DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

New Animal Drugs; Change of Sponsor; Chloramphenicol Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) for chloramphenicol capsules from Nylos Trading Co., Inc., to Pharmaceutical Ventures, Ltd.

DATES: This rule is effective December 20, 2005.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: Nylos Trading Co., Inc., P.O. Box 2, Route 202, Pomona, NY 10970, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 65–150 for Chloramphenicol Capsules to Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970. Accordingly, the regulations are amended in § 520.390b (21 CFR 520.390b) to reflect this change of sponsorship and a current format. In addition, FDA is taking this opportunity to revise § 520.390b to reflect the prohibition of extralabel use of chloramphenicol in food-producing animals under 21 CFR 530.41.

Following these changes of sponsorship, Nylos Trading Co., Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Nylos Trading Co., Inc.

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 removing the entry for ''Nylos Trading Co., Inc.'' and by alphabetically adding a new entry for ''Pharmaceutical Ventures, Ltd.''; and in the table in paragraph (c)(2) by removing the entry for ''027454'' and by numerically adding a new entry for ''050057'' 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
* * *	* *
Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970	050057
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
050057	Pharmaceutical Ventures, Ltd., P.O. Box D1400, Pomona, NY 10970
* *	* * *

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. Revise § 520.390b to read as follows:

§ 520.390b Chloramphenicol capsules.

(a) *Specifications.* Each capsule contains 50, 100, 250, or 500 milligrams (mg) chloramphenicol.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) Nos. 000069, 000185, and 050057 for capsules containing 50, 100, 250, or 500 mg chloramphenicol.

(2) No. 058034 for capsules containing 100 or 250 mg chloramphenicol.

(c) *Special considerations.* Federal law prohibits the extralabel use of this product in food-producing animals.

(d) *Conditions of use in dogs*—(1) *Amount.* 25 mg per pound of body weight every 6 hours.

(2) *Indications for use.* For treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

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

Dated: December 8, 2005.

Bernadette A. Dunham,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AM32

Use of Diagnostic Code Numbers; Schedule of Ratings-Neurological Conditions and Convulsive Disorders

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) Schedule for Rating Disabilities by updating references to diagnostic codes in two regulations. These amendments are necessary to correct outdated references in the Schedule for Rating Disabilities.

DATES: *Effective Date:* December 20, 2005.

FOR FURTHER INFORMATION CONTACT: Maya Ferrandino, Consultant, Compensation and Pension Service, Policy and Regulations Staff, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–7211.

SUPPLEMENTARY INFORMATION: VA's Schedule for Rating Disabilities includes criteria for evaluating disabilities by analogy where there is no specific diagnostic code for the disability being evaluated. In 38 CFR 4.27 and 38 CFR 4.124a, the rating criteria reference examples of diseases that can be rated by analogy to certain specified diagnostic odes. Two of the