

re delegated to the Center for Veterinary Medicine (21 CFR 5.83), Part 520 is amended by redesignating existing § 520.1450 as § 520.1450a and by adding new §§ 520.1450 and 520.1450b, to read as follows:

**PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS NOT SUBJECT
TO CERTIFICATION**

§ 520.1450 Morantel tartrate oral dosage forms.

* * * * *

§ 520.1450b Morantel tartrate cartridge.

(a) *Specifications.* The drug product consists of a stainless-steel cylinder having both ends closed with polyethylene diffusing discs and containing a morantel tartrate paste. The paste contains 22.7 grams of morantel tartrate equivalent to 13.5 grams of morantel base.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Conditions of use—(1) Amount.* Cattle turned out to pasture in spring: 1 cartridge to each animal at turnout. Cattle that remained on pasture during winter: 1 cartridge to each animal between March 1 and April 1.

(2) *Indications for use.* For control of the adult stage of the following gastrointestinal nematode infections in weaned calves and yearling cattle weighing a minimum of 200 pounds through the summer grazing season: *Ostertagia* spp., *Trichostrongylus axei*, *Cooperia* spp., and *Oesophagostomum radiatum*.

(3) *Limitations.* Administer orally with the balling gun to all cattle that will be grazing the same pasture. Do not administer to cattle within 160 days of slaughter. Consult your veterinarian before administering to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

Effective date. December 7, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: November 29, 1984.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 84-31920 Filed 12-6-84; 8:45 am]

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DEPARTMENT OF THE TREASURY

**Bureau of Alcohol, Tobacco and
Firearms**

27 CFR Part 9

[T.D. ATF-192: Reference Notice Nos. 405, 443]

Madera Viticultural Area

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

ACTION: Final rule, Treasury decision.

SUMMARY: This rule establishes a viticultural area located in Madera and Fresno Counties, California, named Madera. This final rule is the result of a petition submitted by Mr. David B. Ficklin, Ficklin Vineyards in Madera, California, and of written comments and oral testimony received at a public hearing.

The Bureau of Alcohol, Tobacco and Firearms believes the establishment of Madera as a viticultural area and its subsequent use as an appellation of origin in wine labeling and advertising will allow wineries to designate their specific grape-growing area and will help consumers identify the wines they purchase.

EFFECTIVE DATE: January 7, 1985.

FOR FURTHER INFORMATION CONTACT: Charles N. Bacon, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, Telephone: (202) 566-7626.

SUPPLEMENTARY INFORMATION:

Background

ATF regulations in 27 CFR Part 4 allow the establishment of definite viticultural areas. These 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. Section 9.11, Title 27 CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features. Under 27 CFR 4.25a(e)(2), any interested person may petition ATF to establish a grape-growing region as an American viticultural area. Approved American viticultural areas are listed in 27 CFR Part 9.

Petition for Madera

In June 1981, David Ficklin, President of Ficklin Vineyards in Madera, California, petitioned ATF to establish a viticultural area known as Madera. This proposed viticultural area was located in central Madera County between the Chowchilla and San Joaquin Rivers, with an adjacent portion of Fresno

County included. The proposed area was 230,000 acres in size of which over 30,000 acres were devoted to grapes.

In response to this petition, ATF proposed the Madera viticultural area in Notice No. 405 on January 26, 1982 [47 FR 3564]. In that notice, ATF solicited comments on alternative boundaries, comments about viticultural and geographic characteristics which distinguish the viticultural area from surrounding areas, and comments concerning the name Madera.

ATF received seven written comments, five of which fully supported the proposed name and boundaries. One comment objected to the proposed boundaries, stating that they should encompass all of western Madera County. The Portuguese government objected to the proposed name Madera and requested a public hearing on the matter.

Public Hearing

In Notice No. 443, December 16, 1982, [47 FR 56369], ATF announced a public hearing to be held in Madera on January 18, 1983, to obtain additional information concerning the proposed area.

Fourteen people presented evidence at that hearing. Representatives of Ficklin Vineyards and Papagni Vineyards testified in favor of the proposed name and boundaries. Eight other persons testified in favor of expanding the viticultural area into western Madera County. One person testified on behalf of the Portuguese government stating their objection to the name Madera.

