

period and the inventory closing balance.

(2) *Notice of determination.* If, based on a verification of a declaration of compliance filed under this section, CBP determines that the applicable 75 or 85 percent standard specified in paragraph (b)(1)(i) or paragraph (b)(1)(ii) of this section was not met, CBP will publish a notice of that determination in the **Federal Register**.

PART 163—RECORDKEEPING

■ 5. The authority citation for Part 163 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1484, 1508, 1509, 1510, 1624.

■ 6. In the Appendix to Part 163 the listing under section IV of "§ 10.228 CBTPA Declaration of Compliance for brassieres" is republished.

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Approved: November 23, 2004.

Robert C. Bonner,

Commissioner of Customs and Border Protection.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 04-26359 Filed 11-29-04; 8:45 am]

BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

New Animal Drugs; Meloxicam

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 supplemental new animal drug applications (NADAs) filed by Boehringer Ingelheim Vetmedica, Inc. The first supplemental NADA provides for use of meloxicam injectable solution in cats for control of postoperative pain and inflammation associated with orthopedic surgery, ovariectomy, and castration when administered prior to surgery. It also provides revised dosage labeling for this product in dogs. The other supplemental NADA provides revised dosage labeling for use of meloxicam oral suspension in dogs.

DATES: This rule is effective November 30, 2004.

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.gov.

SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506-2002, filed a supplement to NADA 141-219 that provides for use of METACAM (meloxicam) Solution for Injection in cats for control of postoperative pain and inflammation associated with orthopedic surgery, ovariectomy, and castration when administered prior to surgery, and also revises dosage information for use of this product in dogs. Boehringer Ingelheim Vetmedica, Inc., also filed a supplement to NADA 141-213 that provides revised dosage information for use of METACAM (meloxicam) Oral Suspension in dogs. The supplemental NADAs are approved as of October 28, 2004, and the regulations are amended in 21 CFR 520.1350 and 522.1367 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

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)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), the supplemental approval of meloxicam injectable solution for use in cats qualifies for 3 years of marketing exclusivity beginning October 28, 2004.

The agency has determined under 21 CFR 25.33(d)(5) 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 Parts 520 and 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 parts 520 and 522 are 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. Section 520.1350 is amended by revising paragraph (c)(1) to read as follows:

§ 520.1350 Meloxicam.

* * * * *

(c) * * *

(1) *Amount.* Administer orally as a single dose at 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) on the first day of treatment. For all treatment after day 1, administer 0.045 mg/lb (0.1 mg/kg) body weight once daily.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Section 522.1367 is amended by revising paragraph (c) to read as follows:

§ 522.1367 Meloxicam.

* * * * *

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

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

(2) *Cats*—(i) *Amount.* Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariectomy, and castration when administered prior to surgery.

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

Dated: November 18, 2004.

Steven D. Vaughn,

*Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.*
[FR Doc. 04-26380 Filed 11-29-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[TTB T.D.-18; Re: Notice No. 14]

RIN: 1513-AA50

Establishment of the Dundee Hills Viticultural Area (2002R-218P)

AGENCY: Alcohol and Tobacco Tax and
Trade Bureau (TTB), Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: This Treasury decision establishes the Dundee Hills viticultural area in Yamhill County, Oregon. This new area is entirely within the existing Willamette Valley viticultural area. 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 DATES: January 31, 2005.

FOR FURTHER INFORMATION CONTACT: N. A. Sutton, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, 925 Lakeville St., #158, Petaluma, CA 94952; telephone 415-271-1254.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (the FAA Act, 27 U.S.C. 201 *et seq.*) requires that alcohol beverage labels provide the consumer with adequate information regarding a product's identity and prohibits the use of misleading information on such labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out its provisions. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers these regulations.

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 geographic 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, soils, elevation, and physical features, 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.

Dundee Hills Petition

General Background

In 2002, TTB received a petition from Alex Sokol Blosser, secretary of the North Willamette Valley AVA Group, proposing the establishment of the 6,490-acre "Red Hills" viticultural area in Yamhill County, Oregon. As explained below, the petitioner subsequently amended the area's name to "Dundee Hills." Located in northwest Oregon near the town of Newberg, the Dundee Hills viticultural area is about 28 miles southwest of Portland and 40

miles inland from the Pacific Ocean. The Dundee Hills area is entirely within the established Willamette Valley viticultural area (27 CFR 9.90). At the time of the petition, the Dundee area had 1,264 acres planted to grapes, with another 800 acres available for future vineyard use.

The Dundee Hills rise above the low, flat floors of the surrounding Willamette and Chehalem Valleys. These hills generally have peaks above 700 feet, with the highest peak rising to 1,067 feet. In addition to their higher elevation, warmer nighttime temperatures and less low-elevation fog and frost distinguish the Dundee Hills area from the surrounding valleys.

Below, we summarize the evidence presented in the petition.

Name Evidence

The North Willamette Valley AVA Group originally proposed the name "Red Hills," for this area, but after learning of other petitioners proposing the same (or a similar) name for other viticultural areas, the Group amended its petitioned name to "Red Hills of Dundee." The Group later amended its petitioned name to "Dundee Hills" to avoid possible confusion with other domestic and international "Red Hill" or "Red Hills" viticultural regions.

The amended petition included evidence showing that local residents, vintners, and others know the region as the "Dundee Hills." The October 2002 Yamhill County, Oregon, Verizon Super Pages telephone book includes "Dundee Hills Estate," while the "Shop Newberg" Web site lists "Dundee Hills Farm." Ellen McCornack's March 1912, Oregon Historical Society Quarterly article, "A Glimpse into Prehistoric Oregon," explains the Willamette Valley was a large, prehistoric body of water, and that "[a]cross a narrow straight from Chehalem was the island of the Dundee Hills * * *"

"In with the New World," an article in the fall/winter 1998 issue of Wine Press Northwest, lists several pioneer Oregon wine growers, including David Lett, who arrived in 1965 with:

a degree in viticulture from the University of California-Davis and a plan to find a cool climate suitable for planting pinot noir and other varieties from Burgundy. Lett decided on the Dundee Hills in the Willamette Valley * * *. Another early pioneer is Dick Erath of Erath Vineyards, also still producing great wine in the Dundee Hills near Newberg.

Fred Delkin, in a 2002 Oregon Magazine article, "Papa Pinot Still Preaching Gospel That Created an Industry," also notes that, in 1966, Lett planted "Pinot Noir and its cousin, Pinot Gris, in the Dundee hills area." A