

reason for this certification is that the amendments reduce, have no effect on, or add no significant burden to the reporting requirements of any entity subject to these provisions.

Dated: July 17, 1981.

John S. R. Shad,
Chairman.

[FR Doc. 81-21698 Filed 7-27-81; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 452

[Docket No. 79N-0459]

Erythromycin Estolate; Extension of Comment Period on Proposal To Revoke Provisions for Certification of Adult Dosage Forms

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; Extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) announces an extension of the comment period on its proposal to revoke regulations for the certification of adult dosage forms of erythromycin estolate. It is taking the action to provide a three-week comment period on the report of the Ad Hoc Advisory Committee on Erythromycin Estolate.

DATE: Written comments may be submitted by August 18, 1981.

ADDRESS: Written comments may be submitted to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Suzanne O'Shea, Bureau of Drugs (HFD-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of December 4, 1979 (44 FR 69670), FDA proposed to revoke regulations that provide for the certification of adult dosage forms (tablets and capsules) of erythromycin estolate (21 CFR 452.115a, 452.115b). FDA proposed the revocation because of new information on the safety of erythromycin estolate which it believes might change the risk/benefit ratio of erythromycin estolate compared to other available erythromycins. If adopted in final form, the effect of the proposed revocation would be to remove the drug products from the market.

Erythromycin estolate tablets and capsules are currently manufactured by two firms:

1. Dista Products Co., Division of Eli Lilly & Co., P.O. Box 1407, Indianapolis, IN 46706.

2. Danbury Pharmacal, Inc., 131 West St., P.O. Box 296, Danbury, CT 06810.

In a notice published in the Federal Register of June 10, 1980 (45 FR 39340), the Commissioner chartered the Ad Hoc Advisory Committee on Erythromycin Estolate to advise the agency in its determination of the risk/benefit ratio of erythromycin estolate.

In a notice published in the Federal Register of February 27, 1981, the Commissioner announced that a public hearing before the Committee would be held on April 16 and 17, 1981. The notice requested that the Bureau of Drugs, manufacturers, and other interested persons submit written information pertinent to the risk/benefit determination and prepare to present their views orally at the hearing. The notice also stated that the Committee was to submit its conclusions in writing to the Commissioner by April 27, 1981, and that written comments would be accepted until three weeks after that, i.e., until May 18, 1981.

Because the Committee was unable to submit its report by April 27, 1981, on May 13, 1981, Eli Lilly & Co. requested that the comment period be extended to permit public comment on the Committee's report.

The report has now been submitted and placed in the Dockets Management Branch under Docket No. 79N-0459. It is available there for public review Monday through Friday, 9 a.m. to 4 p.m. The Committee's executive secretary sent a copy of the report to each hearing participant.

The comment period is hereby extended to permit interested persons three weeks to comment on the Committee's report as set forth in the February 27, 1981 notice. Accordingly, interested persons may submit written comments, identified with Docket No. 79N-0459 to the Dockets Management Branch, on or before August 18, 1981.

Dated: July 23, 1981.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 81-22011 Filed 7-24-81; 10:20 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[Notice No. 376]

Cienega Valley Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is considering the establishment of a viticultural area in San Benito County, California, to be known as "Cienega Valley." This proposal is the result of a petition from an industry member in the area. The establishment of viticultural areas and the subsequent use of viticultural area names in wine labeling and advertising will help consumers better identify wines they purchase.

DATE: Written comments must be received by October 26, 1981.

ADDRESSES: Send written comments to: Chief, Regulations and Procedures Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, D.C. 20044 (Notice No. 376).

Copies of the petition, the proposed regulations, the appropriate maps, 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 4407, Federal Building, 12th and Pennsylvania Avenue, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Robert L. White, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW., Washington, D.C. 20226 (202-566-7626).

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 definite viticultural areas. The regulations also 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 geographical features. Section 4.25a(e)(2) 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 features (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 the features which can be found on the United States Geological Survey (U.S.G.S.) maps of the largest applicable scale; and

(e) A copy of the appropriate U.S.G.S. map with the boundaries prominently marked.

Petition

ATF has received a petition proposing an area in San Benito County, California, as a viticultural area to be known as "Cienega Valley." The proposed area is located at the base of the Gabilan Mountain Range which rises to 3,274 feet and forms a boundary line between San Benito and Monterey Counties. The Pescadero Creek runs through the vineyards and the San Andreas earthquake fault line borders the northeast edge. Cienega Valley lies approximately five miles south, overland, from the town of Hollister. On the east is the Paicines Vineyards. The Cienega Valley area is planted with hundreds of acres of vineyards consisting of numerous varieties of grapes.

Geographical/Viticultural Features

The petitioner claims that the proposed viticultural area is distinguished from surrounding areas by climatic variances and by differences in the soil. The petitioner bases these claims on the following:

(a) Cienega Valley lies northeast of the Salinas Valley which is known as a cooler area and is often blanketed with fog. Salinas Valley strongly influences the micro-climate of the Cienega Valley by sending cooler air and fog into the Cienega grape-growing region.

(b) The terrain is extremely hilly to mountainous and the elevation ranges from approximately 930 feet to well over 1,500 feet. The average elevation in the Cienega Valley area is higher than much of the surrounding area including Paicines.

(c) Due to the closeness of the Cienega Valley area to the Gabilan Mountain Range, Cienega Valley often has more rain than the surrounding area, thus creating different micro-climatic conditions. Rainfall average 15.29 inches per year based on 53 years of records. There is some dry farming around the winery. However, water coming down out of the Gabilan Mountains into the Pescadero Creek is used for irrigation of a portion of the vineyards.

(d) The Cienega Valley area is in a wind tunnel of cool ocean air flowing to the San Joaquin Valley. Trees growing adjacent to the vineyard area help protect the area from the wind. Also, Cienega Valley is protected from the wind due to the location of its east/west canyons. Cienega Valley gets more evening fog than much of the surrounding area because of its location at the foot of the Gabilan Mountains. This fog usually burns off by early morning.

(e) The average temperature in the last four years is 2861 degree-days.

(f) The soil is loamy, generally well drained, and often underlain by weathered granite. The main soil associations of the flood plains and alluvial fans are Sorrento-Yolo-Mocho and Clear Lake-Pacheco-Williams. The soil associations on the uplands are the San Benito-Gazos-Linne association and the Sherdan-Cineba-Auberry association. In general there is good water holding capacity and the root depth ranges from medium to quite deep.

(g) The adjacent mountain range and the cool ocean air that comes into the Cienega Valley each day help create an ideal micro-climate for the growing of fine, distinguished quality grapes.

Historical Background

History in the county of San Benito dates back to the 1700's with the advent of the Spanish Padres and the dedication of the Missions. Cienega, in San Benito County, was planted with vines by Theophile Vache in the early 1850's. The vineyard was sold in 1883 and the new owner planted more acreage. Historical data indicate a winery was built in 1854 and later enlarged.

The quality of the wines from this growing region won a reputation by winning prizes from as far away as France and Italy. The petitioner states

that during Prohibition the grape vines were not pulled and in 1935, when it became legal, wine was made by Mr. Vallant who had acquired the winery. According to the petitioner, both the winery and vineyards were taken over by the Taylor Company in 1943 and later sold to Almaden Vineyards.

Proposed Boundaries

The boundaries of the proposed Cienega Valley viticultural area may be found on four U.S.G.S. 7.5 minute quadrangle maps ("Hollister Quadrangle, California", "Tres Pinos Quadrangle, California", "Mt. Harlan Quadrangle, California", and "Paicines Quadrangle, California"). The specific description of the boundaries of the proposed viticultural area is found in the proposed regulations.

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 is not expected to: have significant secondary or incidental effects on a substantial number of small entities; or impose, or otherwise cause, a significant increase in the reporting, recordkeeping, or other compliance burdens 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 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.

Executive Order 12291

In compliance with Executive Order 12291 the Bureau has determined that this proposal 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, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Public Participation—Written Comments

ATF requests comments concerning this proposed viticultural area from all interested persons. Furthermore, while this document proposes possible boundaries for the Cienega Valley viticultural area, comments concerning other possible boundaries for this viticultural area will be given consideration.

Comments received before the closing date will be carefully considered. Comments received after the closing date and too late for consideration will be treated as possible suggestions for future ATF action.

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

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

Drafting Information

The principal author of this document is Robert L. White, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms. However, other personnel of the Bureau and of the Treasury Department have participated in the preparation of this document, both in matters of substance and style.

