

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.

[FR Doc. 98-22813 Filed 8-25-98; 8:45 am]

BILLING CODE 4160-01-F

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.

Evidence That The Name Of The Area Is Locally Or Nationally Known

An historical survey written by Charles Sullivan spells out the historical use of the name Yountville and vineyard plantings dating back to the late 1800's. Numerous references exist indicating the general use of the name "Yountville" to refer to the petitioned area. The petitioner included copies of title pages of various publications, guide and tour book references, public and private phone book listings and Federal and State agency maps, to illustrate the use of the name. For example, an ad for wine in the 1880's stresses the source of the grapes for the wine as "Yountville." Yountville is also prominently mentioned in James Halliday's Wine Atlas of California.

Historical or Current Evidence That the Boundaries of the Viticultural Area Are as Specified in the Petition

According to the petitioner, the boundaries establish a grape growing area with an identifiable character, based on climate, topography, and historical tradition. The Yountville area boundaries were determined by extending the grape growing area from around the town itself 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 and an area called Oak Knoll on the south, which is currently under consideration on whether it should be recognized as a viticultural area. The proposed boundaries of the area were determined by already existing AVA's and by the distinguishing physical features of the area. The boundary lines are accurately described using the features on the submitted U.S.G.S maps. In sum, the petitioner believes the proposed boundaries encompass an area of remarkable uniformity with respect to soils, climate and existing AVA's.

The history of viticulture in the Napa Valley begins with George C. Yount. Yount first visited the Napa Valley in 1831. He was granted his Rancho Caymus on March 3, 1836. It amounted to approximately 11,000 acres and covered the valley and foothills from the Bale Slough in the north to a line which runs through the town of Yountville today. By the 1840's he had established a small vineyard. In 1855, he commissioned a surveyor to lay out the city. The new community was christened Sebastopol. In 1887, two years after Yount's death, the town was renamed in honor of its founder.

Evidence Relating To The Geographical Features (Climate, Soil, Elevation, Physical Features, Etc.) Which Distinguish Viticultural Features Of The Proposed Area From Surrounding Areas

According to the petitioner, the geographical features of the proposed viticultural area set it apart from the surrounding area in the Napa Valley and produce a unique microclimate. The distinguishing features of the proposed viticultural area are the Napa River, the Napa Valley floor, the alluvial soils, the hills north of Yountville called the Yountville Mounts and the hills west of Yountville which form the western boundary of the Napa Valley.

The petitioner has submitted evidence showing that the weather is specific to the Yountville area with cool marine air currents reaching the Yountville Mounts (northern border of the proposed area) and which form a weather barrier to further expansion of the fogs and winds. Also the soils which form the alluvial fan just across the southern boundary of the Yountville area can be seen to come from the Dry Creek watershed (see U.S.G.S. maps). The soils just north of the Yountville border come from the hills that form the western side of the area. The line along Ragatz Lane was selected to delineate the two areas. The soils between Yountville and Stags Leap District can be seen to differ north of the Yountville crossroad with the Rector canyon being the parent and the area between the Napa River and the Silverado Trail belonging to the hills immediately to the east.

According to the petitioner, the Yountville area, and specifically the area near and west of the town of Yountville, is one of the coolest vineyard regions of the Napa Valley viticultural area with long, cool growing season for grapevines. The Amerine and Winkler (1944) climate scheme rates this area as a Region II climate in a typical year, with a growing season degree-day totals of 2600 to 2900. This makes the area around the town of Yountville warmer than most of the Carneros viticultural area, but cooler than parts of Mt. Veeder and Oakville.

According to the petitioner, the Yountville area is unusual as a Napa Valley floor viticultural region in that it is not dominated geomorphically by large alluvial fans. It is most similar geologically to the Stags Leap District, which also is dominated by an old Napa River channel. However, the petitioner alleges that the Yountville area is also geologically and geomorphologically distinct from the Stags Leap District, as Yountville was an area of intense coastal deposition along what must have

been a nearshore current set up on the western side of the valley. The only similar coastal deposits found in the Napa Valley are in the Hagen Road area east of the City of Napa off Olive Hill Lane. Geomorphic deposits strongly influence soil types in the regions. Pronounced differences in soils are seen between Yountville, Oakville, the Stags Leap District, Mt. Veeder, and the proposed Oak Knoll viticultural area.

Proposed Boundaries

The boundaries of the proposed Yountville viticultural area may be found on four U.S.G.S. Quadrangle (7.5 Minute Series) maps titled: Napa, CA (1951); Rutherford, CA (1951); Sonoma, CA (1951); and Yountville, CA (1951).

Public Participation-Written Comments

ATF requests comments from all interested persons. Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so. However, assurance of consideration can only be given on or before the closing date.

ATF will not recognize any submitted material as confidential and 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 comments. The name of the person submitting a comment is not exempt from disclosure.

Comments may be submitted by facsimile transmission to (202) 927-8602, provided the comments: (1) are legible; (2) are 8 1/2" x 11" in size, (3) contain a written signature, and (4) are three pages or less in length. This limitation is necessary to assure reasonable access to the equipment. Comments sent by FAX in excess of three pages will not be accepted. Receipt of FAX transmittals will not be acknowledged. Facsimile transmitted comments will be treated as originals.

Any person who desires an opportunity to comment orally at a public hearing on the proposed regulation should submit his or her request, in writing, to the Director within the 60-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, whether a public hearing will be held.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j)) and its implementing regulations, 5 CFR Part 1320, do not apply to this notice of proposed

rulemaking because no requirement to collect information is proposed.

Regulatory Flexibility Act

It is hereby certified that this proposed regulation will not have a significant impact on a substantial number of small entities. The establishment of a viticultural area is neither an endorsement nor approval by ATF of the quality of wine produced in the area, but rather an identification of an area that is distinct from surrounding areas. ATF believes that the establishment of viticultural areas merely allows wineries to more accurately describe the origin of their wines to consumers, and helps consumers identify the wines they purchase. Thus, any benefit derived from the use of a viticultural area name is the result of the proprietor's own efforts and consumer acceptance of wines from the region.

Accordingly, a regulatory flexibility analysis is not required because the proposal, if promulgated as a final rule, is not expected (1) to have significant secondary, or incidental effects on a substantial number of small entities; or (2) to impose, or otherwise cause a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

Executive Order 12866

It has been determined that this proposed regulation is not a significant regulatory action as defined by Executive Order 12866. Accordingly, this proposal is not subject to the analysis required by this executive order.

Drafting Information

The principal author of this document is Thomas B. Busey, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 9

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

Authority and Issuance

Title 27, Code of Federal Regulations, Part 9, American Viticultural Areas, is proposed to be amended as follows:

PART 9—AMERICAN VITICULTURAL AREAS

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

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

Par. 2. Subpart C is amended by adding § 9.160 to read as follows:

§ 9.160 Yountville.

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

(b) *Approved maps.* The appropriate maps for determining the boundary of the Yountville viticultural area are four 1:24,000 Scale U.S.G.S. topography maps. They are titled:

(1) Napa, CA 1951 photorevised 1980.

(2) Rutherford, CA 1951 photorevised 1968.

(3) Sonoma, CA 1951 photorevised 1980.

(4) Yountville, CA 1951 photorevised 1968.

(c) *Boundary.* The Yountville viticultural area is located in the State of California, entirely within the Napa Valley viticultural area. The boundaries of the Yountville viticultural area, using landmarks and points of reference found on appropriate U.S.G.S. maps are as follows:

(1) Beginning on the Rutherford quadrangle map at the intersection of the 500 foot contour line with an unnamed stream known locally as Hopper Creek north of the center of Section 3, T6N, R5W, Mount Diablo Meridan (MDM);

(2) Then along the unnamed stream (Hopper Creek) southeasterly, and at the fork in Section 3, northeasterly along the stream to the point where the stream intersects with an unnamed dirt road in the northwest corner of Section 2, T6N, R5W, MDM;

