

contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the SECG to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

**FOR FURTHER INFORMATION CONTACT:** Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5671, [sujaya.dessai@fda.hhs.gov](mailto:sujaya.dessai@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b), as amended by section 105 of the Animal Drug Use Fee Amendments of 2008 (ADUFA 105) (Pub. L. 110-316), to submit to us an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. We are also required by ADUFA 105 to publish annual summary reports of the data we receive from animal drug sponsors. In accordance with the law, sponsors of the affected antimicrobial new animal drug products began submitting their sales and distribution data to us on an

annual basis, and we have published summaries of such data for each calendar year beginning with 2009.

In the **Federal Register** of May 11, 2016 (81 FR 29129), we published a final rule entitled “Antimicrobial Animal Drug Sales and Distribution Reporting” that amended our existing records and reports regulation in part 514 (21 CFR part 514) to incorporate the sales and distribution data reporting requirements specific to antimicrobial new animal drugs that were added to the FD&C Act by ADUFA 105. The rule also added an additional reporting provision intended to improve our understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species. In accordance with the new rule, the sponsor of each approved or conditionally approved new animal drug product that contains an antimicrobial active ingredient must submit an annual report to us on the amount of each such ingredient in the drug product that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The final rule, which is codified at §§ 514.80 and 514.87, became effective July 11, 2016.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will not have a significant economic impact on a substantial number of small entities (81 FR 29129 at 29138). Nonetheless, we determined not to certify that finding due to the remote possibility that, in the future, a very small company could enter the market and sponsor an application for an antimicrobial new animal drug product that would be sold or distributed for use in food-producing animals. Thus, in compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available this SECG to explain the actions that a potential future market entrant small entity must take to comply with the rule.

We are issuing this SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

**II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 514.87 have been approved under OMB control number 0910-0659. The collections of information in § 514.80 have been approved under OMB control number 0910-0284.

**III. Electronic Access**

Persons with access to the internet may obtain the SECG at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: June 26, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF THE TREASURY**

**Alcohol and Tobacco Tax and Trade Bureau**

**27 CFR Part 9**

[Docket No. TTB-2016-0012; T.D. TTB-151; Ref: Notice No. 166]

**RIN 1513-AC33**

**Establishment of the Dahlonega Plateau Viticultural Area**

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

**ACTION:** Final rule; Treasury decision.

**SUMMARY:** The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes the approximately 133-square mile Dahlonega Plateau viticultural area in portions of Lumpkin and White counties in Georgia. The Dahlonega Plateau viticultural area is not located within any other established viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

**DATES:** This final rule is effective July 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Dana Register, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202-453-1039, ext. 022.

**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 FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120-01, dated December 10, 2013 (superseding Treasury Order 120-01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these laws.

Part 4 of the TTB regulations (27 CFR part 4) authorizes the establishment of definitive viticultural areas and regulates 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) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

*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 having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established 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 the wine's geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA 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 (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA boundary;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

**Dahlonega Plateau Petition**

TTB received a petition from Amy Booker, President of the Dahlonega-Lumpkin Chamber & Visitors Bureau, on behalf of the Vineyard and Winery Operators of the Dahlonega Region of Northern Georgia. The petitioner is proposing the establishment of the "Dahlonega Plateau" AVA in portions of Lumpkin and White counties in Georgia.

The proposed Dahlonega Plateau AVA derives its name from a long, narrow, northeast-southwest trending plateau in the northern foothills of the Georgia Piedmont known as the Dahlonega Plateau. The plateau covers most of Lumpkin, Dawson, White, Pickens, and Cherokee Counties. However, the proposed AVA is limited to the northeastern portion of the plateau, in Lumpkin and White Counties, due to a lack of viticulture in the southwestern region of the plateau, as well as topographical and climatic differences.

The proposed Dahlonega Plateau AVA covers approximately 133 square miles and is not located within any other AVA. The petition notes that, at present, there are 7 wineries and 8 commercial vineyards covering a total of approximately 110 acres distributed

throughout the proposed AVA. In the next few years, the proposed AVA would likely be expanded by an additional 12 acres of vineyards. According to the petition, the distinguishing features of the proposed Dahlonega Plateau AVA are its topography and climate. Unless otherwise noted, all information and data pertaining to the proposed AVA contained in this final rule comes from the petition for the proposed Dahlonega Plateau AVA and its supporting exhibits.

