List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Revise § 522.812 to read as follows:

§ 522.812 Enrofloxacin.

(a) *Specifications*. Each milliliter (mL) of solution contains:

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerance*. See § 556.228 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

(e) *Conditions of use*—(1) *Dogs*. Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

(ii) *Indications for use*. For the management of diseases associated with bacteria susceptible to enrofloxacin.

(2) *Cattle*. Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount*. Single-dose therapy: 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 mL per 100 pounds) by subcutaneous injection. Multiple-day therapy: 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL per 100 pounds) by subcutaneous injection once daily for 3 to 5 days.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*.

(iii) *Limitations*. Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been establishedfor this product in pre-ruminating calves. Do not use in calves to be processed for veal. The effect of enrofloxacin on bovine reproductive performance, pregnancy, and lactation have not been determined.

Dated: February 28, 2007.

Steven D. Vaughn,

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

[FR Doc. E7–4206 Filed 3–8–07; 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; Imidacloprid and Moxidectin

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 two new animal drug applications (NADAs) filed by Bayer HealthCare LLC. The NADAs provide for the topical use by veterinary prescription of topical solutions containing imidacloprid and two strengths of moxidectin, one for use on dogs and the other for use on cats, for the prevention of heartworm disease, the treatment of flea infestations, and the treatment and control of several internal parasites.

DATES: This rule is effective March 9, 2007.

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

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141–251 that provides for veterinary prescription use of ADVANTAGE MULTI (imidacloprid 10% and moxidectin 2.5%) for Dogs, a topical solution used for the prevention of heartworm disease, the treatment of flea infestations, and the treatment and control of several internal parasites. Bayer HealthCare LLC also filed NADA 141–254 that provides for veterinary prescription use of ADVANTAGE MULTI (imidacloprid 10% and moxidectin 1%) for Cats, a topical solution used for the prevention of heartworm disease, the treatment of flea infestations, and the treatment and control of ear mites and several internal parasites. NADA 141–251 is approved as of December 20, 2006, and NADA 141–254 is approved as of January 19, 2007. Accordingly, the regulations are amended in part 524 (21 CFR part 524) by adding § 524.1146 to reflect these approvals.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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 under NADA 141–251 qualifies for 3 years of marketing exclusivity beginning December 20, 2006, and this approval under NADA 141–254 qualifies for 3 years of marketing exclusivity beginning January 19, 2007.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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 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. Add § 524.1146 to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

(a) *Specifications*—(1) Each milliliter of solution contains 100 milligrams (mg) imidacloprid and 25 mg moxidectin for use as in paragraph (d)(1) of this section.

(2) Each milliliter of solution contains 100 mg imidacloprid and 10 mg moxidectin for use as in paragraph (d)(2) of this section.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 1.1 mg/lb (2.5 mg/kg) moxidectin, once a month.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*; and the treatment and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and whipworms (*Trichuris vulpis*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(2) *Cats*—(i) *Amount.* Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin, once a month.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*; for the treatment and control of ear mite (*Otodectes cynotis*) infestations, intestinal roundworms (*Toxocara cati*), and hookworms (*Ancylostoma tubaeforme*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

Dated: February 27, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–4226 Filed 3–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[T.D. TTB–59; Re: Notice No. 60]

RIN 1513–AB22

Establishment of the Snake River Valley Viticultural Area (2005R–463P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: This Treasury decision establishes the 8,263-square mile ''Snake River Valley'' viticultural area in southwestern Idaho and southeastern Oregon. We designate viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

EFFECTIVE DATE: April 9, 2007.

FOR FURTHER INFORMATION CONTACT: N.A. Sutton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 925 Lakeville St., No. 158, Petaluma, CA 94952; phone 415–271–1254.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the regulations promulgated under the FAA Act.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) contains the list of approved viticultural areas.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been recognized and defined in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographical origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.3(b) of the TTB regulations requires the petition to include—

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that supports setting the boundary of the proposed viticultural area as the petition specifies;
- Evidence relating to the geographical features, such as climate, elevation, physical features, and soils, that distinguish the proposed viticultural area from surrounding areas;
- A description of the specific boundary of the proposed viticultural area, based on features found on United States Geological Survey (USGS) maps; and
- A copy of the appropriate USGS map(s) with the proposed viticultural area's boundary prominently marked.

Snake River Valley Viticultural Area

Background

The wine grape growers of the Snake River Valley in Idaho, the Idaho Grape Growers and Wine Producers Commission, and the Idaho Department of Commerce and Labor, collectively referred to as the ''petitioner,'' submitted a petition to establish the 8,263-square mile Snake River Valley viticultural area. The proposed viticultural area includes Ada, Adams, Boise, Canyon, Elmore, Gem, Gooding, Jerome, Owyhee, Payette, Twin Falls, and Washington Counties in southwestern Idaho and Baker and Malheur Counties in southeastern Oregon. The proposed boundary encompasses 15 wineries, 46 vineyards, and 1,107 acres of commercial vineyard production. We summarize below the supporting evidence presented with the petition.

Name Evidence

The petitioner provided multiple sources of ''Snake River Valley'' name evidence for the proposed viticultural area. References include winemaking and vineyards, agriculture, early regional exploration, and other name uses.

The Fall 2001 edition of Wine Press Northwest ran an article titled ''Idaho Wineries at a Glance,'' which states, ''At first glance, the Snake River Valley seems an idyllic place to grow grapes