

exists as a white to yellowish powder with a slight tallow-like odor. Commercially, sodium oleate is made by mixing and heating flaked sodium hydroxide and oleic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard used for food packaging, and a component of lubricants with incidental food contact in accordance with § 178.3570 of this chapter, with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

5. By adding new § 186.1771 to read as follows:

§ 186.1771 Sodium palmitate.

(a) Sodium palmitate ($C_{16}H_{33}O_2Na$, CAS Reg. No. 408-35-5) is the sodium salt of palmitic acid (hexadecanoic acid). It exists as a white to yellow powder. Commercially, sodium palmitate is made by mixing and heating flaked sodium hydroxide and palmitic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated May 15, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-12345 Filed 6-2-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 201

[Docket No. 85N-0554]

Labeling Requirements for Over-the-Counter Drugs; Proposed Amendment of Statement of Identity Requirements; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Notice of Proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 16, 1986, the comment period for the notice of proposed rulemaking to amend the labeling requirements for over-the-counter (OTC) drugs in § 201.61(b) (21 CFR 201.61(b)). This action responds to a request to extend the comment period for an additional 30 days to allow more time for interested persons to review the

proposal and to prepare meaningful comments.

DATE: Written comments by July 16, 1986.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 17, 1986 (51 FR 13023), FDA issued a notice of proposed rulemaking to amend the labeling requirements for OTC drugs in § 201.61(b) (21 CFR 201.61(b)), as follows: (1) To clarify that the statement of identity requirements apply to both single active ingredients and combinations of active ingredients, and (2) to state that OTC drug monographs established under Part 330 (21 CFR Part 330) are the source of the statement of identity of an OTC drug, unless otherwise stated in an approved new drug application, or unless there is no applicable monograph. Interested persons were given until June 16, 1986, to comment on the notice of proposed rulemaking.

In response to the proposal, The Proprietary Association requested a 30-day extension of the comment period in order to allow adequate time for the association to review the proposal. The Proprietary Association stated that the rulemaking is of significant interest to the OTC drug industry and that extending the comment period will allow greater participation by all those who will be affected by the proposal.

FDA has carefully considered the request. The agency believes that greater participation by those affected by the proposal is in the public interest, and may be of assistance in amending the statement of identity labeling requirements for OTC drug products. Thus, the agency considers a general extension of the comment period for 30 days to be appropriate.

Interested persons may, on or before July 16, 1986, submit to the Dockets Management Branch (address above) written comments concerning the notice of proposed rulemaking. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number 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 May 28, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-12343 Filed 5-29-86; 10:32 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[Notice No. 592]

Revision of the Boundary of the El Dorado Viticultural Area

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

ACTION: Notice of proposed rulemaking.

SUMMARY: ATF is proposing to amend the approved boundary of the El Dorado viticultural area to include vineyard which was unintentionally omitted from the original petition which ATF adopted in T.D. ATF-152 (48 FR 46518). This proposal is based on a petition submitted by Mr. A.G. Boissevain, President, El Dorado Wine Grape Growers Association, Camino, California. 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 better identify wines they purchase. The use of viticultural area appellations of origin will also help wineries distinguish their products from wines made in other areas.

DATE: Written comments must be received by July 3, 1986.

ADDRESSES: Send written comments to: Chief, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044-0385.

Copies of the petition and the written comments received in response to this notice will be available for public inspection during normal business hours at: ATF Reading Room, Room 4406, Ariel Rios Federal Building, 12th and Pennsylvania Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: James A. Hunt, Coordinator, FAA, Wine and Beer Branch, (202) 566-7626.

SUPPLEMENTARY INFORMATION: The El Dorado Wine Grape Growers Association in Camino, California, petitioned ATF for the establishment of an American viticultural area to be

named "El Dorado." The El Dorado viticultural area is located within El Dorado County, east of Sacramento, California. In response to this petition, ATF published a notice of proposed rulemaking, Notice No. 439 (47 FR 55954), in the *Federal Register* on December 14, 1982, proposing the establishment of El Dorado as a viticultural area. On October 13, 1983, ATF published T.D. ATF-152 (48 FR 46518) establishing the El Dorado viticultural area. On December 13, 1984, a petition was received from Mr. A.G. Boissevain, President, El Dorado Wine Grape Growers Association, to include a vineyard just outside of the western boundary of the El Dorado viticultural area. The vineyard was unintentionally omitted when the boundaries were established along Range and Township lines rather than along a more complicated contour line of 1200 foot elevation. Mr. Boissevain stated that the petitioned for area has the same name identification, topography, soil types, amount of rainfall, elevation and temperatures as found in the El Dorado viticultural area and would be distinguished from the surrounding area.

Public Participation—Written Comments

Based on the above discussion, ATF is issuing this notice of proposed rulemaking to request comments concerning this proposed revision of the El Dorado viticultural area boundary.

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

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this proposal because the notice of proposed rulemaking, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities. The proposal will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The proposal is not expected to have significant secondary or incidental effects on a 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 this notice of proposed

rulemaking, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities.

Executive Order 12291

In compliance with Executive Order 12291, 46 FR 13193 (1981), 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 geographic 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.

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.

List of Subjects in 27 CFR Part 9

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

Drafting Information

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

Authority and Issuance

PART 9—[AMENDED]

27 CFR Part 9—American Viticultural Areas—is amended as follows:

Paragraph 1. The authority citation for Part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Para. 2. Section 9.61(c) is amended by revising paragraph (12), designating existing paragraphs (13) through (15) as (17) through (19) respectively, and adding new paragraphs (13) through (16), to read as follows:

§9.61 El Dorado.

* * * * *

(c) * * *
(12) Tehnce north along the range line to its intersection with U.S. Route 50;

(13) Thence west along U.S. Route 50 to its intersection with Cameron Park Drive;

(14) Tehnce north along Camron Park Drive to its intersection with Green Valley Road;

(15) Thence east along Green Valley Road to its intersection with range line R. 10 E./ R. 9 E.;

(16) Thence north along the range line to its intersection with the township line T. 10. N./ T. 11 N.;

* * * * *
Signed: May 18, 1986.

W.T. Drake,

Acting Director.

[FR Doc. 86-12245 Filed 6-2-86; 8:45 am]

BILLING CODE 4810-31-M

27 CFR Part 9

[Notice No. 593]

Bell Mountain Viticultural Area, Texas; Consideration of Establishment

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 Texas to be known as "Bell Mountain." This proposal is the result of a petition submitted by Mr. Robert P. Oberhelman, a grape grower in the proposed area. The establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising will enable winemakers to label wines more precisely and will help consumers to better identify the wines they purchase.

Comment date: Written comments must be received by July 18, 1986.

ADDRESSES: 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. 593).

Copies of the petition, the proposed regulations, the appropriate map, and the written comments will be available for public inspection during normal business hours at: ATF Reading Room, Office of Public Affairs and Disclosure, Room 4406, Ariel Rios Federal Building, 1200 Pennsylvania Avenue NW, Washington, DC.

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