

the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following District of Columbia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Act 2-79, section 5, except as provided in paragraph (a) of this section.

Dated: November 25, 1981.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and
Firearms

27 CFR Part 9

[T.D. ATF-96; Re: Notice No. 360]

Sonoma Valley Viticultural Area; Establishment

AGENCY: Bureau of Alcohol, Tobacco
and Firearms, Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area in Sonoma County, California, named "Sonoma Valley." The Bureau of Alcohol, Tobacco and Firearms (ATF) believes the establishment of the Sonoma Valley viticultural area and the subsequent use of its name as an appellation of origin on wine labels and in wine advertisements will help consumers to identify the wines from this distinctive grape-growing area. The use of this viticultural area as an appellation of origin will also help winemakers distinguish their products from wines made in other areas.

EFFECTIVE DATE: January 4, 1982.

FOR FURTHER INFORMATION CONTACT:
John A. Linthicum, Research and
Regulations Branch, Bureau of Alcohol,
Tobacco and Firearms, Washington, DC
20226 (202 566-7602).

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37672, 54624) revising regulations in 27 CFR Part 4. These regulations allow the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements. Section 4.25a(e)(1) defines an American

viticultural area as a delimited grape-growing region distinguishable by geographical features. Section 4.25a(e)(2) outlines procedures for proposing an American viticultural area.

In response to a petition, ATF published a notice of proposed rulemaking in the Federal Register on December 15, 1980 (45 FR 82470), proposing the Sonoma Valley viticultural area in Sonoma County, California. ATF solicited written comment and held a public hearing on the proposal on January 13, 1981, in Santa Rosa, California.

ATF received several comments relating to Sonoma Valley among the numerous comments relating to the five viticultural areas proposed in Notice No. 360. All of the comments relating to Sonoma Valley were generally in favor of establishment of the Sonoma Valley viticultural area. Some commenters submitted additional historical evidence relating to the name.

Historical Evidence

The Sonoma Valley viticultural area has a long history of grape growing and wine making. In 1825, the first grapes were planted in Sonoma at the Mission San Francisco de Solano. In 1834, General Mariano Guadalupe Vallejo expanded these plantings. In the 1850's, the first major plantings of *Vitis vinifera* in the United States were established in the Sonoma Valley area. By 1900, there were approximately 4,000 acres of vines in the Sonoma Valley. The area has continued to be a center for grape production and wine making. Thus, ATF feels the viticultural area meets the requirement of 27 CFR 9.3(b)(1) that the name of the viticultural area is locally or nationally known as referring to the area specified in the viticultural area proposal.

Several persons testified at the public hearing that the proposed boundaries reasonably delineate the area historically known as "Sonoma Valley." Based on the record of the rulemaking proceedings, ATF feels that the boundaries described in 27 CFR 9.29 delineate the area historically known as Sonoma Valley, as required by 27 CFR 9.3(b)(2).

Geographical Features

Under 27 CFR 9.3(b)(3), a viticultural area must possess geographical features which distinguish the viticultural features of the area from surrounding areas. Based on the record, ATF believes that the Sonoma Valley viticultural area is distinguishable from the surrounding areas because of its climate.

The viticultural area, located in the southeastern corner of Sonoma County, receives less rainfall than other portions of Sonoma County north of the city of Santa Rosa. In addition, the Sonoma Mountains, ranging along the western border of the viticultural area, prevent the heavy fog often found in the area of Petaluma from intruding into most of the Sonoma Valley area. These same mountains along with the Mayacamas Range on the eastern boundary of the viticultural area geographically isolate the area from surrounding areas. This geographical isolation and the proximity of the San Pablo Bay on the southern end of the area combine to moderate the summer and winter temperature extremes in the valley.

