

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.*

[FR Doc. 2011-5147 Filed 3-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

## 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

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.*

[FR Doc. 2011-5144 Filed 3-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

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## DEPARTMENT OF AGRICULTURE

### Forest Service

#### 36 CFR Part 242

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 100

[Docket No. FWS-R7-SM-2009-0061; 70101-1261-0000L6]

RIN 1018-AW71

### Subsistence Management Regulations for Public Lands in Alaska—2011-12 and 2012-13 Subsistence Taking of Fish and Shellfish Regulations

**AGENCIES:** Forest Service, Agriculture; Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** This final rule establishes regulations for seasons, harvest limits, methods, and means related to taking of fish and shellfish for subsistence uses in Alaska during the 2011-12 and 2012-13 regulatory years. The Federal Subsistence Board (Board) completes the biennial process of revising subsistence hunting and trapping regulations in even-numbered years and subsistence fishing and shellfish regulations in odd-numbered years; public proposal and review processes take place during the preceding year.

The Board also addresses customary and traditional use determinations during the applicable biennial cycle. This rulemaking replaces the fish and shellfish taking regulations that expire on March 31, 2011. This rule also revises the address of the Office of Subsistence Management; the new address should be used to obtain maps delineating the boundaries of the subsistence resource regions.

**DATES:** This rule is effective April 1, 2011.

**ADDRESSES:** The Board meeting transcripts are available for review at the Office of Subsistence Management, 1011 East Tudor Road, Mail Stop 121, Anchorage, Alaska 99503, or on the Office of Subsistence Management Web site (<http://alaska.fws.gov/asm/index.cfm>).

**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](mailto: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](mailto: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. Those modifications, along with some administrative corrections, were published in the **Federal Register** as follows: