

industry to develop procedures to implement the effective date, the agency is announcing an interim stay of the retail level effective date in a document published elsewhere in this issue of the **Federal Register**.

In addition to relying on its own study to determine the quantities of OTC products that are not in compliance with the tamper-resistant packaging requirements in retail channels, the agency is seeking comments, data, and information that may be helpful to it in reviewing the necessity for a retail level effective date of what alternative measures may be appropriate.

The options before the agency include the following:

1. At the end of the agency's review it may establish a new retail level effective date and implement it.

2. The agency may modify the retail level effective date concept (e.g., to establish a wholesale level effective date in place of a retail level effective date).

3. The agency may withdraw the retail level effective date requirement completely.

If options 1 or 2 were selected, the agency would provide adequate time for the industry to implement the necessary procedures. The agency's current plan is that if one of these options is selected, the effective date would be 4 months after the date that the agency's decision is published as a final rule in the **Federal Register**.

In addition to evaluating its own study, the agency is seeking comments generally and, in particular, on specific questions related to the retail level effective date. The agency is especially interested in receiving comments responding to the following questions:

1. How should the agency determine whether a retail level effective date is necessary based on results of its survey?

Once the agency determines an approximate level of compliance that can be anticipated for the retail level, it must make a decision as to what level of noncompliance constitutes a trivial hazard to the consumer and a minimal potential for tampering. The agency is seeking advice on what that level should be and what constitutes an appropriate method for determining that level.

2. What are the costs of implementing a wholesale level effective date and what are the costs of implementing a retail level effective date? Among the options that are available is a modification of a full scale, retail level effective date. The agency needs to determine for its decisionmaking the costs associated with both a wholesale and a retail level effective date.

3. How much time is needed by industry to implement a retail or wholesale level effective date if a decision is made to require either?

If the agency determines that a retail level effective date is appropriate, the agency would want to avoid a disruption in the marketplace that might lead to drug shortages and therefore affect the availability of affected products or their prices. Therefore, the agency needs information in addition to what it already has regarding the time that is necessary to avoid disruptions in the OTC marketplace that may result from the elimination of products that are not in tamper-resistant packaging.

Although the agency is evaluating the need for the retail level effective date, the agency reemphasizes its commitment to the goal of compliance with the tamper-resistant packaging regulations to minimize the opportunity for tampering with OTC products.

Economic Considerations

FDA has examined the regulatory impact and regulatory flexibility implications of this proposed rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act. Because this proposed rule would stay the retail level effective date, it would postpone any effects on products in non-tamper-resistant packages. Therefore, the proposal would not be a major rule as specified in the Order and would not have a significant economic impact on a substantial number of small entities.

Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(d) (12) and (13) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 211

Drugs, manufacturing, Labeling, Laboratories, Packaging and containers, Warehouses.

21 CFR Part 700

Cosmetics, Definitions, Prohibited cosmetic ingredients.

21 CFR Part 800

Administrative detention, Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n),

501, 502, 505, 506, 507, 515, 521, 601, 602, 701, 52 Stat. 1041 as amended, 1049-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 90 Stat. 552-559, 574 (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 360e, 360k, 361, 362, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Parts 211, 700, and 800 be amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

§ 211.132 [Stayed in part]

1. In Part 211 by staying paragraph (g)(3) of § 211.132, *Tamper-resistant packaging requirements for over-the-counter drug products*.

PART 700—GENERAL

§ 700.25 [Stayed in part]

2. In Part 700 by staying paragraph (e)(3) of § 700.25, *Tamper-resistant packaging requirements for cosmetic products*.

PART 800—GENERAL

§ 800.12 [Stayed in part]

3. In Part 800 by staying paragraph (f)(3) of § 800.12 *Contact lens solutions and tablets; tamper-resistant packaging*.

Interested persons may, on or before October 17, 1983, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 12, 1983.

Mark Novitch,
Acting Commissioner of Food and Drugs.

[FR Doc. 25294 Filed 9-15-83. 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[Notice No. 485]

Clarksburg Viticultural Area

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is considering the establishment of a viticultural area in north central California, to be known as "Clarksburg." This proposal is the result of a petition submitted by the Clarksburg Vintners and Growers Association. ATF feels that the establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising will help consumers identify the wines they may purchase.

DATE: Written comments must be received by October 17, 1983.

ADDRESS: Send written comments to: Chief, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044-0385, (Notice No. 485).

