

demonstrate that the device performs as intended under anticipated conditions of use.

(4) Professional training must include the ear impression procedure, correct placement, fitting, monitoring, care, and maintenance of the device.

(5) Labeling must include the following:

(i) A detailed summary of the adverse events and effectiveness outcomes from the clinical performance testing;

(ii) Detailed instructions on how to fit the device to the patient;

(iii) Instructions for periodic cleaning of any reusable components;

(iv) Information related to electromagnetic compatibility; and

(v) Patient labeling that includes:  
(A) A patient card that identifies if a patient has been fitted with any non-self-removable components of the device and provides relevant information in cases of emergency;

(B) Information on how to correctly use and maintain the device;

(C) The potential risks and benefits associated with the use of the device; and

(D) Alternative treatments.

Dated: January 13, 2016.

**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-2015-0004; T.D. TTB-132; Ref: Notice No. 148]

RIN 1513-AC11

#### Establishment of the Los Olivos District 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 22,820-acre “Los Olivos District” viticultural area in Santa Barbara County, California. The viticultural area is located within the Santa Ynez Valley viticultural area and the larger, multicounty Central Coast 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 February 22, 2016.

#### FOR FURTHER INFORMATION CONTACT:

Karen A. Thornton, 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. 175.

#### 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 Department Order 120-01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these provisions.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate 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.

###### Los Olivos District Petition

TTB received a petition from C. Frederic Brander, owner and winemaker of the Brander Vineyard, proposing the establishment of the “Los Olivos District” AVA in Santa Barbara County, California. There are 12 bonded wineries and approximately 47 commercially producing vineyards covering a total of 1,120 acres within the proposed AVA. The proposed Los Olivos District AVA shares its western boundary with the eastern boundary of the Ballard Canyon AVA (27 CFR 9.230) and its eastern boundary with the western boundary of the Happy Canyon of Santa Barbara AVA (27 CFR 9.217), but it does not overlap either of these AVAs. It is located within the Santa Ynez Valley viticultural area and the larger, multicounty Central Coast viticultural area.

According to the petition, the distinguishing features of the proposed Los Olivos District AVA include its topography, soils, and climate. The proposed AVA is located on a broad alluvial terrace plain of the Santa Ynez

River. The topography of the proposed AVA is relatively uniform, with nearly flat terrain that gently slopes southward toward the Santa Ynez River. The lack of steeply sloped hills reduces the risk of erosion and facilitates mechanical tiling and harvesting in the vineyards. Additionally, the open terrain allows vineyards throughout the proposed AVA to receive uniform amounts of sunlight, rainfall, and temperature-moderating fog because there are no significant hills or mountains within the proposed AVA to block the rainfall and fog or to shade the vineyards. By contrast, the regions surrounding the proposed Los Olivos District all have higher elevations and steep, rugged terrain.

Over 95 percent of the soils within the proposed Los Olivos District AVA are from the Positas–Ballard–Santa Ynez soil association and are derived from alluvium, including Orcutt sand and terrace deposits. The soils are moderately to well drained gravelly fine sandy loams and clay loams with low to moderate fertility. The soils within the proposed AVA drain quickly enough to reduce the risk of root disease but do not drain so excessively as to require frequent irrigation. Soil nutrient levels within the proposed AVA are adequate to produce healthy vines and fruit without promoting excessive growth. By contrast, the majority of soils in the surrounding regions are not from the Positas–Ballard–Santa Ynez soil association and are generally less fertile and drain faster.

Within the Central Coast AVA, where the proposed Los Olivos District AVA is located, temperatures are affected by cooling marine fog. However, the proposed Los Olivos District AVA is located about 30 miles inland from the Pacific Ocean, so much of the marine fog has diminished by the time it reaches the proposed AVA in the late afternoon. The thin fog within the proposed AVA allows the daytime temperatures to rise higher and the nighttime temperatures to drop lower than in the regions farther to the west, where heavy fog is present throughout the day. The region to the east receives even less fog than the proposed AVA, so daytime temperatures rise higher and nighttime temperatures drop lower. The warm daytime temperatures within the proposed AVA encourage fruit maturation and sugar production, and the cool nighttime temperatures minimize acid loss.

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

TTB published Notice No. 148 in the **Federal Register** on March 3, 2015 (80

FR 11355), proposing to establish the Los Olivos District AVA. In the document, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features for the proposed AVA. The document also compared the distinguishing features of the proposed AVA to the surrounding areas. In Notice No. 148, TTB solicited comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. In addition, TTB solicited comments on whether the geographic features of the proposed Los Olivos District are so distinguishable from the established Santa Ynez Valley AVA and the Central Coast AVA that the proposed AVA should not be part of either established AVA. The comment period closed on May 4, 2015.

In response to Notice No. 148, TTB received 76 comments, all of which supported the establishment of the Los Olivos District AVA, with many citing to its distinct topography, climate, and soils. The comments did not raise any new issues concerning the proposed AVA. TTB received no comments opposing the establishment of the Los Olivos District AVA. TTB also did not receive any comments in response to its question of whether the proposed Los Olivos District AVA is so distinguishable from the established Santa Ynez Valley AVA or the established Central Coast AVA that the proposed AVA should not be part of either established AVA.

#### **TTB Determination**

After careful review of the petition and the comment received in response to Notice No. 148, TTB finds that the evidence provided by the petitioner supports the establishment of the Los Olivos District AVA. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and part 4 of the TTB regulations, TTB establishes the “Los Olivos District” AVA in Santa Barbara County, California, effective 30 days from the publication date of this document.