(3) Then in a straight line to the light duty road to the immediate northeast in Section 2, then along the light duty road in a northeasterly direction to the point at which the road turns 90 degrees to the left;

(4) Then northerly along the light duty road 625 feet, then northeasterly (N 40° by 43') in a straight line 1,350 feet, along the northern property line of Assessor's Parcel Number 27-380-08, to State Highway 29, then continuing in a straight line approximately 500 feet to the peak of the 320 plus foot hill along the western edge of the Yountville hills;

(5) Then east to the second 300 foot contour line, then along said contour line around the Yountville hills to the north to the point at which the 300 foot line exits the Rutherford quadrangle for the second time;

(6) Then, on the Yountville quadrangle map, in a straight line in a northeasterly direction approximately N34° by 30°E approximately 1,000 feet

to the 90 degree bend in the unimproved dirt road shown on the map, then along that road, which coincides with a fence line to the intersection of Conn Creek and Rector Creek;

(7) Then along Rector Creek to the northeast past Silverado Trail to the Rector Reservoir spillway entrance, then south approximately 100 feet to the 400 foot contour line, then southerly along the 400 foot contour line approximately 4200 feet to the intersection with a gully in section 30, T7N, R4W, MDM;

(8) Then southwesterly down the center of the gully approximately 800 feet to the medium duty road known as Silverado Trail, then southeasterly along the Silverado Trail approximately 590 feet to the medium duty road known locally as Yountville Cross Road;

(9) Then southwesterly along the Yountville Cross Road (denoted as GRANT BDY on the map) approximately 4,700 feet to the main branch of the Napa River, then following the western boundary of the Stags Leap District viticultural area, first southerly down the center of the Napa River approximately 21,000 feet, then leaving the Napa River northeasterly in a straight line approximately 900 feet to the intersection of the Silverado Trail with an intermittent stream at the 60 foot contour line in T6N, R4W, MDM;

(10) Then along the Silverado Trail southerly approximately 3,200 feet, passing into the Napa quadrangle, to a point which is east of the confluence of Dry Creek with the Napa River; then west approximately 600 feet to said confluence; then northwesterly along Dry Creek approximately 3,500 feet, passing into the Yountville quadrangle to a fork in the creek; then northwesterly along the north fork of Dry Creek approximately 5,700 feet to the easterly end of the light duty road labeled Ragatz Lane;

(11) Then southwesterly along Ragatz Lane to the west side of State Highway 29, then southerly along Highway 29 by 982 feet to the easterly extension of the north line boundary of Napa County Assessor's parcel number 034-170-015, then along the north line of APN 034-170-015 and its extension westerly 3,550 feet to the dividing line Between R4W and R5W on the Napa quadrangle, then southwesterly approximately 1000 feet to the peak denoted as 564 (which is about 5,500 feet easterly of the northwest corner of the Napa quadrangle); then southwesterly approximately 4,000 feet to the peak northeast of the reservoir gauging station denoted as 835.

(12) Then southwesterly approximately 1,500 feet to the reservoir

gauging station, then west to the 400 foot contour line on the west side of Dry Creek, then northwesterly along the 400 foot contour line to the point where the contour intersects the north line of Section 10. T6N, R5W, MDM, immediately adjacent to Dry Creek on the Rutherford, CA map;

(13) Then northwesterly along Dry Creek approximately 6,500 feet to BM503, then northeasterly approximately 3,000 feet to the peak denoted as 1478, then southeasterly approximately 2,300 feet to the beginning of the creek known locally as Hopper Creek, then southeasterly along Hopper Creek approximately 2,300 feet to the point of beginning.

Signed: August 19, 1998.

John W. Magaw,

Director.

[FR Doc. 98-22875 Filed 8-25-98; 8:45 am]

BILLING CODE 4810-31-U

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY-216-FOR]

Kentucky Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening of public comment period.

