

# Proposed Rules

Federal Register

Vol. 62, No. 202

Monday, October 20, 1997

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 1240

[Docket No. 97N-0418]

#### Revocation of Lather Brushes Regulation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revoke its regulation pertaining to the treatment, sterilization, handling, storage, marking, and inspection of lather brushes. FDA is proposing to revoke this regulation because it has tentatively concluded that the regulation is no longer necessary to protect the public health.

**DATES:** Written comments by January 5, 1998.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Policy Development and Coordination Staff (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of January 19, 1949 (14 FR 278), the Federal Security Agency issued a regulation to prohibit "interstate traffic" in lather brushes unless the brushes complied with 42 CFR 71.151 or with certain requirements in 42 CFR 72.21. 42 CFR 71.151 barred importation of lather brushes made from animal hair or bristles, unless the brushes were permanently marked with the manufacturer's name or identifying mark and a U.S. medical officer had determined that the brushes were free of

anthrax spores. The regulation also directed medical officers to sample brushes from each shipment, subject them to laboratory analysis, and to issue a certificate if the shipment appeared to be free of spores. If the shipment contained anthrax spores, the shipment would be denied entry into the United States.

The Federal Security Agency was abolished in a reorganization in 1953, and its functions were transferred to the then newly-created Department of Health, Education, and Welfare. The department later became the Department of Health and Human Services.

42 CFR 72.21, which applied primarily to lather brushes manufactured in the United States, established specific treatment, sterilization, handling, storage, and marking requirements for these products; and it required that persons engaged in processing or handling of hair or bristles for use in lather brushes, as well as persons manufacturing lather brushes, permit inspections by authorized representatives of the Surgeon General. The rule was transferred, without change, from title 42 to title 21 of the Code of Federal Regulations on February 6, 1975 (40 FR 5620), and, as a result, became § 1240.70 (21 CFR 1240.70).

In the **Federal Register** of August 9, 1983 (48 FR 36143 at 36144), the Centers for Disease Control (CDC), now known as the Centers for Disease Control and Prevention, proposed to revoke various foreign quarantine regulations, including 42 CFR 71.151. The preamble to that proposal explained that:

The proposed regulations will no longer require lather brushes made from animal hair or bristles, imported into the United States, to carry identifying markings or to be certified as treated and stored to prevent possible contamination with spores of *Bacillus anthracis*. No case of cutaneous anthrax in the United States has been associated with lather brushes since 1930, and the continuation of existing requirements is unnecessary to protect the public health. Should the importation of anthrax in lather brushes become a threat to public health in the future, inspection and control measures authorized under provisions of the regulations will be implemented.

CDC revoked 42 CFR 71.151 on January 11, 1985 (50 FR 1516), without any further discussion.

In the **Federal Register** of June 12, 1989 (54 FR 24890), FDA issued a final rule amending various regulations to correct outdated cross-references and typographical errors and to make other corrections. This rule revised § 1240.70, without explanation, to eliminate the reference to 42 CFR 71.151. Yet, in all other respects, § 1240.70 has remained essentially unchanged since 1949.

Recently, FDA has been reexamining its regulations to determine whether any are obsolete or no longer necessary. One regulation that caught the agency's attention is § 1240.70. The agency is unaware of any reliance on the lather brush requirements in this regulation or of any current concerns associated with lather brushes. Additionally, CDC's decision to remove 42 CFR 71.151 because no case of cutaneous anthrax in the United States has been associated with lather brushes since 1930 suggests that § 1240.70 also is no longer necessary to protect the public health. Consequently, FDA is proposing to revoke this regulation.

##### II. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages). The agency believes that this proposed rule is consistent with the principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule, if finalized, would eliminate certain manufacturing requirements for lather brushes. Consequently, the proposed rule would not impose any additional regulatory burdens on small entities, and so, under the Regulatory Flexibility Act, no further analysis is required.

##### III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type

that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### IV. Request for Comments

Interested persons may, on or before January 5, 1998, 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 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.

