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.

[FR Doc. 05–24270 Filed 12–19–05; 8:45 am]

BILLING CODE 4160–01–S

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

diagnostic codes listed in 38 CFR 4.27 and 4.124a, for rheumatoid (atrophic) arthritis and for dementia, are outdated due to changes to the diagnostic criteria for evaluating these diseases. Therefore, we are amending 38 CFR 4.27 and 4.124a to replace outdated references with the current diagnostic codes for ankylosing spondylitis, a disability similar to rheumatoid arthritis, and for dementia.

Section 4.27, Use of diagnostic code numbers, includes as an example: ''Thus, rheumatoid (atrophic) arthritis rated as ankylosis of the lumbar spine should be coded 5002–5289.'' However, Diagnostic Code 5289 was removed from 38 CFR 4.71a, Schedule of ratings-musculoskeletal system, by a rulemaking published on August 27, 2003, at 68 FR 51454. Therefore, the reference to 5289 for ankylosis of the lumbar spine is outdated. We will replace the outdated reference to Diagnostic Code 5289 with the current Diagnostic Code for ankylosing spondylitis, 5240, which is a disability similar to rheumatoid arthritis.

Similarly, in § 4.124a, Schedule of ratings-neurological conditions and convulsive disorders, the paragraph discussing Mental Disorders in Epilepsies which appears after Diagnostic Code 8914 includes references to Diagnostic Codes 9304 and 9307 for dementia: ''(e.g., 9304 or 9307)'' and ''(e.g., Diagnostic Code 9304 or 9307)''. However, Diagnostic Code 9307 was removed by a rulemaking published on October 8, 1996, at 61 FR 52695. Therefore, the reference to Diagnostic Code 9307 currently in 38 CFR 4.124a is outdated. We will remove the reference to Diagnostic Code 9307 and insert a reference to Diagnostic Code 9326, which replaced Diagnostic Code 9307.

Administrative Procedures Act

This final rule merely replaces inaccurate examples and does not alter the content of the regulations. Accordingly, there is a basis for dispensing with prior notice and comment and the delayed effective date provisions of 5 U.S.C. 553.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required in connection with the adoption of this final rule, no regulatory flexibility analysis is required under the Regulatory Flexibility Act (5 U.S.C. 601–612). Even so, the Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers: The Catalog of Federal Domestic Assistance program numbers and titles for this proposal are 64.104, Pension for Non-Service-Connected Disability for Veterans, and 64.109, Veterans Compensation for Service-Connected Disability.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Approved: December 14, 2005.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

■ For the reasons set out in the preamble, 38 CFR part 4 is amended as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

§ 4.27 [Amended]

■ 2. Amend § 4.27 by removing ''5002–5289'' and adding, in its place, ''5002–5240''.

§ 4.124a [Amended]

■ 3. Amend § 4.124a following the undesignated center heading ''The Epilepsies'' at the conclusion of the table in the undesignated paragraph ''Mental Disorders in Epilepsies'' remove ''9307'' and add in its place ''9326''.

[FR Doc. 05–24272 Filed 12–19–05; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R07–OAR–2005–IA–0006; FRL–8010–9]

Approval and Promulgation of Implementation Plans and Operating Permits Program; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) revision submitted by the state of Iowa. This revision includes the general rulemaking that Iowa completes for the purpose of updating and clarifying various rules, and making other minor revisions as generally described in this document. EPA is also proposing approval of revisions to the Iowa Operating Permits Program for the purpose of updating and clarifying various rules included in the general rulemaking. These revisions add new definitions, as well as an administrative correction to a previously submitted rule. Approval of these revisions will ensure consistency between the state and Federally-approved rules, and ensure Federal enforceability of the State's revised air program rules.

DATES: This direct final rule will be effective February 21, 2006, without further notice, unless EPA receives adverse comment by January 19, 2006. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2005–IA–0006, by one of the following methods:

1. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. E-mail: Heather Hamilton at *hamilton.heather@epa.gov.*

3. Mail: Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

4. Hand Delivery or Courier. Deliver your comments to Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2005–IA–0006. EPA's policy is that all comments received will be included in