Boundaries

Much of the hearing testimony was on the proposed boundaries with controversy arising over the boundaries in the northeastern and southeastern corners of the viticultural area. One vineyard owner felt that the northeastern corner of the Sonoma Valley viticultural area should be part of a future viticultural area which he planned to propose. He stated that he did not object, however, to the proposed Sonoma Valley boundaries as long as the approval of the boundary would not preclude a future viticultural area from partially overlapping that corner of the Sonoma Valley viticultural area. ATF does not object to a proposed viticultural area solely on the grounds that it may partially overlap another area. Each area must be judged individually on the criteria required in the regulations. Each area must meet the same requirements concerning the area's proposed name and the presence of distinguishing geographical characteristics. In addition, the establishment of viticultural areas is an evolutionary process. ATF will continue to consider any new information concerning viticultural areas. The boundary in the northeast corner of the Sonoma Valley viticultural area is drawn along the peaks of the mountains surrounding Sonoma Valley. ATF feels that this boundary delineates an area which meets the requirements for a viticultural area. This area includes the area traditionally known as Sonoma Valley and which possesses generally similar geographical features which distinguish it from the surrounding areas.

The boundary in the southeastern corner of the viticultural area was controversial because it conflicted with the previously proposed Napa Valley viticultural area by including a small

portion in Napa County bounded by Los Amigos, Duhig, and Ramal Roads. ATF subsequently approved the Napa Valley viticultural area (including this disputed portion) using the Sonoma County-Napa County line as the boundary (46 FR 9061). This boundary is based on historical evidence presented at the Napa Valley hearing indicating that that part of Napa County has been traditionally known as part of "Napa Valley." ATF does not feel that there is sufficient evidence indicating that any portion of Napa County has been traditionally considered a part of "Sonoma Valley" or any portion of Sonoma County has been part of "Napa Valley." Each viticultural area has been traditionally identified with the county of the same name. ATF is establishing the county line as the common boundary between the two areas. Therefore, the area in Napa County bounded by Los Amigos, Duhig, and Ramal Roads and proposed as part of the Sonoma Valley viticultural area will remain in the Napa Valley area and not become part of the Sonoma Valley area.

At the public hearing a commenter suggested that the final regulations should allow property owners whose property is divided by the viticultural area boundary to choose whether their property, in its entirety, is in or out of the viticultural area.

ATF believes that although there may be some viticultural similarities between an area in Napa County and an area in the Sonoma Valley viticultural area, the area in Napa County does not meet the requirements of 27 CFR 9.3(b)(1) since the area has not been known as Sonoma Valley.

Also, property located outside the boundaries of a viticultural area may not be included in that viticultural area even if it is part of a larger parcel of property divided by the viticultural area boundary. ATF believes that to hold otherwise would make the regulations meaningless and possibly mislead consumers of wines labeled with a viticultural area appellation of origin.

Finally, evidence was presented at both the Napa Valley and Sonoma Valley hearings indicating that the United States Geological Survey (USGS) maps are inaccurate and are different from the actual county line as drawn by the tax assessors of both Napa County and Sonoma County. ATF is using the actual Napa County-Sonoma County line as the eastern boundary of the Sonoma Valley viticultural area regardless of where the USGS maps place it. ATF normally uses USGS maps because they are generally available throughout the United States. However, in this case, ATF is using the Sonoma

County tax assessor's maps as the approved maps defining the Sonoma County-Napa County line.

Regulatory Flexibility Act

Section 4 of Pub. L. 96-354, the Regulatory Flexibility Act, specifically waives the requirements for an initial regulatory flexibility analysis and a final regulatory flexibility analysis for any rule for which the notice of proposed rulemaking was issued before January 1, 1981. The applicable notice of proposed rulemaking for this final rule was published in the Federal Register on December 15, 1980 at 45 FR 82470.

Effective Date

These regulations are effective January 4, 1982. However, since 27 CFR 4.25a, which allows the name of an approved American viticultural area to be used as an appellation of origin, is not mandatory before January 1, 1983, and the name "Sonoma Valley" is currently used as an appellation on wine labels, ATF has determined that Section 9.29 establishing specific boundaries for the Sonoma Valley viticultural area will not be mandatory before January 1, 1983.

