

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

[Docket No. 98N-0044]  
RIN 0910-AA59

**Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Extension of Comment Period**

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

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to September 28, 1998, the comment period for the proposed rule that appeared in the **Federal Register** of April 29, 1998 (63 FR 23624). The document proposed regulations defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. Interested persons were given until August 27, 1998, to comment on the proposed rule. This action is being taken in response to requests for an extension of the comment period.

**DATES:** Written comments by September 28, 1998.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jeanne Latham, Center for Food Safety and Applied Nutrition (HFS-456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4697.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 29, 1998 (63 FR 23624), FDA issued a proposed rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body.

Interested persons were given until August 27, 1998, to comment on the proposal. FDA has received several requests for an extension of the comment period. After evaluating these requests, the agency has decided to extend the comment period on the proposed rule until September 28, 1998.

To be considered, written comments regarding the proposed rule must be received by September 28, 1998, by the Dockets Management Branch (address above). Two copies of any comments are

to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 98N-0044. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 20, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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**DEPARTMENT OF THE TREASURY**

**Bureau of Alcohol, Tobacco and Firearms**

**27 CFR Part 9**

[Notice No. 864]

RIN 1512-AAD7

**Yountville Viticultural Area ( 98R-28P)**

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Bureau of Alcohol, Tobacco and Firearms (ATF) has received a petition for the establishment of a viticultural area in Napa County, California, to be known as "Yountville." This proposal is the result of a petition submitted by Yountville appellation committee.

**DATES:** Written comments must be received by October 26, 1998.

**ADDRESSES:** Send written comments to: Chief, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, D.C. 20091-0221 (Attn: Notice No. 864). Copies of the petition, the proposed regulation, the appropriate maps, and written comments will be available for public inspection during normal business hours at: ATF Public Reading Room, Office of Public Affairs and Disclosure, Room 6480, 650 Massachusetts Avenue, NW., Washington, D.C.

**FOR FURTHER INFORMATION CONTACT:**

Thomas B. Busey, Specialist, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, D.C. 20226, (202) 927-8230.

**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 definitive viticultural areas. The regulations 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 geographic features, the boundaries of which have been delineated in Subpart C of part 9.

Section 4.25(e)(2), Title 27, CFR, 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 (or copies) of the appropriate U.S.G.S. map(s) with the proposed boundaries prominently marked.

**Petition**

ATF has received a petition from Mr. Richard Mendelson, submitted on behalf of a number of wineries and grape growers in the Yountville area. The proposed viticultural area is located entirely within the Napa Valley. It contains approximately 8260 acres, of which 3500 are planted to vineyards. The proposed viticultural area was determined by extending the wine growing area from around the town of Yountville until it abuts the already established viticultural areas of Oakville on the north, Stags Leap District on the east, and Mt. Veeder on the west. On the south is an area called Oak Knoll which has petitioned to be considered a viticultural area.