Seven persons filed post-hearing written comments; all of them favored expanding the viticultural area into part or all of western Madera County.

Boundaries

Western Viticultural Area Boundary

As proposed, the Madera viticultural area extended between the Chowchilla and San Joaquin Rivers. The western boundary was formed by a line from the Chowchilla River south along Road 15 to Avenue 17; east along Avenue 17 to Road 19; south along Road 19 to Avenue 12 [Firebaugh Road]; east on Avenue 12 to Road 22; and south along Road 22 and a line extending south to the San Joaquin River.

The petitioner based this western boundary on soil differences. The petition stated that the proposed viticultural area contains well drained, non-alkali soils well suited to the cultivation of grapes while in the western part of the county, the soils

change to a highly alkali type unsuited for grape growing. During the hearing, Steven Ficklin representing the petitioner stated that a period of several years of soil treatment would be needed to leach the alkali (high sodium) content of this soil to below the rootline of grapes, and that if the soils were not leached, the alkali content would damage grape vines.

Several respondents representing grape growers in western Madera County objected to the exclusion of the western part of the county based on soil. Mr. Robert Smith, a Madera vineyard owner and manager of vineyards in western Madera County, testified that sodium could be leached out of alkaline soils through the application of large amounts of water, such as by irrigation during farming. He also stated this process could be hastened by the application of sulfuric acid or gypsum. Smith testified that the soils in the two vineyards which he manages in western Madera County do not have high sodium levels.

Seven other persons testified during the public hearing that they have grown grapes in the western part of Madera County, some for as long as 25 years. Morgan Johnson, a Madera County grapegrower, testified that some of the soil in the western part of the county is neutral and not alkaline. He also testified that drip irrigation could substantially reduce the alkaline content of some soils in one year's time.

In post hearing comments, one additional person commented that he is growing grapes in western Madera County. The Bisceglia Brothers Wine Company in Madera also stated that they purchase grapes from western Madera County and that they favor extending the viticultural area into the western part of the county.

ATF has examined all the evidence presented in written comments, in oral testimony received at the public hearing, and in post-hearing submissions. On the basis of all available evidence, the western boundary of the viticultural area is established as the San Joaquin River, and all of the western portion of Madera County is included.

Evidence shows that grapes are grown throughout central and western Madera County, although plantings in the western portion of the county tend to be newer. Also, soil differences exist throughout western and central Madera County, based on a soil map submitted by Steven Ficklin during the public hearing. This map shows large areas of free (non alkaline) soil within the western portion of Madera County; these areas are centered along the proposed north-south boundary, and to

the north along the Chowchilla River. The same map also shows substantial areas of intermittent free and saline soils in the western part of the county along the San Joaquin River.

Because of these soil types found within western Madera County, it is not possible to characterize all of the soil within this area as highly alkaline. By testimony given during the hearing, vineyards exist in free soils in this area which are identical to soils found in the central part of the county. Therefore, in order to use soils as a basis for the western boundary of the Madera viticultural area, ATF would have to draw very exact boundaries based on soil types. This is impossible due to the lack of any distinguishing geographical features appearing on U.S.G.S. maps covering western Madera County. ATF has thus determined that a geographical feature other than soils should be used to define the western boundary of the viticultural area. This geographical feature is the San Joaquin River, which divides Madera County from Fresno County, and distinguishes the viticultural area from the area to the west which is both drier and has a longer growing season.

Fresno County

As proposed, the Madera viticultural area included a small portion of Fresno County east of the San Joaquin River. This was included because Papagni Vineyards grows grapes in this area from which they produce estate bottled wines, and because it is separated from other wine growing areas in Fresno County by urban areas.

ATF is including this area in the Madera viticultural area. This area enjoys a long historical association with the Madera area due to the Papagni Vineyards there, and the fact that Papagni Vineyards makes wine using grapes both from the Madera and these Fresno County Vineyards. All available evidence shows this area of Fresno County has similar geographic criteria to the Madera area.

Name

The name Madera was well documented in the petition, and supported by written and oral testimony as referring to the viticultural area. Madera is the name of the county and largest city within the viticultural area. Moreover, the name Madera has been associated with local wines since as far back as the 1880's when the Madera Winery shipped wines bearing the Madera label to many parts of the world. Madera is currently being used by Ficklin Vineyards and Papagni

Vineyards to label wines made from area grapes.

Mr. Felix Dias, Commercial Counselor to the Portuguese Embassy objected to the designation of Madeira. He pointed out possible confusion with the Portuguese island of Madeira which has produced world famous wines for over 500 years and possible confusion with Madeira wine, a class and type of dessert wine. ATF recognizes Madeira as a class and type of wine, and as a semi-generic wine designation with geographical significance. When used as a class and type designation, Madeira must be qualified with an appellation of origin if the wine is not from the island of Madeira. Mr. Dias stated use of the term "Madera" would mislead and confuse consumers, and would be unfair to the Portuguese wine industry. In its place, Mr. Dias suggested use of "San Joaquin River Valley" or other similar American appellation for the viticultural area.

ATF recognizes the similarity in the names "Madera" and "Madeira." However, all evidence shows that the viticultural area is known locally and nationally as "Madera," thus meeting the requirement of 27 CFR 4.25a(e)(2)(i). Moreover, no evidence was presented that the viticultural area is known as the "San Joaquin River Valley." The term "San Joaquin Valley" refers to a geographical area far larger than the proposed Madera viticultural area. ATF does not see any consumer confusion between Madera and Madeira wines when Madera is used as an appellation of origin on domestic wines. Madera has been used on labels of domestic wines for many years to denote wines from Madera County, California and this has not resulted in consumer confusion. Therefore, ATF is adopting the name Madera for the viticultural area.

Geographical Criteria

Elevation of the Madera viticultural area increases from west to east, from 130' along the San Joaquin River on the west, to 400' on the eastern boundary in Fresno County. Rainfall throughout the viticultural area is sparse, from 5 to 20 inches per year, and averaging 11 or 12 inches per year in the Madera-Fresno area. This differentiates the viticultural area from the west where rainfall averages 7 to 8 inches in the Los Banos-Mendota-Firebaugh areas, and from the east where rainfall is higher averaging 13 to 15 inches per year in the Friant-Auberry area.

In terms of degree days, Madera averages 4259 degree days according to records kept by the Madera Irrigation District. This contrasts with warmer

areas both to the north where Merced averages 4430 degree days, and to the south where Fresno averages 4680 degree days.

The growing season in the Madera viticultural area averages between 260-270 days, with periodic freezing temperatures during the winter which trigger vine dormancy. To the east in the Friant-Auberry area, the growing season is 220 days, while to the west in the Los Banos-Mendota-Firebaugh area, the growing season averages 285 or more days per year. Thus, the Madera viticultural area is distinguished from surrounding areas by the length of the growing season.

Conclusion

ATF is adopting a viticultural area located in Madera and Fresno Counties, California. The boundaries are Sunnyside Road on the west, the San Joaquin River and Shepherd Avenue on the south, the county boundary and Chowchilla River on the north, and Road 26, the Santa Fe Railroad, and Avenue 15 (extended into Fresno County) on the east and northeast. The name is "Madera."

Overall, the Madera viticultural area contains approximately 700 square miles or 448,000 acres, and over 33,000 acres of wine grapes plus substantial acreages of raisin and table grapes. Primary wine grape varieties include Carignane, Barbera, Chenn Blanc, French Colombard, Grenache, Rubired, and Ruby Cabernet. Six bonded wineries have been established within the viticultural area.

Miscellaneous

ATF does not wish to give the impression that by approving Madera as a viticultural area, it is approving or endorsing the quality of the wine from the area. ATF is approving this area as being distinct and not better than other areas. By approving this area, wine producers are allowed to claim a distinction on labels and advertisements as to the origin of the grapes. Any commercial advantage gained can only come from consumer acceptance of Madera wines.

Regulatory Flexibility Act

The notice of proposed rulemaking which resulted in this final rule contained a certification under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that if promulgated as a final rule, it would not have a significant impact on a substantial number of small entities. Therefore, the requirement contained in the Regulatory Flexibility Act (5 U.S.C.

603, 604) for a final regulatory flexibility analysis does not apply to this final rule.

Compliance With Executive Order 12291

It has been determined that this final regulation is not a "major rule" within the meaning of Executive Order 12291 of February 17, 1981, because it will not have an annual effect on the economy of \$100 million or more; it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 27 CFR Part 9

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

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this final rule because no requirement to collect information is imposed.

Drafting Information

The principal author of this document is Charles N. Bacon, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

Authority and Issuance

Accordingly, under the authority contained in 27 U.S.C. 205, the Director is amending 27 CFR Part 9 as follows:

PART 9—AMERICAN VITICULTURAL AREAS

Paragraph 1. The table of sections in 27 CFR Part 9 is amended by adding § 9.92. As amended, the table of sections reads as follows:

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Subpart C—Approved American Viticultural Areas

* * * * *

Sec. 9.92 Madera.

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Para. 2. Subpart C is amended by adding § 9.92 which reads as follows:

§ 9.92 Madera.

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

(b) *Approved maps.* The approved maps for determining the boundary of the Madera viticultural area are eleven U.S.G.S. maps. They are entitled:

(1) "Clovis, Cal.," 7½ minute series, edition of 1964, photorevised 1972;

(2) "Fresno North, Cal.," 7½ minute series, edition of 1935, photorevised 1972;

(3) "Friant, Cal.," 7½ minute series, edition of 1964;

(4) "Lanes Bridge, Cal.," 7½ minute series, edition of 1964, photoinspected 1973;

(5) "Gregg, Cal.," 7½ minute series, edition of 1965;

(6) "Madera, Cal.," 7½ minute series, edition of 1963;

(7) "Kismet, Cal.," 7½ minute series, edition of 1961;

(8) "Raynor Creek, Cal.," 7½ minute series, edition of 1961;

(9) "Fresno, Cal.," scaled 1:250,000, edition of 1962, revised 1971;

(10) "Monterey, Cal.," scaled 1:250,000, edition of 1974; and

(11) "San Jose, Cal.," scaled 1:250,000, edition of 1982, revised 1969.

(c) *Boundaries.* The Madera viticultural area is located in Madera County, California. The beginning point is found on the "Fresno North," 7½ minute series U.S.G.S. map at the point where the San Joaquin River intersects the section line dividing sections 20 and 29, and sections 21 and 28, T. 12 S., R. 20 E.,

(1) Then east approximately 6 miles following the section line and Shepherd Avenue to the intersection with Sunnyside Road;

(2) Then north approximately 7 miles following Sunnyside Road and continuing along the section line to the point of intersection of sections 16, 17, 20, and 21, T. 11 S., R. 20 E.;

(3) Then west approximately 17.6 miles following the section line and continuing along Avenue 15 to the intersection with the Atchison, Topeka and Santa Fe Railroad;

(4) Then northwest following the Atchison, Topeka and Santa Fe Railroad to Road 26;

(5) Then north following Road 26 and continuing north in a straight line to the Chowchilla River in the "Raynor Creek" 7½ minute series U.S.G.S. map, and in the "San Jose" scaled 1:250,000 U.S.G.S. map;

(6) Then west following the Chowchilla River to the point where the Madera County-Merced County boundary diverges from the river;

(7) Then southwest following the Madera County-Merced County boundary to the San Joaquin River;

(8) Then following the San Joaquin River south and east returning to the point of beginning.

Signed: October 24, 1984.

W.T. Drake,
Acting Director.

Approved: November 15, 1984.

Edward T. Stovenson,
Deputy Assistant Secretary (Operations).

[FR Doc. 84-32007 Filed 12-6-84; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 915

Permanent Program Amendment From the State of Iowa Under the Surface Mining Control and Reclamation Act of 1977

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

ACTION: Final rule.

SUMMARY: OSM is announcing the approval of certain amendments to the Iowa permanent regulatory program (hereinafter referred to as the Iowa program) under the provisions of the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

On May 8, 1984, Iowa submitted proposed program amendments pertaining to public notice of subsidence control, the amount and duration of performance bonds including methodology for determining bond amounts, and the deletion of the 10-acre prime farmland exemption which was inadvertently retained when the Iowa program was approved in 1981.

After providing an opportunity for public comment and conducting a thorough review of the program amendments, the Director of OSM has determined that the amendments meet the requirements of SMCRA and the Federal regulations, with the exception of the provisions discussed below. Accordingly, the Director is approving those amendments which are consistent with SMCRA and no less effective than the Federal regulations there under, and has notified Iowa, pursuant to 30 CFR 732.17, of additional program amendments which are required. Pursuant to 30 CFR 732.17(f), Iowa must respond to this notification within 60 days.

The Federal rules at 30 CFR Part 915 which codify decisions concerning the Iowa program are being amended to implement these actions.

EFFECTIVE DATE: December 7, 1984.

ADDRESSES: Copies of the Iowa program and the Administrative Record on the Iowa program are available for public inspection and copying during business hours at:

Office of Surface Mining, Kansas City Field Office, Professional Building, 1103 Grand Avenue, Kansas City, Missouri 64108; Telephone: (816) 374-3920.

Office of Surface Mining, Administrative Record, Room 5124, 1100 "L" Street, NW., Washington, D.C. 20240; Telephone: (202) 343-7896.

Iowa Department of Soil Conservation, Mines and Minerals Division, Wallace State Office Building, Des Moines, Iowa 50319; Telephone: (515) 281-5851.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Rieke, Field Office Director, Kansas City Field Office, Office of Surface Mining, Professional Building, 1103 Grand Avenue, Kansas City, Missouri 64108; Telephone: (816) 374-3920.

SUPPLEMENTARY INFORMATION:

I. Background

The Iowa program was conditionally approved by the Secretary of the Interior on January 21, 1981 (46 FR 5885). The approval was made effective April 10, 1981. Information pertinent to the general background, revisions, modifications, and amendments to the Iowa program submission, as well as the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Iowa program can be found in the January 21, 1981 Federal Register.

II. Submission of Amendments

By letters dated May 9, 1984, Iowa submitted proposed program amendments consisting of:

(1) An amendment to Iowa subrule 4.523(63), subsidence control; public notice, to adopt by reference 30 CFR 817.122, as promulgated June 1, 1983. The rule concerns notice to surface owners of underground mining activities and would give underground mine operators some flexibility in providing notice;

(2) An amendment to Iowa subrules 4.41(1), 4.42, 4.322(3), and 4.332(3), to provide revised provisions on the amount and duration of performance bonds including a methodology for determining bond amounts; and

(3) An amendment to Iowa subrule 4.322(14) to delete the 10-acre prime farmland exemption which was inadvertently retained when the Iowa program was approved in 1981.

On June 8, 1984, OSM published a notice in the Federal Register

announcing receipt of the Iowa amendment and inviting public comment on whether the proposed amendment was no less effective than the Federal regulations (49 FR 23872-23873). The public comment period ended July 9, 1984. An opportunity to request a public hearing was provided, but none was requested.

During review of the amendments, OSM identified two concerns:

(1) Iowa's proposed methodology for determining bond amounts does not explicitly demonstrate that it represents a good approximation of actual reclamation costs; and

(2) Iowa's proposed maximum bond amount of \$10,000 per acre might not be sufficient to assure completion of reclamation in the event of bond forfeiture.

OSM notified Iowa about these concerns by letter dated July 24, 1984, and Iowa responded by submitting clarifying information on August 30, 1984. The clarifying information identified the reasons why the specific methodology was chosen for Iowa and explained why the maximum bond amount will be sufficient.

On September 27, 1984, OSM reopened and extended the comment period for 15 days to solicit public comment on Iowa's clarifying information (49 FR 38150). The comment period closed on October 15, 1984, and no comments were received.

III. Director's Findings

The Director finds, in accordance with SMCRA and 30 CFR 732.17, that the amendments submitted by Iowa on May 9, 1984, meet the requirements of SMCRA and the Federal regulations with the exception of the provisions discussed below. Only those provisions of particular concern are discussed in the specific findings which follow. Unless specifically stated, the Director approves the revisions to the Iowa subrules. Discussion of only those provisions for which specific findings are made does not imply any deficiency in any provision not discussed. The provisions not specifically discussed are found to be consistent with SMCRA and no less effective than the Federal regulations. All of the provisions involved in the amendment are cited at the end of this notice in the amendatory language in new sections 30 CFR 915.15 and 30 CFR 915.16.

Subrule 4.523(63), subsidence control; public notice

Iowa is adopting by reference 30 CFR 817.122 as promulgated June 1, 1983. The rule concerns notice to surface owners