DATES: This rule is effective January 20, 2011.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: cindy.burnsteel@fda.hhs.gov.


In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:


2. Add §522.1664 as follows:

§522.1664 Oxytetracycline and flunixin.

(a) Specifications. Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base as amphoteric oxytetracycline and 20 mg flunixin base as flunixin meglumine.

(b) Sponsor. See No. 055529 in §510.600(c) of this chapter.

(c) Related tolerances. See §§556.286 and 556.500 of this chapter.

(d) Conditions of use cattle—(1) Amount. Administer once as an intramuscular or subcutaneous injection of 1 mL per 22 pounds (lb) body weight (BW) (13.6 mg oxytetracycline and 0.9 mg flunixin per lb BW) where retreatment of calves and yearlings for bacterial pneumonia is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable.

(2) Indications for use. For the treatment of bacterial pneumonia associated with Pasteurella spp. and for the control of associated pyrexia in beef and nonlactating dairy cattle.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Discontinue treatment at least 21 days prior to slaughter of cattle. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Use of dosages other than those indicated may result in residue violations.

Dated: January 11, 2011.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 9, and 70

[Docket No. TTB–2007–0068; T.D. TTB–90; Re: Notice Nos. 78 and 80]

RIN 1513–AB39

Revision of American Viticultural Area Regulations

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: In this Treasury decision, the Alcohol and Tobacco Tax and Trade Bureau amends the regulations concerning the establishment of American viticultural areas (AVAs). The changes provide clearer regulatory standards for the establishment of AVAs and clarify the rules for preparing, submitting, and processing viticultural area petitions.

DATES: Effective Date: This final rule is effective on February 22, 2011.


SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the regulations promulgated under the FAA Act.

Part 4 of the TTB regulations (27 CFR part 4) provides for the establishment of definitive viticultural areas and for the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) prescribes the standards for submitting a petition to establish a new American viticultural area (AVA) or to modify an existing AVA, and it contains a list with descriptions of all approved AVAs. Part
70 of the TTB regulations (27 CFR part 70) concerns procedure and administration and includes, at § 70.701 (27 CFR 70.701), provisions regarding rulemaking procedures.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region distinguishable by geographic features, the boundaries of which have been recognized and defined in part 9 of the TTB regulations. These AVA designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Current AVA Petition Process

Section 9.3 of the TTB regulations (27 CFR 9.3) sets forth the current procedure and standards for the establishment of AVAs. Paragraph (a) of that section states that TTB will use the rulemaking process based on petitions to establish AVAs received in accordance with §§ 4.25(e)(2) and 70.701(c). Paragraph (b) of § 9.3 provides that a petition for the establishment of an AVA must contain the following:

- Evidence that the name of the viticultural area is locally and/or nationally known as referring to the area specified in the application;
- Historical or current evidence that the boundaries of the viticultural area are as specified in the application;
- Evidence relating to the geographical features (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;
- 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
- A copy of the appropriate U.S.G.S. map(s) with the boundaries prominently marked.

Notice of Proposed Rulemaking

On November 20, 2007, TTB published a notice of proposed rulemaking, Notice No. 78, in the Federal Register (72 FR 65261) setting forth, among other things, a revision of subparts A and B of part 9. The original comment period closing date of January 22, 2008, was extended an additional 60 days in Notice No. 80, published in the Federal Register (72 FR 71290) on December 17, 2007.

In Notice No. 78, TTB and Treasury stated that a comprehensive review of the AVA program was warranted in order to maintain the integrity of the program. We considered the impact that the establishment of an AVA can have on the use of existing brand names. In this regard, we stated that we did not believe it to be appropriate for a government agency to choose between competing commercial interests, in the context of the labeling provisions of the FAA Act, where a conflict exists between a proposed AVA name and an established brand name used on a wine label approved by TTB, if such choices can be avoided.

We also noted that there has been an increase in the number of petitions for the establishment of new AVAs within already existing AVAs. Since recognizing the existence of an AVA is based on the idea that the defined area is unique for viticultural purposes with reference to what is outside it, we stated that preserving the integrity of the AVA program warrants clarifying the standards concerning the establishment of new AVAs within existing AVAs.