Compliance with E.O. 12291

In compliance with Executive Order 12291 ATF has determined that this final rule is not a major rule since it will not result in—

- (a) An annual effect on the economy of \$100 million or more;
- (b) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographical regions; or
- (c) Significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Drafting Information

The principal author of this document is Thomas Minton of the Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms.

Authority and Issuance

This Treasury decision issued under the authority of 27 U.S.C. 205.

Regulations

On the basis of the foregoing, 27 CFR Part 9 is amended by the addition of § 9.29 as follows:

PART 9—AMERICAN VITICULTURAL AREAS

1. The table of sections in 27 CFR Part 9 is amended to include the title of

§ 9.29. As amended the table of sections reads as follows:

Subpart C—Approved American Viticultural Areas

Sec.

* * * * *

9.29 Sonoma Valley (not mandatory before January 1, 1983).

* * * * *

2. Subpart C, 27 CFR Part 9, is amended by adding § 9.29. As amended, Subpart C reads as follows:

Subpart C—Approved American Viticultural areas

* * * * *

§ 9.29 Sonoma Valley (not mandatory before January 1, 1983).

(a) *Name.* The name of the viticultural area described in this section is "Sonoma Valley."

(b) *Approved Maps.* The maps showing the boundaries of the Sonoma Valley viticultural area are the—

- (1) "Cuttings Wharf, Calif." USGS 7.5 minute quadrangle;
- (2) "Petaluma Point, Calif." USGS 7.5 minute quadrangle;
- (3) "Sears Point, Calif." USGS 7.5 minute quadrangle;
- (4) "Petaluma River, Calif." USGS 7.5 minute quadrangle;
- (5) "Glen Ellen, Calif." USGS 7.5 minute quadrangle;
- (6) "Cotati, Calif." USGS 7.5 minute quadrangle;
- (7) "Santa Rosa, Calif." USGS 7.5 minute quadrangle;
- (8) "Kenwood, Calif." USGS 7.5 minute quadrangle; and

(9) Appropriate Sonoma County tax assessor's maps showing the Sonoma County-Napa County line.

(c) *Boundaries.* The Sonoma Valley viticultural area is located within Sonoma County, California. From the beginning point at the junction of Tolay Creek and San Pablo Bay, the boundary runs—

- (1) Northerly along Tolay Creek to Highway 37;
- (2) Westerly along Highway 37 to its junction with Highway 121;
- (3) Northwesterly in a straight line to the peak of Wildcat Mountain;
- (4) Northwesterly in a straight line to Sonoma Mountain to the horizontal control station at elevation 2,271 feet;
- (5) Northwesterly in a straight line to the peak of Taylor Mountain;
- (6) Northeasterly in a straight line to the point at which Los Alamos Road joins Highway 121;
- (7) Easterly in a straight line to the peak of Buzzard Peak;

(8) Easterly in a straight line to the peak of Mount Hood;

(9) Easterly in a straight line to an unnamed peak located on the Sonoma County-Napa County line and identified as having an elevation of 2,530 feet (This unnamed peak is located in the northeast quarter of Section 9, Township 7 North, Range 6 West, Mt. Diablo Base and Meridian);

(10) Southerly along the Sonoma County-Napa County line to the point at which Sonoma Creek enters San Pablo Bay; and

(11) Southwesterly along the shore of San Pablo Bay to the beginning point.

Signed: October 9, 1981.

G. R. Dickerson,
Director.

Approved: November 18, 1981.

John P. Simpson,

Acting Assistant Secretary (Enforcement and Operations).

[FR Doc. 81-34780 Filed 12-3-81; 8:45 am]

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27 CFR Part 9

[T.D. ATF-98; Ref: Notice No. 360]

Establishment of Santa Cruz Mountains Viticultural Area, California

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area in portions of San Mateo, Santa Clara, and Santa Cruz Counties, California, to be named "Santa Cruz Mountains." The Bureau of Alcohol, Tobacco and Firearms (ATF) believes the establishment of viticultural areas and their subsequent use as appellations of origin in wine labeling and advertising will allow wineries to better designate the specific grape-growing areas where their wines come from and will enable consumers to better identify the wines they purchase.