*Topography*

According to the petition, the distinctive topography of the proposed AVA is due to the underlying geology, which is comprised of layers of rocks that weather uniformly and are moderately resistant to erosion. Over time, wind and water have gradually worn down the underlying rocks and formed a gently rolling landscape with an average elevation of approximately 1,554 feet above sea level. The resulting broad, rounded hilltops separated by wide valleys have moderate slope angles and adequate sunlight for the cultivation of vineyards.

By contrast, the petition states that the topography of the regions surrounding the proposed AVA are less suitable for vineyards. The Blue Ridge Mountains and Hightower Ridges to the north, east, and southeast of the proposed AVA generally have higher elevations and narrow valleys that are often shadowed by the surrounding steep, high slopes. The steep, high slopes allow less light to reach any vineyard planted on the valley floors, when compared to vineyards planted in the proposed AVA. The steepness of the slopes would also make mechanical cultivation of any vineyard planted on the sides of the mountains impractical. In the lower elevations of the regions to the south and west of the proposed AVA, the cool air draining from higher elevations eventually settles and pools and would increase the risk of frost damage in any vineyard planted there.

*Climate*

The petition for the proposed Dahlonega Plateau AVA provided climate information including length of the growing season, growing degree day accumulations, and precipitation amounts from within the proposed AVA and the surrounding regions.

*Length of Growing Season*

According to the petition, the proposed Dahlonega Plateau AVA has a mean growing season length of 195 days. Over 60 percent of the terrain

within the proposed AVA has a growing season length in the range of 190 to 200 days. The petition cited a publication by the College of Agriculture and Life Sciences at Cornell University in conjunction with the Institute for the Application of Geospatial Technology,<sup>1</sup> which states that sites with growing seasons between 190 and 200 days are “not limited by growing season” because most grape varieties will be able to ripen within 200 days, while sites with growing seasons shorter than 160 days are not recommended for vineyards because most grape varieties would not have time to ripen fully. Based on this guidance, the petition proposes that the vineyard owners can plant many different grape varieties in the majority of the proposed AVA without the fear of having too short of a growing season for the grapes to ripen.

The petition also provided the growing season lengths for the areas surrounding the proposed AVA. The regions to the north and northeast each have a mean growing season of 164 days. Regions to the west and south, have growing seasons of 201 and 203 to 205 days, respectively. The proposed AVA has a higher percentage of terrain with a growing season length between 190 and 200 days than all surrounding areas except the Hightower Ridges to the east, where approximately 76 percent of the terrain is within this range of growing season lengths.

#### *Growing Degree Days*

The petition noted that although growing season length is important because it reflects the number of frost-free days, the temperatures that are reached during that frost-free period are just as important to viticulture. The petition further stated that grape vines do not grow and fruit does not mature when temperatures are below 50 degrees Fahrenheit (F). Therefore, a region that has a 180-day frost-free growing season would still be unsuitable for viticulture if temperatures seldom or never rise above 50 degrees F.

The petition presented growing degree days (GDD) data using the Winkler zone scale<sup>2</sup> from the very cool Zone I, for regions accumulating 2,500 or fewer GDDs in a growing season, to the very warm Zone V, for regions accumulating over 4,000 GDDs. The data showed that the terrain within the proposed Dahlenega Plateau AVA is classified in the intermediate ranges of

the Winkler scale (Zones III and IV). The proposed AVA has a higher percentage of terrain within Zone IV than any of the surrounding regions and lacks any terrain in the very cool Zone I, the cool Zone II, or the very warm Zone V. The petition indicated, that regions classified as Zones III or IV, such as the proposed AVA, are suitable for growing a diverse range of late-ripening grape varieties.