Finally, we believed that there was a need to explain and clarify the AVA petition submission and review process and to clearly state the existing authority to deny, and the grounds for denying, an AVA rulemaking petition.

AVA Name and Brand Name Conflict

As we stated in Notice No. 78, the designation of a new AVA can create a conflict with existing brand names. This conflict can arise because a brand name that includes an approved AVA name may not be used unless at least 85 percent of the wine is derived from grapes grown within the boundaries of the AVA. See 27 CFR 4.25(e)(3). Moreover, TTB prohibits the use of misleading brand names (27 CFR 4.33), and also prohibits brand names that tend to create the impression that the wine is entitled to be designated recognized by TTB unless the wine meets the requirements for that designation (27 CFR 4.39(a)(8)). The establishment of a new AVA could also give rise to a misleading impression regarding the provenance of a wine that carries a known brand name similar to the AVA name that does not meet the 85 percent requirement that applies to AVA name usage, thereby not providing the consumer with adequate information as to the identity and quality of the wine and creating confusion for consumers.

TTB noted in Notice No. 78 that the effect of the current regulatory provisions is to give precedence to the establishment of an AVA over the use of a brand name on a previously approved label. This precedence is derived from the combined effect of the appellation of origin and geographic brand name requirements of 27 CFR 4.25(e) and 4.39(i)(1). If a wine is not eligible for labeling with the viticultural area name and that name appears in the brand name, then the label would not be in compliance with TTB regulations and TTB would require the bottler to obtain approval of a new label with a new brand name in order to market it. Therefore, vintners are on notice that the decision to establish a brand name having geographical significance could result in the continued use of that brand name being restricted or prohibited by the subsequent establishment of an AVA using an identical or similar name. Whenever possible, however, TTB works with petitioners to amend petitions in order to limit the adverse impact on established brand names because established brand names have value to label holders, the sudden use of a new AVA name on labels instead of a long-established brand name may be confusing to consumers, and the AVA process can be used intentionally as a method of limiting competition from pre-existing brand name holders.

AVAs Within AVAs

Notice No. 78 noted that, in recent years, TTB has received an increasing number of petitions that propose a boundary change to an existing AVA, the establishment of an AVA entirely or partially within an existing AVA, or the establishment of a new, larger AVA that would encompass all of one or more existing AVAs. Such petitions can create the appearance of a conflict or inconsistency because, with reference to the criteria set forth in § 9.3(b), the new petition might draw into question the accuracy and validity of the evidence presented in support of the establishment of the existing AVA or the legitimacy of the justification for establishing a new AVA. For example, with reference to the boundary description and the geographical features criteria, a change in an existing AVA boundary, or the adoption of a new AVA within an existing AVA, could suggest that the original boundary description improperly draws in that there is no unity or consistency in the features of the existing AVA that give it a unique
and distinctive identity in a viticultural sense.

Further, we noted in Notice No. 78 that when a new AVA is established entirely within an existing AVA, depending on the unique facts presented in each AVA petition, an argument could be made that the smaller AVA is, by its very existence, distinct from the AVA that surrounds it, with the result that wine produced within it should not be labeled with the name of the larger AVA.

Petition Submission and Review Process

In Notice No. 78, we noted that the part 9 regulations could more completely describe the submission and review process, including the various actions that TTB may take at each stage of the AVA petitioning procedure.

Under TTB’s current AVA petition process, we process all AVA petitions that are submitted to us. TTB’s practice is to work with petitioners both before and after submission of the petition to ensure that it contains all necessary information. TTB specialists spend considerable time reviewing the petition, contacting the petitioner, and requesting missing evidence from the petitioner. In some cases, deficient petitions are returned to the petitioner for revision and resubmission. Only after the petition is perfected (that is, it appears to contain all of the information required under §9.3) do we proceed with preparation of an appropriate rulemaking document. As we noted in Notice No. 78, as a general rule, the practice of TTB has been to accept the information provided by the petitioner in a perfected petition with the assumption that the information provided is correct. TTB does not conduct a detailed, separate investigation of the validity of the petition evidence at that point. To confirm or refute the information provided by the petitioner, TTB has relied on comments provided in response to the published notice of proposed rulemaking (NPRM). We also noted in Notice No. 78 that whereas the TTB regulations in part 9 speak in terms of what an AVA petition must contain, they do not clearly reflect the fundamental administrative principle that the authority to grant carries a concomitant authority to deny an AVA petition. We have come to realize that some believe that all that is necessary to successfully petition for the establishment of an AVA is to submit a petition with evidence under the terms of §9.3(b).

We also noted that TTB has authority not to initiate rulemaking, or not to approve the petitioned-for AVA action after publication of a proposal, for any one of a number of reasons, such as:

- The evidence submitted with the petition does not adequately support use of the name proposed for a new AVA;
- The evidence of distinguishing features submitted with the petition does not support drawing or redrawing the AVA boundary as proposed;
- The extent of viticulture within the proposed boundary is not sufficient to constitute a grape-growing region within the intention of the AVA program; or
- Approval of a proposed new AVA would be inconsistent with the purpose of the FAA Act, contrary to another statute or regulation, or otherwise not in the public interest.

Summary of Proposed Changes

In Notice No. 78, TTB proposed to amend three provisions within part 4 of the TTB regulations that concern AVAs, to revise subparts A and B of part 9 of the TTB regulations, to amend various sections within subpart C of part 9, and to amend one provision within part 70 of the TTB regulations.

Part 4 Amendments

To permit the establishment of an AVA and at the same time mitigate the impact on existing brand labels which contain terms that would be viticulturally significant if the proposed AVA was established, TTB proposed, in Notice No. 78 to amend §4.39(i) of the TTB regulations (27 CFR 4.39(i)) by adding a new “grandfathering” standard that would apply in the case of AVAs established after adoption of the final rule in this matter and that would be based on a specified number of years that an affected Certificate of Label Approval (COLA) had been issued and that the brand label had been in actual commercial use prior to receipt by TTB of a perfected AVA petition.

By way of background, Notice No. 78 noted that at the beginning of the AVA program, TTB’s predecessor agency and Treasury adopted §4.39(i) to permit the continued use of brand names that had been used in COLAs issued before July 7, 1986, subject to application of any one of three conditions. This original “grandfather” approach was intended to protect brand names that had existed prior to the development of the AVA program. This solution did not specifically address conflicts between AVAs and brand names in COLAs that came into existence after July 7, 1986, although it effectively put all vintners on notice that the use of a brand name with geographic significance could later be restricted by the establishment of a viticultural area.

While TTB in Notice No. 78 noted its intention to continue to work with future AVA petitioners to limit the adverse impact on established brand names, TTB also recognized that sometimes it would not be possible to amend a petition to achieve this result. To address this possibility, TTB proposed a new grandfathering standard.

In addition, we proposed in Notice No. 78 to update two provisions within §4.25(e) and conform them to the proposed changes to part 9 described below.

Part 9 Amendments

Notice No. 78 proposed to revise subparts A and B of part 9 to clarify the operation of the AVA petition and rulemaking process by explaining how a petitioner must submit an AVA petition to TTB, by setting forth with considerably greater specificity what information a petition must contain, and by explaining how TTB would process these petitions. In addition to setting forth standards for the establishment of an AVA, the proposed amendments addressed the requirements for proposed boundary and name changes to existing AVAs to ensure that an AVA proposal published by TTB to change an existing AVA (for example, a boundary expansion) would have adequate supporting evidence. The specification of requirements for boundary changes was proposed to ensure that TTB receives petitions that conform to AVA regulatory standards rather than to considerations that are not central to the AVA concept.

The proposed regulatory language also reflected the principle that TTB may decide not to proceed with rulemaking after receipt of a petition, in which case TTB would provide an explanation of the decision to the petitioner. The proposed amendments also specifically delineated the authority of TTB to decide not to proceed with approval of the petitioned-for AVA action after publication of the NPRM. The proposed regulatory amendments attempted to make a clear distinction between the petition process and the rulemaking process, because a decision not to go forward may be made at either stage.

The proposed amendments in subpart C involved the addition of statements regarding the viticultural significance of names of previously established AVAs, or notable portions of those names, for wine labeling purposes under part 4 of the TTB regulations. TTB stated in Notice No. 78 that these amendments were consistent with the practice employed by TTB over the past several
years of including a second sentence in paragraph (a) of each section covering a new AVA, to specify what is viticulturally significant as a result of the establishment of the AVA. While in many cases only the full name of the AVA was specified in each of the subpart C amendments proposed in Notice No. 78, in some instances a portion of the name was also identified as viticulturally significant if, based on TTB’s label approval practice, its use on a label could be taken to represent the full AVA name. We specifically invited comments on whether any existing labels would be at risk if the proposed amendments were adopted as a final rule.

Comments Invited on the Regulatory Proposals

In Notice No. 78, TTB invited interested parties to comment on the proposed rulemaking and regulatory texts. In addition, we invited comments on the following specific questions:

1. Whether additional or different standards should apply to the establishment of an AVA; for example, whether there should be a requirement that a specified percentage of the land mass of the proposed AVA be involved in viticultural activities.

2. Whether in some or all cases the establishment of a smaller AVA located within the boundaries of a larger AVA should result in a prohibition against the use of the larger AVA name on wine labels.

3. Whether the use of a “grandfather” provision to avoid conflicts between an established brand name and the establishment of a proposed AVA is appropriate.

4. Whether the terms of the proposed “grandfather” provision are appropriate and, if so, what time periods should apply to establish commercial use of the brand name involved in a conflict.

5. Whether it would be more appropriate to adopt an alternative to the “grandfather” provision proposed that would apply to brand names that have longstanding commercial use under one or more existing certificates of label approval without specifying a time period.

6. What type of dispelling information would prevent consumers from being misled as to the origin of the wine when a “grandfather” provision applies. Other comments for a requirement on dispelling information were encouraged.

Comments Received and TTB Analyses/Responses

TTB received 191 comments in response to Notice No. 78. The table below summarizes who submitted comments and the number of comments submitted.

<table>
<thead>
<tr>
<th>Who submitted comments</th>
<th>Number of comments</th>
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<tbody>
<tr>
<td>Federal Government</td>
<td>2</td>
</tr>
<tr>
<td>State Government</td>
<td>2</td>
</tr>
<tr>
<td>Local Government</td>
<td>6</td>
</tr>
<tr>
<td>Wine Industry Members</td>
<td>88</td>
</tr>
<tr>
<td>Interest Groups/Trade Organizations</td>
<td>31</td>
</tr>
<tr>
<td>Concerned Citizens</td>
<td>48</td>
</tr>
<tr>
<td>Other</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>191</td>
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</table>

In the category of Interest Groups/Trade Organizations, there were no consumer groups that submitted comments. With regard to Concerned Citizens, it cannot be determined in what capacity the commenters have submitted their comments (e.g., as consumers, or as owners of an alcohol beverage business).

Twenty-four of the comments received were either requests for extension of the Notice No. 78 comment period or requests that TTB end the suspension of AVA petition processing then in place. The latter comments were submitted in support of the then-proposed Lehigh Valley AVA, which was established on March 11, 2008, by T.D. TTB–66 (73 FR 12870). Since the Notice No. 78 comment period was extended as requested, the establishment of the Lehigh Valley AVA was approved, and the suspension was ended, these issues have been resolved as the commenters had requested and are now moot.

Comments From Government Officials

We received a comment from one U.S. Senator, a joint comment from two U.S. Congressional Representatives, and comments from one California State Senator and several other California State and local government officials concerning Notice No. 78. All of the commenters expressed general opposition to Notice No. 78, and a number of the commenters expressed opposition to specific portions of the proposed regulations. All of the commenters also opposed TTB Notice No. 77, published in the Federal Register on November 20, 2007 (72 FR 65256), which proposed the establishment of a “Calistoga” AVA.