TTB has also determined that the Los Olivos District AVA will remain part of both the established Santa Ynez Valley AVA and the established Central Coast AVA. As discussed in Notice No. 148, the Los Olivos District AVA receives some of the marine breezes and fog that are the primary characteristics of both the Santa Ynez Valley AVA and the Central Coast AVA. However, due to its central location within the Santa Ynez Valley AVA, the Los Olivos District AVA receives less marine air and heavy fog than the western portion of the

Santa Ynez Valley AVA, which is closer to the Pacific Ocean, and it receives more cooling breezes and fog than the eastern portion. The topography of the Los Olivos District AVA is also more uniform than that of the Santa Ynez Valley AVA, which has mountains and canyons as well as flatter terrain. Additionally, due to its smaller size, the Los Olivos District AVA is more uniform in its geographical and climatic characteristics than the much larger, multicounty Central Coast AVA.

#### **Boundary Description**

See the narrative description of the boundary of the 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.

With the establishment of this AVA, its name, “Los Olivos District,” is recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). The text of the regulation clarifies this point. Consequently, wine bottlers using the name “Los Olivos District” 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. In Notice No. 148, TTB proposed to recognize “Los Olivos,” standing alone, as a term of viticultural significance. However TTB is not designating “Los Olivos,”

standing alone, as a term of viticultural significance in this final rule. We make this change in light of new information concerning the current use of “Los Olivos” on wine labels.

The approval of the Los Olivos District AVA does not affect any existing AVA, and this approval does not affect any bottlers using “Central Coast” or “Santa Ynez Valley” as an appellation of origin or in a brand name for wines made from grapes grown within the Central Coast or Santa Ynez Valley AVAs. The establishment of the Los Olivos District AVA allows vintners to use “Los Olivos District,” “Santa Ynez Valley,” and “Central Coast” as appellations of origin for wines made from grapes grown within the Los Olivos District 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

Karen A. Thornton 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. Add § 9.253 to subpart C to read as follows:

#### § 9.253 Los Olivos District.

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

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

- (1) Los Olivos, CA, 1995;
- (2) Zaca Creek, Calif., 1959;
- (3) Solvang, CA, 1995; and
- (4) Santa Ynez, CA, 1995.

(c) *Boundary.* The Los Olivos District viticultural area is located in Santa Barbara County, California. The boundary of the Los Olivos District viticultural area is as described below:

(1) The beginning point is on the Los Olivos map at the intersection of Foxen Canyon Road with California State Road 154 (known locally as San Marcos Pass Road/Chumash Highway), section 23, T7N/R31W.

(2) From the beginning point, proceed southwesterly in a straight line approximately 0.3 mile, crossing onto the Zaca Creek map, to the intersection of Ballard Canyon Road and an unnamed, unimproved road known locally as Los Olivos Meadows Drive, T7N/R31W; then

(3) Proceed south-southeasterly in a straight line approximately 1 mile, crossing onto the Los Olivos map, to a marked, unnamed structure within a circular-shaped 920-foot contour line in the southwest corner of section 26, T7N/R31W; then

(4) Proceed south-southwesterly in a straight line approximately 1.25 miles, crossing onto the Zaca Creek map, to the point marked by the “Ball” 801-foot elevation control point, T6N/R31W; then

(5) Proceed south-southwesterly in a straight line approximately 1.45 miles, crossing onto the Solvang map, to a marked, unnamed 775-foot peak, T6N/R31W; then

(6) Proceed south-southwesterly in a straight line approximately 0.55 mile to a marked communication tower located within the 760-foot contour line, T6N/R31W; then

(7) Proceed south-southeasterly in a straight line approximately 0.6 mile to the intersection of Chalk Hill Road with an unnamed creek descending from Adobe Canyon, northwest of the unnamed road known locally as Fredensborg Canyon Road, T6N/R31W; then

(8) Proceed southwesterly (downstream) along the creek approximately 1 mile to the creek's

intersection with the Santa Ynez River, T6N/R31W; then

(9) Proceed easterly (upstream) along the Santa Ynez River approximately 8 miles, crossing onto the Santa Ynez map, to the river's intersection with State Highway 154, T6N/R30W; then

(10) Proceed north-northwest in a straight line approximately 1.2 miles to the marked 924-foot elevation point, T6R/R30W; then

(11) Proceed north-northwest in a straight line 1.2 miles to the “Y” in an unimproved road 0.1 mile south of the 800-foot contour line, west of Happy Canyon Road, T6R/R30W; then

(12) Proceed north-northwest in a straight line for 0.5 mile, crossing onto the Los Olivos map, and continuing approximately 2.3 miles to the third intersection of the line with the 1,000-foot contour line northwest of BM 812, T7N/R30W; then

(13) Proceed westerly along the meandering 1,000-foot contour line to the contour line's intersection with an unnamed, unimproved road, an unnamed light-duty road, and the northern boundary line of section 23, T7N/R31W; then

(14) Proceed northerly, then westerly, along the unnamed, unimproved road to Figueroa Mountain Road, near the marked 895-foot elevation, T7N/R31W; then

(15) Proceed north on Figueroa Mountain Road approximately 400 feet to the 920-foot contour line, T7N/R31W; then

(16) Proceed initially south, then northwesterly along the meandering 920-foot contour line, crossing onto the Zaca Creek map, to Foxen Canyon Road, T7N/R31W; then

(17) Proceed southeasterly on Foxen Canyon Road approximately 1.7 miles, crossing onto the Los Olivos map, returning to the beginning point.

Signed: December 9, 2015.

**John J. Manfreda,**  
Administrator.

Approved: January 14, 2016.

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

[FR Doc. 2016–01155 Filed 1–20–16; 8:45 am]

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