Authority

Accordingly, under the authority in 27 U.S.C. 205, the Director proposes the amendment of 27 CFR Part 9 as follows:

Part 9—American Viticultural Areas

Par. 1. The table of sections in 27 CFR Part 9, Subpart C, is amended to add the title of § 9.38. As amended, the table of sections reads as follows:

Subpart C—Approved American Viticultural Areas

Sec.
* * * * *
9.38 Cienega Valley.

Par. 2. Subpart C is amended by adding § 9.38. As amended, Subpart C reads as follows:

Subpart C—Approved American Viticultural Areas

* * * * *
§ 9.38 Cienega Valley.

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

(b) Approved maps. The appropriate maps for determining the boundaries of Cienega Valley viticultural area are four U.S.G.S. maps. They are titled:

- (1) "Hollister Quadrangle, California," 7.5 minute series;
(2) "Tres Pinos Quadrangle, California," 7.5 minute series;
(3) "Mt. Harlan Quadrangle, California," 7.5 minute series; and
(4) "Paicines Quadrangle, California," 7.5 minute series.

(c) Boundaries. The Cienega Valley viticultural area is located in San Benito County, California. The beginning point is the Gaging Station, located on U.S.G.S. map "Paicines Quadrangle" at the southeast edge of Township 14 South, Range 6 East, Section 21, the southeast corner.

(1) From the beginning point, the boundary follows the Pescadero Creek Bed southeast about 100 feet to the unimproved road and continues south southwest on the unimproved road .5 mile to where it intersects with the south border of Township 14 South, Range 6 East, Section 21;

(2) Thence continuing along the south border of Township 14 South, Range 6 East, Section 20; thence along the west border of Township 14 South, Range 6 East, Section 17 to where it intersects with the 1200-foot contour line;

(3) Thence following the 1200-foot contour line in a generally northwestern direction to where it intersects with the north boundary of Township 14 South, Range 5 East, Section 10; then following this boundary line in a northwest direction to where this boundary intersects with the 1600-foot contour line; thence following the 1600-foot contour line in a generally northern direction to where it intersects with the unimproved road;

(4) Thence looping southward and continuing on in an easterly direction to the designated "Spring" and continuing on the unimproved road in a northeast direction parallel with the gulch to the Vineyard School on Cienega Road; then continuing southeast on Cienega Road .4 mile to where the unimproved road intersects; thence traveling north and following the unimproved road northwest about .5 mile; then looping in an easterly direction .75 mile to the

intersection of the unimproved road and branching in a southeast direction;

(5) Thence crossing Township 13 South to Township 14 South and following the unimproved road to the intersection of the western border of Township 14 South, Range 5 East, Section 6; thence south to the northwest corner of Section 7;

(6) Thence continuing in a diagonal line of the southeast corner of Township 14 South, Range 6 East, Section 7; thence from the corner of Section 7 .25 mile west to where it intersects with an unimproved road;

(7) Thence following this unimproved road in a southeast direction to the Gaging Station, the point of beginning.

Signed: June 9, 1981.

G. R. Dickerson,
Director.

Approved: July 12, 1981.

John P. Simpson,
Acting Assistant Secretary (Enforcement and Operations).

[FR Doc. 81-21980 Filed 7-27-81; 8:45 am]
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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD Regulation 6010.8-R]

Implementation of the Civilian Health and Medical Program of the Uniformed Services; Amendment

AGENCY: Office of the Secretary, DOD.

ACTION: Proposed amendment to rule.

SUMMARY: This proposed rule amends the comprehensive CHAMPUS Regulation 6010.8-R (32 CFR 199) which implements the Civilian Health and Medical Program of the Uniformed Services. It sets forth revised criteria for determining when a hearing impairment will be considered to constitute a serious physical handicap.

DATES: Written public comments must be received on or before September 1, 1981. If adopted, this amendment would become effective on October 1, 1981.

ADDRESS: Office of the Secretary of Defense (Health Affairs), Room 3E339, The Pentagon, Washington, D.C. 20301.

FOR FURTHER INFORMATION CONTACT: Lorraine F. Carpenter, Special Assistant for CHAMPUS, telephone (202) 697-5185.

SUPPLEMENTARY INFORMATION: In FR Doc. 77-7834, appearing in the Federal Register on April 4, 1977 (42 FR 17972), the Office of the Secretary of Defense