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will establish a safety zone on the waters of the Trent River between New Bern and James City, North Carolina in the vicinity of the U.S. Route 70 Highway Swing Bridge. This safety zone is necessary to provide for the safety of life on navigable waters during the movement of bridge construction equipment from the southern end of the bridge construction project to the northern end of the project.

DATES: This rule is effective from 10 a.m. on January 8, 2008 through 2 p.m. on January 24, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2007-0169 and are available for inspection or copying at Sector North Carolina 2301 East Fort Macon Road Atlantic Beach, NC 28512 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Commander Jennifer Williams, Prevention Department Head, United States Coast Guard Sector North Carolina at (252) 247-4570 or (252) 247-457046.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this

regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The publishing of an NPRM would be impracticable and contrary to public interest since immediate action is needed to protect the maritime public from the hazards associated with this maintenance project. The necessary information to determine whether the construction poses a threat to persons and vessels was not provided with sufficient time to publish an NPRM. For the safety concerns noted, it is in the public interest to have this regulation in effect during the construction.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the public interest, since immediate action is needed to ensure the public's safety.

Background and Purpose

From 10 a.m. to 2 p.m. on each Tuesday, Wednesday, and Thursday from January 8, 2008 through January 24, 2008 Balfour Beatty Infrastructure Inc. will relocate construction equipment in the vicinity of the U.S. Route 70 Highway Swing Bridge from James City, NC to New Bern, NC. To provide for the safety of the public, the Coast Guard will temporarily restrict access to this section of the Trent River during equipment relocation.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone that will extend from the Norfolk Southern Railroad Bridge and Union Point, New Bern, NC to the U.S. Route 17 Highway Bridge at James City, NC, latitude 35°05.8' N, longitude 77°02.2' W. This zone will require mariners to avoid entry into the area. Entry into the zone will not be permitted except as specifically authorized by the Captain of the Port or his designated representative.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary.

Although this regulation will restrict access to the regulated area, the effect of this rule will not be significant because: