

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 ($C_{16}H_{31}O_2Na$, 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.

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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]

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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