SUMMARY: OSM is reopening the public comment period on a proposed amendment to the Kentucky regulatory program (hereinafter the "Kentucky program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of changes to provisions of the Kentucky regulations pertaining to subsidence and subsidence control, water replacement, impoundments, definitions, sedimentation ponds, hydrology, and permits. The amendment is intended to revise the Kentucky program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., [E.S.T.], September 10, 1998.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to William J. Kovacic, Director, at the address listed below.

Copies of the Kentucky program, the proposed amendment, a listing of any scheduled public hearings, and all

written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Lexington Field Office.

William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503, Telephone: (606) 233-2494.

Department of Surface Mining Reclamation and Enforcement, 2 Hudson Hollow Complex, Frankfort, Kentucky 40601, Telephone: (502) 564-6940.

FOR FURTHER INFORMATION CONTACT:

William J. Kovacic, Director, Lexington Field Office, Telephone: (606) 233-2494.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

II. Description of the Proposed Amendment

By letter dated July 30, 1997 (Administrative Record No. KY-1410), Kentucky submitted a proposed amendment to its program revising section 405 of the Kentucky Administrative Regulations (KAR) at 8:001, 8:030, 8:040, 16:001, 16:060, 16:090, 16:100, 16:160, 18:001, 18:060, 18:090, 18:100, 18:160, and 18:210. The proposed amendment was announced in the September 5, 1997, **Federal Register** (62 FR 46933).

On November 14, 1997, a Statement of Consideration of public comments received by Kentucky was filed with the Kentucky Legislative Research Committee. As a result of the comments, by letter dated March 4, 1998, Kentucky made changes to the original submission (Administrative Record No. KY-1422). The revisions were made at 405 KAR 8:040, 16:060, 18:060, and 18:210. By letter dated July 14, 1998 (Administrative Record No. KY-1431), Kentucky submitted the final version of

the proposed amendments. Following are the changes to 405 KAR made in the final submission and not previously described in the September 5, 1997, **Federal Register** notice. Deletions of previously proposed language will not be described in this notice nor will revisions concerning nonsubstantive wording, format, or organizational changes.

Kentucky deleted the phrase or a variation of the phrase, "but not limited to," in the definitions of "Coal Processing Plant," "Community or Institutional Building," "Sedimentation Pond," "Surface Blasting Operations," and "Significant Imminent Environmental Harm." The phrase was also deleted at 405 KAR 8030: 3(3), 11(2)(a), 13(1)(b), 13(3), 14(5), 15(5), 23(1)(g), 24(4)(e), 27(2)(e), 34(6), 37(1)(b); at 405 KAR 8040: 3(3), 11(2)(a), 13(1)(b), 13(3), 14(5), 15(5), 24(4)(e), 26(3)(e), 34(6), 37(1)(b); at 405 KAR 16:060: 1(4)(b), 2(2), 8(2)(a); and at 405 KAR 18:060 1(1)(b) and 2(2).

At section 8:001—Definitions (405 KAR Chapter 8), Kentucky cites the Kentucky Revised Statutes (KRS) at 350.028 (1), (5), and 350.465(2) as the authorization to promulgate administrative regulations for surface and underground coal mining operations. Kentucky defines the following terms:

Acquisition means purchase, lease, or option of the land for the purpose of conducting or allowing through resale, lease, or option, the conduct of surface coal mining and reclamation operations.

The definition of *Community or Institutional Building* is slightly revised from the original submission to clarify "for another public service" as a possible use. The word "primarily" is also deleted to described the listed uses.

Historically Used for Cropland means land that: (a) Has been used for cropland for any of five years or more of the ten years immediately preceding the application or acquisition of the land for the purpose of conducting a surface coal mining and reclamation operation; (b) would likely have been used for cropland for any five of the ten years immediately preceding the acquisition or application, but for some fact of ownership or control of the land unrelated to the productivity of the land; (c) falls outside the five of ten years criteria, but the cabinet determines is clearly cropland on the basis of additional cropland history of (1) surrounding land, and (2) the land under consideration.

The definition of *Material Damage* is revised from the original submission to delete the reference to 405 KAR 18:210.