Copies of the petition, the proposed regulations, the appropriate maps, and the written comments will be available for public inspection during normal business hours at: ATF Reading Room, Room 4407, Federal Building, 12th and Pennsylvania Avenue, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW, Washington, DC 20226 (202-566-7626).

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.

On October 2, 1979, ATF published Treasury Decision ATF-60 (44 FR 56692) which added a new Part 9 to 27 CFR, providing for the listing of approved American viticultural areas, the names of which may be used as appellations of origin.

Section 4.25a(e)(1), Title 27, CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been delineated in Subpart C of Part 9.

Section 4.25a(e)(2), outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area. The petition should include:

(a) Evidence that the name of the proposed viticultural area is locally

and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence relating to the geographical characteristics (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;

(d) A description of the specific boundaries of the viticultural area, based on features which can be found on United States Geological Survey (U.S.G.S.) maps of the largest applicable scale; and

(e) A copy of the appropriate U.S.G.S. maps with the boundaries prominently marked.

Petition

AFT has received a petition proposing an area, in the north central part of California within Yolo, Solano and Sacramento Counties, as a viticultural area to be known as "Clarksburg." The proposed area, located just southwest of Sacramento, is approximately sixteen miles long and eight miles wide, encompassing 101 square miles (64,640 acres). It includes two bonded wineries and 25 vineyards, with approximately 2,300 acres of *Vitis Vinifera* grapes. In addition, the Merritt Island viticultural area is located within the proposed clarksburg area.

Historical and current evidence regarding the name as well as the boundaries of the proposed area include:

(a) Excerpts from articles that appeared in *Vintage Magazine*, Robert Finigan's *Private Guide to Wines*, and *Bon Appetit* magazine, indicate that the proposed area is locally and nationally known.

(b) A Clarksburg Chenin Blanc won a medal in four major competitions in 1981, including the Orange and Los Angeles County Fairs.

(c) The large number of settlers arriving after the discovery of gold in 1849 led to the founding of Clarksburg and many other towns in the Sacramento River Delta Region.

(d) The town of Clarksburg was named after Judge Robert C. Clark, who is credited with having the first peach orchard in Yolo County.

(e) The earliest record of vineyard activity, circa 1870, was near Courtland, located in the southern portion of the proposed area.

(f) In the early 1900's many Italian settlers established small vineyards throughout the area, the grapes used to make wine for home consumption.

(g) The first commercial vineyard within the past twenty years was established in 1963 near Courtland, and the first wineries (Bogle Vineyards and R.J. Cook) were established in 1979.

Geographical features of the proposed Clarksburg viticultural area include the following:

(a) Average yearly precipitation within the proposed area is 16 inches, unlike the surrounding areas which average more to the north and east, and less to the west and south.

(b) The proposed area is dominated by poorly drained clay and clay loam soils. West of the proposed area the soil classification and the annual flooding of the Yolo Bypass make grape-growing impossible. The lower terraces east of the proposed area are subject to the 100 year flood and are considered a flood prone area. Land south of the proposed area is dominated by poorly drained organic and mineral soils.

(c) The northern boundary separates the northern area where the natural cooling fades out. Normally on a hot summer day Sacramento will be eight to ten degrees warmer than Clarksburg area.

The boundaries of the proposed Clarksburg viticultural area may be found on eight California U.S.G.S. maps (Sacramento West, Saxon, Clarksburg, Florin, Liberty Island, Courtland, Bruceville, and Isleton).

The boundaries, as proposed by the petitioner, are described in § 9.95.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to initial and final regulatory flexibility analyses (5 U.S.C. 603, 604) are not applicable to this notice of proposed rulemaking because the proposal is not expected (1) to have significant secondary or incidental effects on a substantial number of small entities; nor (2) to impose, nor otherwise cause, a significant increase in the reporting, recordkeeping, or other compliance burdens on substantial number of small entities.

Accordingly, it is hereby certified under the provisions of Section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that the notice of proposed rulemaking, if promulgated as a final rule, will not have a significant economic impact nor compliance burdens on a substantial number of small entities.

Compliance With Executive Order 12291

It has been determined that this proposed rulemaking is not classified as a "major rule" within the meaning of Executive Order 12291, 46 13193 (1981),

because it will not have an annual effect on the economy of \$100 million or more; it will not result in a major increase in costs or prices for consumer, individual industries, Federal, State, or local government agencies, or geographic regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this notice because no requirement to collect information is proposed.

Public Participation—Written Comments

ATF requests comments from all interested persons concerning this proposed viticultural area. This document proposes possible boundaries for the Clarksburg viticultural area. However, comments concerning other possible boundaries for this viticultural area will be given consideration.