EFFECTIVE DATE: January 4, 1982.

FOR FURTHER INFORMATION CONTACT: Roger L. Bowling, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226 (202-566-7626).

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37671, 54624) revising regulations in 27 CFR Part 4. These regulations allow for the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to

be used as an appellation of origin in wine labeling and advertising.

Section 4.25a(e)(1) defines an American viticultural area as a delimited grape-growing region distinguishable by geographic characteristics. Section 4.25a(e)(2) outlines the procedures for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area.

The Santa Cruz Mountains Vintners submitted a petition to establish a viticultural area in portions of San Mateo, Santa Clara, and Santa Cruz Counties, California, to be named "Santa Cruz Mountains." In response to this petition, ATF published a notice of proposed rulemaking, Notice No. 360, in the Federal Register on December 15, 1980 (45 FR 82275), proposing the establishment of the Santa Cruz Mountains as a viticultural area.

Public Hearing

A public hearing was held on this issue on January 19, 1981, in Santa Clara, California. Nine persons testified at the hearing. The evidence gathered at this hearing and the petition and comments received was sufficient for ATF to base its final decision concerning the Santa Cruz Mountains.

Historical and Current Evidence of the Name

Testimony at the hearing established that the name, "Santa Cruz Mountains", was used to designate an area having a long history as a grape-growing region in California.

The area has been recorded as the "Santa Cruz Mountains" since 1838. As early as 1867, when the first government surveyor laid section lines in the area, the vineyards of the region were noted. Moreover, numerous books and articles dealing with wine refer to the "Santa Cruz Mountains" as a specific grape-growing area. Testimony was also received which indicated that although the proposed area encompassed parts of three counties, the "Santa Cruz Mountains" constitutes a well-defined area forming a distinct geographical and phytogeographical unit.

ATF believes this testimony establishes the historical and current use of the name, Santa Cruz Mountains, as a distinguishable region and is the most appropriate for the viticultural area.

Geographical Evidence

In accordance with 27 CFR 4.25a(e)(2), a viticultural area should possess geographical features which distinguish the viticultural area from surrounding

grape-growing areas. The petitioner claimed the "Santa Cruz Mountains" possesses a soil type, climate, and protective setting which provides a singular viticultural identity.

The petitioner stated that the "Santa Cruz Mountains" is characterized by a climate which is greatly influenced in the western portion by the Pacific Ocean breezes and fog movements, and in the eastern portion by the moderating influences of the San Francisco Bay. These two influences tend to produce weather which is generally cool during the growing season. Temperatures in the slopes of the hillsides where most of the vineyards are located appear to vary from that at the lower elevations. This is caused by the marine influence coming off the Pacific Ocean which cools the mountains at night much more than the valley floor.

The area is characterized by a growing season in excess of 300 days. This is apparently due to cool air coming down the mountains forcing warmer air upward, thereby lengthening the season in which the necessary conditions for grape-growing are present. Moreover, while the climate, in terms of temperature can be characterized as mild, the "Santa Cruz Mountains" has an average rainfall much greater than the surrounding areas.

The soils in the proposed area were identified as Franciscan shale which is unique to this particular area south of San Francisco. The soil is basically residual material from the decomposition of bedrock and the soil types in the area differ depending on the type of underlying bedrock. Generally, these residual soils tend to be thin and stony, and somewhat excessively drained. They were characterized as impoverished, making it extremely difficult to grow grapes. This contrasts greatly with the soil of the surrounding area which is primarily alluvium and is more fertile.

Based on this evidence, ATF has determined that the Santa Cruz Mountains is viticulturally distinguishable from the surrounding areas. This is based upon the evidence presented regarding the rainfall, soil, and general climate. The Santa Cruz Mountains can be seen as a defined area exhibiting features and characteristics unique to its boundaries when compared to the surrounding area.

Boundaries

The boundaries of the "Santa Cruz Mountains" viticultural area are based, in general, on contour lines and man-made features. Evidence was presented at the hearing that the contour lines