#### *Precipitation*

According to the petition, the rising elevations of the proposed Dahlenega Plateau AVA and the regions to the north and east cause the moisture-laden winds travelling inland from the Gulf of Mexico and Atlantic Ocean to drop their rain in the proposed AVA. Annual rainfall amounts within the proposed AVA are approximately 62 inches per year and 17 inches during the winter months. The regions to the north and east generally receive more rainfall annually and during winter than the proposed AVA, and the regions to the south and west generally receive less. The petition stated that the proposed AVA receives adequate annual rainfall amounts, which make vineyard irrigation seldom necessary. Furthermore, the petition provides data collected from the proposed AVA and surrounding regions showing that the low winter rainfall amounts within the proposed AVA are relevant to viticulture because, when compared to the data from the surrounding regions, low levels of rain in winter in the proposed AVA reduce the possibility of a delayed bud break and subsequent later harvest.

#### **Notice of Proposed Rulemaking and Comments Received**

TTB published Notice No. 166 in the **Federal Register** on December 2, 2016 (81 FR 86980), proposing to establish the Dahlenega Plateau AVA. In the notice, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features for the proposed AVA. The notice also compared the distinguishing features of the proposed AVA to the surrounding areas. For a detailed description of the evidence relating to the name, boundary, and distinguishing features of the proposed AVA, and for a detailed comparison of the distinguishing features of the proposed AVA to the surrounding areas, see Notice No. 166 and the petition for the proposed AVA, which are posted in Docket No. TTB–2016–0012 at <http://www.regulations.gov>. In Notice No. 166, TTB solicited comments on whether it should establish the proposed

viticultural area, and also asked for comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. The comment period closed on January 31, 2017.

In response to Notice No. 166, TTB received one comment, which supported the proposed AVA. The commenter stated that the Dahlenega plateau is a “gorgeous mountain region” that has “unique wine-growing characteristics” that qualify it as an AVA.

#### **TTB Determination**

After careful review of the petition and the comment received in response to Notice No. 166, TTB finds that the evidence provided by the petitioner supports the establishment of the Dahlenega Plateau AVA. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and parts 4 and 9 of the TTB regulations, TTB establishes the “Dahlenega Plateau” AVA in Lumpkin and Whites counties of Georgia, effective 30 days from the publication date of this document.

#### **Boundary Description**

See the narrative description of the boundary of the Dahlenega AVA in the regulatory text published at the end of this final rule.

#### **Maps**

The petitioner provided the required maps, and they are listed below in the regulatory text.

#### **Impact on Current Wine Labels**

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine’s true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

<sup>1</sup> A.N. Lakso & T.E. Martinson, “The Basics of Vineyard Site Evaluation and Selection” (2014), available at <http://arcserver2.iagt.org/vll/downloads/BasicSiteEvaluation-2015.pdf>.

<sup>2</sup> A.J. Winkler *et al.*, *General Viticulture* 60–71 (2nd. Ed. 1974).

With the establishment of this AVA, its name, “Dahlonge Plateau,” will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations. The text of the regulation clarifies this point. Consequently, wine bottlers using the name “Dahlonge Plateau” in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the AVA name as an appellation of origin. The establishment of the Dahlonge Plateau AVA will not affect any existing AVA. The establishment of the Dahlonge Plateau AVA will allow vintners to use “Dahlonge Plateau” as an appellation of origin for wines made primarily from grapes grown within the Dahlonge Plateau AVA if the wines meet the eligibility requirements for the appellation.

#### Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor’s efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

#### Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

#### Drafting Information

Dana Register of the Regulations and Rulings Division drafted this final rule.

#### List of Subjects in 27 CFR Part 9

Wine.

#### The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

#### PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

#### Subpart C—Approved American Viticultural Areas

■ 2. Subpart C is amended by adding § 9.263 to read as follows:

#### § 9.263 Dahlonge Plateau.

(a) *Name.* The name of the viticultural area described in this section is “Dahlonge Plateau”. For purposes of part 4 of this chapter, “Dahlonge Plateau” is a term of viticultural significance.

