

not have a significant economic impact. Therefore the FAA preliminarily certifies that this rule will not have a significant economic impact on a substantial number of small entities.

The FAA solicits comments regarding this determination on this supplemental regulatory flexibility analysis. Please provide detailed economic analysis to support the position of higher cost. The FAA also invites comments regarding other small entity concerns with respect to the final rule.

**Nan Shellabarger,**

*Director, Office of Aviation Policy and Plans.*

[FR Doc. 2011-5257 Filed 3-7-11; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 1, 14, and 17**

[Docket No. FDA-2010-N-0560]

RIN 0910-AG55

**Amendments to General Regulations of the Food and Drug Administration; Confirmation of Effective Date**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of April 14, 2011, for the final rule that appeared in the **Federal Register** of November 30, 2010 (75 FR 73951). The direct final rule amends certain general regulations of FDA to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act, by revising the Agency's regulations to require tobacco products to be subject to the same general requirements that apply to other FDA-regulated products. This document confirms the effective date of the direct final rule.

**DATES:** Effective date confirmed: April 14, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., rm. 204G, Rockville, MD 20850, 1-877-CTP-1373.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 30, 2010 (75 FR 73951), FDA solicited comments concerning the direct final rule for a 75-

day period ending February 14, 2011. FDA stated that the effective date of the direct final rule would be on April 14, 2011, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

**Authority:** Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 14, and 17 are amended. Accordingly, the amendments issued thereby are effective.

Dated: March 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

[Docket No. FDA-2011-N-0003]

**Oral Dosage Form New Animal Drugs; Spinosad and Milbemycin Oxime**

**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 chewable tablets containing spinosad and milbemycin oxime in dogs for the treatment and prevention of flea infestations and for the prevention and control of various internal parasites.

**DATES:** This rule is effective March 8, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Angela Clarke, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8318, e-mail: [angela.clarke@fda.hhs.gov](mailto:angela.clarke@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-321 that provides for veterinary prescription use of TRIFEXIS (spinosad and milbemycin oxime) Chewable Tablets in dogs for the treatment and prevention of flea infestations and for the prevention and control of various internal parasites. The NADA is

approved as of January 4, 2011, and the regulations in part 520 (21 CFR part 520) are amended by adding § 520.2134 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33 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 § 520.2134 to read as follows:

**§ 520.2134 Spinosad and milbemycin.**

(a) *Specifications.* Each chewable tablet contains 140 milligrams (mg) spinosad and 2.3 mg milbemycin oxime, 270 mg spinosad and 4.5 mg milbemycin oxime, 560 mg spinosad and 9.3 mg milbemycin oxime, 810 mg spinosad and 13.5 mg milbemycin oxime, or 1,620 mg spinosad and 27 mg milbemycin oxime.

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

(c) *Conditions of use in dogs—(1) Amount.* Administer once a month at a