#### List of Subjects in 21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1240 be amended as follows:

#### PART 1240—CONTROL OF COMMUNICABLE DISEASES

1. The authority citation for 21 CFR part 1240 continues to read as follows:

**Authority:** 42 U.S.C. 216, 243, 264, 271.

#### § 1240.70 [Removed]

2. Section 1240.70 *Lather brushes* is removed.

Dated: October 10, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 97-27694 Filed 10-17-97; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

#### 24 CFR Parts 1000, 1003, and 1005

[Docket No. FR-4170-N-14]

#### Native American Housing Assistance and Self-Determination Negotiated Rulemaking Committee; Meetings

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Negotiated Rulemaking Committee meetings.

**SUMMARY:** This notice announces the final implementation meetings

sponsored by HUD to develop the regulations necessary to carry out the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA) (Pub. L. 104-330, approved October 30, 1996).

**DATES:** The meetings will be held on October 27, 28 and 29, 1997. The October 27 and 28, 1997 meetings will begin at approximately 8:30 a.m. and end at approximately 5:00 p.m., local time. The October 29, 1997 meeting will begin at approximately 8:30 a.m. and end at approximately noon, local time.

**ADDRESS:** The meetings will be held at the Loews L'Enfant Plaza Hotel, 480 L'Enfant Plaza East, SW, Washington, DC 20024; telephone 1-800-635-5065 or (202) 484-1000; FAX (202) 863-4497 (With the exception of the "800" telephone number, these are not toll-free numbers).

#### FOR FURTHER INFORMATION CONTACT:

Karen Garner-Wing, Acting Deputy Assistant Secretary for Native American Programs, Department of Housing and Urban Development, 1999 Broadway, Suite 3390, Denver, CO; telephone (303) 675-1600 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

**SUPPLEMENTARY INFORMATION:** The Secretary of HUD established the Native American Housing Assistance & Self-Determination Negotiated Rulemaking Committee (Committee) to negotiate and develop a proposed rule implementing NAHASDA. The proposed rule was published on July 2, 1997 (62 FR 35718) and provided for a 45-day public comment period. The public comment deadline was August 18, 1997.

The Committee met from August 22-29, 1997 in Denver, Colorado and from September 21-26, 1997 in Arlington, Virginia to consider the public comments submitted on the proposed rule. The Committee is meeting for a final time to discuss issues left unresolved and to reach consensus on the Committee's final report to the Secretary of HUD.

*The meeting dates are:* October 27, 28, and 29 1997. The agenda planned for the meetings includes: (1) discussion of the draft Committee report; (2) discussion of issues left unresolved; and (3) approval of a final Committee report for submission to the Secretary of HUD.

The meetings will be open to the public without advance registration. Public attendance may be limited to the space available. Members of the public may make statements during the meetings, to the extent time permits,

and file written statements with the Committee for its consideration. Written statements should be submitted to the address listed in the **FOR FURTHER INFORMATION** section of this notice. Summaries of Committee meetings will be available for public inspection and copying at the address in the same section.

Dated: October 14, 1997.

**Kevin Emanuel Marchman,**

*Acting Assistant Secretary for Public and Indian Housing.*

[FR Doc. 97-27674 Filed 10-17-97; 8:45 am]

BILLING CODE 4210-33-P

#### DEPARTMENT OF THE TREASURY

#### Bureau of Alcohol, Tobacco and Firearms

#### 27 CFR Part 9

RIN 1512-AA07

[Notice No. 856]

#### Establishment of the San Francisco Bay Viticultural Area and the Realignment of the Boundary of the Central Coast Viticultural Area (97-242)

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Bureau of Alcohol, Tobacco and Firearms (ATF) has received a petition proposing the establishment of a viticultural area in the State of California to be known as San Francisco Bay. The proposed area is located mainly within five counties which border the San Francisco Bay and partly within two other counties. These counties are: San Francisco, San Mateo, Santa Clara, Alameda, Contra Costa, and partly in Santa Cruz and San Benito Counties. The proposed San Francisco Bay viticultural area encompasses approximately 3,087 square miles total containing nearly 6,000 acres planted to grapes and over 70 wineries. In conjunction with the petition, ATF received a proposal to amend the boundaries of the current Central Coast viticultural area to include the proposed San Francisco Bay viticultural area. As the current boundaries already encompass part of the proposed San Francisco Bay viticultural area, approximately 1,278 square miles would be added to Central Coast with an additional 3,027 acres planted to grapes and 21 more wineries.

**DATES:** Written comments must be received by January 20, 1997.

**ADDRESSES:** Send written comments to: Chief, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol,