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.

FOR FURTHER INFORMATION CONTACT:
Angela Clarke, Center for Veterinary Medicine, Rockville, MD 20852, 1–877–363–1594, angela.clarke@fda.hhs.gov.

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 Family Smoking Prevention and Tobacco Control Act, by revising the general requirements that apply to other tobacco products. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: April 14, 2011.


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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 520
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, Rockville, MD 20852, 202–262–8000, 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)(iii), 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 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:


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
minimum dosage of 13.5 mg/pound (lb) (30 mg/kilogram [kg]) of body weight spinosad and 0.2 mg/lb (0.5 mg/kg) of body weight milbemycin oxime.

(2) Indications for use. To kill fleas; for the prevention and treatment of flea infestations (*Ctenocephalides felis*); for the prevention of heartworm disease (*Dirofilaria immitis*); and for the treatment and control of adult hookworm (*Ancylostoma caninum*), adult roundworm (*Toxocara canis* and *Toxascaris leonina*), and adult whipworm (*Trichuris vulpis*) infections in dogs and puppies 8 weeks of age or older and 5 lbs of body weight or greater.

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

Dated: March 2, 2011.

Leslie Kux, Acting Assistant Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o U.S. Fish and Wildlife Service, Attention: Peter J. Probasco, Office of Subsistence Management; (907) 786–3888 or subsistence@fws.gov. For questions specific to National Forest System lands, contact Steve Kessler, Subsistence Program Leader, USDA, Forest Service, Alaska Region, (907) 743–9461 or skessler@fs.fed.us.

SUPPLEMENTARY INFORMATION:

Background

Under Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111–3126), the Secretary of the Interior and the Secretary of Agriculture (Secretaries) jointly implement the Federal Subsistence Management Program. This program provides a preference for take of fish and wildlife resources for subsistence uses on Federal public lands and waters in Alaska. The Secretaries published temporary regulations to carry out this program in the *Federal Register* on June 29, 1990 (55 FR 27114), and final regulations were published in the *Federal Register* on May 29, 1992 (57 FR 22940). The Program has subsequently amended these regulations a number of times. Because this program is a joint effort between Interior and Agriculture, these regulations are located in two titles of the Code of Federal Regulations (CFR): Title 36, “Parks, Forests, and Public Property,” and Title 50, “Wildlife and Fisheries,” at 36 CFR 242.1–28 and 50 CFR 100.1–28, respectively. The regulations contain subparts as follows: Subpart A, General Provisions; Subpart B, Program Structure; Subpart C, Board Determinations; and Subpart D, Subsistence Taking of Fish and Wildlife.

Consistent with subpart B of these regulations, the Secretaries established a Federal Subsistence Board to administer the Federal Subsistence Management Program. The Board is currently made up of:

- A Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture;
- The Alaska Regional Director, U.S. Fish and Wildlife Service;
- The Alaska Regional Director, U.S. National Park Service;
- The Alaska State Director, U.S. Bureau of Land Management;
- The Alaska Regional Director, U.S. Bureau of Indian Affairs; and
- The Alaska Regional Forester, U.S. Forest Service.

Through the Board, these agencies participate in the development of regulations for subparts C and D, which, among other things, set forth program eligibility and specific harvest seasons and limits.

In administering the program, the Secretaries divided Alaska into 10 subsistence resource regions, each of which is represented by a Regional Advisory Council. The Regional Advisory Councils provide a forum for rural residents with personal knowledge of local conditions and resource requirements to have a meaningful role in the subsistence management of fish and wildlife on Federal public lands in Alaska. The Regional Advisory Council members represent varied geographical, cultural, and user interests within each region.

The Board addresses customary and traditional use determinations during the applicable biennial cycle. Section 24 (customary and traditional use determinations) was originally published in the *Federal Register* on May 29, 1992 (57 FR 22940). The regulations at 36 CFR 242.4 and 50 CFR 100.4 define “customary and traditional use” as “a long-established, consistent pattern of use, incorporating beliefs and customs which have been transmitted from generation to generation.” Since 1992, the Board has made a number of customary and traditional use determinations at the request of affected subsistence users. These modifications, along with some administrative corrections, were published in the *Federal Register* as follows: