V–75 [Corrected]

From Morgantown, WV; Bellaire, OH; Briggs, OH; DRYER, OH; INT DRYER 325° and Waterville, OH, 062° radials. The airspace within Canada is excluded.

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Issued in Washington, DC, on February 2, 2007.

Edith V. Parish,

Manager, Airspace and Rules.

[FR Doc. E7–2229 Filed 2–9–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Fluoxetine

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 Elanco Animal Health. The NADA provides for veterinary prescription use of fluoxetine hydrochloride chewable tablets for the treatment of canine separation anxiety.

DATES: This rule is effective February 12, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141 272 that provides for veterinary prescription use of RECONCILE (fluoxetine hydrochloride) Chewable Tablets for the treatment of canine separation anxiety in conjunction with a behavior modification plan. The NADA is approved as of January 19, 2007, and the regulations in part 520 (21 CFR part 520) are amended by adding new § 520.980 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning January 19, 2007.

FDA has determined under 21 CFR 25.33(d)(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 in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Add § 520.980 to read as follows:

§ 520.980 Fluoxetine.

(a) *Specifications.* Each chewable tablet contains 8, 16, 32, or 64 milligrams (mg) fluoxetine hydrochloride.

(b) *Sponsor.* See No. 000986 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) Amount. 1 to 2 mg per kilogram body weight once daily.

(2) *Indications for use.* For the treatment of canine separation anxiety in conjunction with a behavior modification plan.

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

Dated: January 31, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–2172 Filed 2–9–07; 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; Ivermectin Topical Solution

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 supplemental abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites when cattle are treated with a topical solution of ivermectin.

DATES: This rule is effective February 12, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed a supplement to ANADA 200–272 for Ivermectin Pour-On for Cattle. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites that were approved for the pioneer product with 3 years of marketing exclusivity (69 FR 501, January 6, 2004). The supplemental ANADA is approved as of January 19, 2007, and 21 CFR 524.1193 is amended to reflect the approval.

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 congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

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 part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 524.1193, revise the section heading, and paragraphs (b) and (e)(2) to read as follows:

§ 524.1193 Ivermectin topical solution.

* * * * *

(b) *Sponsors.* See Nos. 050604, 051311, 054925, 055529, 058829, 059130, and 066916 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

* * * * *

(e) * * *

(2) *Indications for use in cattle.* For the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Oesophagostomum radiatum*; (adults) *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Sarcoptes scabiei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinia bovis*, *Solenoptes capillatus*; and horn flies *Haematobia irritans.* It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *H. placei*, *C. oncophora*, and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

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Dated: February 2, 2007.

Steven D. Vaughn,

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

[FR Doc. E7–2368 Filed 2–9–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 773

[FHWA Docket No. FHWA–05–22707]

RIN 2125–AF13

Surface Transportation Project Delivery Pilot Program

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: Section 6005 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) established a pilot program to allow the Secretary of Transportation to assign, and the State to assume, the Secretary's responsibilities under the National Environmental Policy Act (NEPA) for one or more highway projects. The Secretary may permit not more than five States (including the States of Alaska, California, Ohio, Oklahoma, and Texas) to participate in the program. Upon assigning NEPA responsibilities, the Secretary may further assign to the State all or part of the Secretary's responsibilities for environmental review, consultation or other action required under any Federal environmental law pertaining to the review of a specific project. In order to be selected for the pilot program a State must submit an application to the Secretary. Section 6005 requires the Secretary to promulgate rules that establish requirements relating to information required to be contained in an application by a State to participate in the pilot program. This final rule establishes these application requirements.

DATES: Effective March 14, 2007.

FOR FURTHER INFORMATION CONTACT: Ms. Ruth Rentch, Office of Project Development and Environmental Review, HEPE, 202–366–2034 or Mr. Michael Harkins, Office of the Chief Counsel, 202–366–4928, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

Internet users may access this document, the notice of proposed rulemaking (NPRM), and all comments received by the U.S. DOT by using the universal resource locator (URL) *http://dms.dot.gov*. It is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *http://www.archives.gov* or the Government Printing Office's Web page at *http://www.gpoaccess.gov/nara*.

Background

Section 6005 of SAFETEA–LU (Pub. L. 109–59, 119 Stat. 1144), codified at 23 U.S.C. 327, established a pilot program that allows the Secretary of Transportation (Secretary) to assign up to five States, including Alaska, California, Oklahoma, Ohio, and Texas, the responsibilities of the Secretary for implementation of the National Environmental Policy Act (NEPA)(42 U.S.C. 4321–4347) for one or more highway projects. Upon assumption of NEPA responsibilities, a State may also be assigned all or part of the Secretary's responsibilities for environmental review, consultation or other action required under any Federal environmental law pertaining to the review or approval of highway projects. Whenever a State assumes the Secretary's responsibilities under this program, the State becomes solely responsible and solely liable for carrying out, in lieu of the Secretary, the responsibilities it has assumed, including coordination and resolution of issues with Federal environmental resource and regulatory agencies and responding to litigation. The Secretary's NEPA and other environmental responsibilities pertaining to the review and approval of highway projects, as well as the administration and implementation of this pilot program, has been delegated to the FHWA pursuant to 49 CFR 1.48.

In order to participate in this pilot program, a State must submit an application. Section 327(b)(2) of title 23, United States Code, requires the Secretary to promulgate regulations that establish requirements relating to the information that States must submit as part of their applications to participate in this pilot program. This final rule establishes these requirements.