(b) *Approved maps.* The 9 United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the Dahlonge Plateau viticultural area are titled:

- (1) Dawsonville, GA, 1997;
- (2) Campbell Mountain, GA, 2014;
- (3) Nimblewill, GA, 1997;
- (4) Noontootla, GA, 1988;
- (5) Suches, GA, 1988;
- (6) Neels Gap, GA, 1988;
- (7) Dahlonge, GA, 1951;
- (8) Cowrock, GA, 1988; and
- (9) Cleveland, GA, 1951; photo revised 1973; photo inspected 1981.

(c) *Boundary.* The Dahlonge Plateau viticultural area is located in Lumpkin and White Counties, Georgia. The boundary of the Dahlonge Plateau viticultural area is as described below:

(1) The beginning point is found on the Dawsonville map at the marked 1,412-foot elevation point at the intersection of an unnamed light-duty road known locally as Castleberry Bridge Road and an unimproved road known locally as McDuffie River Road.

(2) From the beginning point, proceed north-northeast in a straight line approximately 0.89 mile to the marked 1,453-foot elevation point; then

(3) Proceed northwest in a straight line approximately 1.94 miles, crossing onto the Campbell Mountain map, to the intersection of Arrendale Road and Windy Oaks Road; then

(4) Proceed northwest in a straight line approximately 0.77 mile to the intersection of the 1,400-foot elevation contour and Dennson Branch; then

(5) Proceed northwest in a straight line approximately 0.79 mile to the intersection of the 1,360-foot elevation contour and Mill Creek; then

(6) Proceed northwest in a straight line approximately 0.48 mile to the intersection of the 1,500-foot elevation contour and Sheep Wallow Road; then

(7) Proceed northwest in a straight line approximately 1.74 miles to the intersection of State Route 52 and the Chattahoochee National Forest boundary; then

(8) Proceed northwest in a straight line approximately 1.89 miles, crossing onto the Nimblewill map and then crossing over the marked 1,749-foot elevation point along an unnamed light duty road known locally as Nimblewill Church Road, to the line’s intersection with the 1,800-foot elevation contour; then

(9) Proceed generally east-northeast along the 1,800-foot elevation contour approximately 170.72 miles (straight line distance between points is approximately 20.43 miles), crossing over the Noontootla, Suches, Neels Gap and Dahlonge maps and onto the Cowrock map, to the intersection of the 1,800-foot elevation contour with Tom White Branch; then

(10) Proceed southeast along Tom White Branch approximately 0.73 mile to the 1,600-foot elevation contour; then

(11) Proceed southeast in a straight line approximately 1.10 miles to the intersection of Cathey Creek and the secondary highway marked Alt. 75; then

(12) Proceed southwest in a straight line approximately 3.77 miles, crossing into the Cleveland map, to the intersection of two unnamed light-duty roads known locally as Dockery Road and Town Creek Road; then

(13) Proceed south in a straight line approximately 0.58 mile to the marked 1,774-foot elevation point; then

(14) Proceed southwest in a straight line approximately 0.60 mile to the 1,623-foot benchmark; then

(15) Proceed southwest in a straight line approximately 2.73 miles, crossing into the Dahlonge map, to the 1,562-foot benchmark; then

(16) Proceed southwest in a straight line approximately 3.46 miles to the marked 1,480-foot elevation point near the Mt. Sinai Church; then

(17) Proceed southwest in a straight line approximately 2.13 miles to the summit of Crown Mountain; then

(18) Proceed west in a straight line approximately 1.28 miles, crossing onto the Campbell Mountain map, to the intersection of the 1,160-foot elevation contour and Cane Creek; then

(19) Proceed southwest in a straight line approximately 1.61 miles to the intersection of the 1,300-foot elevation contour and Camp Creek; then

(20) Proceed southwest in a straight line approximately 2.02 miles, crossing into the Dawsonville map, to the intersection of the 1,200-foot elevation contour with the Etowah River, then

(21) Proceed southwest in a straight line approximately 1.29 miles to the beginning point.

Signed: March 6, 2018.

**John J. Manfreda,**  
Administrator.

Approved: June 25, 2018.

**Timothy E. Skud,**  
Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 2018–14035 Filed 6–28–18; 8:45 am]

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