Comments received before the closing date will be carefully considered. Comments received after the closing date and too late for consideration will be treated as possible suggestions for future ATF action.

ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting a comment is not exempt from disclosure.

Any interested person who desires an opportunity to comment orally at a public hearing on these proposed regulations should submit his or her request, in writing, to the Director within the 30-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing will be held.

List of Subjects in 27 CFR Part 9

Administrative practice and procedure, Viticultural areas, Consumer protection, and Wine.

Drafting Information

The principal author of this document is James P. Ficaretta, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

Authority

Accordingly, under the authority in 27 U.S.C. 205, the Director proposes the amendment of 27 CFR Part 9 as follows:

PART 9—AMERICAN VITICULTURAL AREAS

Paragraph 1. The table of sections in 27 CFR Part 9, Subpart C, is amended to add the title of § 9.95 to read as follows:

Subpart C—Approved American Viticultural Areas

Sec.

* * * * *

9.95 Clarksburg.

Par. 2. Subpart C is amended by adding § 9.95 to read as follows:

§ 9.95 Clarksburg.

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

(b) *Approved maps.* The appropriate maps for determining the boundaries of the Clarksburg viticultural area are eight U.S.G.S. topographic maps in the 7.5 minute series, as follows:

- (1) Sacramento West, Calif., 1967 (photorevised 1980)
- (2) Saxon, Calif., 1952 (photorevised 1968)
- (3) Clarksburg, Calif., 1967 (photorevised 1980)
- (4) Florin, Calif., 1968 (photorevised 1980)
- (5) Liberty Island, Calif., 1978
- (6) Courtland, Calif., 1978
- (7) Bruceville, Calif., 1978 (photorevised 1980)
- (8) Isleton, Calif., 1978

(c) *Boundaries.* Beginning at a point (on the Sacramento West topographic map) in Yolo County in T8N/R4E, at the intersection of Jefferson Blvd. and Burrows Ave.,

(1) Then southwest in a straight line 1.2 miles along Jefferson Blvd. to the eastern bank of the Sacramento River Deep Water Ship Channel.

(2) Then southwest along the Sacramento River Deep Water Ship Channel, approximately 17 miles to T5N/R3E, to the Class 5 trail on the levee connecting the Sacramento River Deep Water Ship Channel and the dredger cut Miner Slough, approximately 2 miles from the Salano/Yolo County line.

(3) Then east along the trail to the Miner Slough.

(4) Then east along Miner Slough to the point where it joins Sutter Slough, then south along Sutter Slough around the tip to Sutter Island to the junction of Sutter Slough and Steamboat Slough; then north around Sutter Island along Steamboat Slough to Section 8 in T5N/

R4E where Steamboat Slough joins the Sacramento River.

(5) Then southeast following the Sacramento River to the point where the Sacramento River meets the Delta Cross Channel at the Southern Pacific Railroad in Section 35, T5N/R4E.

(6) Then northeast along the Southern Pacific Railroad for 2 miles, to a point ½ mile past the intersection of the Southern Pacific Railroad and the eastern branch of Snodgrass Slough.

(7) Then east approximately 2½ miles along the levee to Interstate 5 (under construction).

(8) Then north approximately 8½ miles along Interstate 5 (under construction, proposed, and completed) to Section 18 in T6N/R5E, at the intersection of Interstate 5 and Hood Franklin Road.

(9) Then southeast along Hood Franklin Road to the Southern Pacific Railroad Levee, .1 mile northeast of Hood Junction.

(10) Then north approximately 18 miles along the Southern Pacific Railroad Levee to Section 11 in T7N/R4E, at Freeport Blvd., and then across the Sacramento River at the line between Sections 11 and 4.

(11) Then northwest along the west bank of the Sacramento River to Borrows Ave.

(12) Then northwest along Borrows Ave. to the starting point at the intersection of Jefferson Blvd. and Borrows Ave.

Approved: September 9, 1983.

Stephen E. Higgins,
Director.

[FR Doc. 83-25305 Filed 9-15-83; 8:45 am]

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27 CFR Part 9

[Notice No. 484]

The Umpqua Valley Viticultural Area

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is considering the establishment of a viticultural area in Douglas County, Oregon, to be known as "Umpqua Valley." This proposal is the result of a petition from Mr. David B. Adelsheim, Chairman of the Appellation committee, Oregon Winegrowers Association. The establishment of viticultural areas and the subsequent use of viticultural area names in wine labeling and advertising