One U.S. Senator’s comment was in the form of a letter to the Secretary of the Treasury to “express my opposition to the Notices * * * as the actions in these rules will have a detrimental affect on the way wine is identified, branded and labeled in the United States.” The Senator’s comment further noted that “California’s wine industry contributes over $125 billion annually to the Nation’s economy.” Two Members of the U.S. House of Representatives wrote a joint letter to the Secretary of the Treasury and the TTB Administrator to “express our grave concern over two Notices * * * which would significantly and detrimentally alter the American Viticultural Area (AVA) system.” They further stated, “Even after the successful establishment of 189 viticultural areas by rulemaking, TTB now proposes major changes in Notices No. 77 and 78 that would have substantial, complicated and irreparable consequences for the future of America’s growing wine industry, which now contributes over $100 billion a year to our economy.” In addition, they stated, “We strongly believe that the existing AVA regulations have successfully served their purpose for over twenty years, and in fact, work very well. These NPRMs are not needed and are not supported by the wine industry.” Fifty-nine other Members of Congress also signed the letter.

A California State Senator submitted the contents of California Senate Joint Resolution 22, which she stated was passed unanimously in the State Senate and the State Assembly, “as a statement of the California Legislature’s concern and opposition to” Notice Nos. 77 and 78. She further stated that the “Senate and the Assembly of the State of California, jointly request the Tobacco Tax and Trade Bureau to protect and preserve the ability of California wineries, as well as all American wineries, to contribute to the economy of California and the nation by withdrawing the Notices.” The Secretary of the California Department of Food and Agriculture had concerns with our regulatory proposals, stating, “The revised regulations provide certain wine brands the right to market and sell their products with deceptive labels, leading consumers to believe their wines are from grapes grown in certain appellations or winemaking regions, when they are not.” This commenter also believes that these proposals “are far-reaching and could have substantial and severe consequences for all U.S. wine regions and wine brands.”

The city manager of Calistoga, California, opposed changes (in Notice Nos. 77 and 78) that would “eliminate the common and internationally understood practice of nesting wine appellations within larger wine appellations. Napa Valley is highly recognized and respected wine growing region throughout the world.”
The mayor of Paso Robles, California, opposed the proposed changes in Notice Nos. 77 and 78, stating that “the TTB proposed revisions to the regulations * * * will undermine decades of work on the part of the wine industry.” He stated further, “The effects of these proposals are far-reaching and will have substantial and severe consequences to all U.S. wine regions and wine brands and to the truth in labeling rights of consumers.” In specific regard to Notice No. 78, he wrote that it “threatens to eliminate the common and internationally understood practice of ‘nesting’ wine appellations within larger wine appellations.” He also stated that “this proposal [Notice No. 78] looks to create ‘Rolling Grandfather’ clauses that will allow new brands that would undermine the basic tenets of established law by allowing the use of misdescriptive geographic brands on an ongoing basis and creates loopholes for a select few.” He also stated, “These regulations will have a substantial negative impact on consumer confidence and compromise the integrity of the American wine industry.”

The president of the Napa County Farm Bureau opposed our proposals in Notice No. 78, stating, “The Board also opposes Notice 78, which would end the common and internationally understood practice of ‘nesting’ wine appellations * * *. Nesting transmits crucial information to consumers.” He also provided a copy of a Resolution passed by the board in regard to this opposition.

The Napa County agricultural commissioner also opposed our proposals in Notice No. 78, stating, “I also oppose Notice 78, which would end the common and internationally understood practice of ‘nesting’ wine appellations * * *. Nesting transmits crucial information to consumers.”

TTB Response

TTB appreciates the concerns and reservations these officials have expressed over our proposed changes to the AVA regulations. We recognize that viticulture and wine making are industries important to the American economy and are especially important to the economy of the State of California. However, we disagree with those commenters who suggested that the regulatory proposals we made in Notice No. 78 would result in a severe economic impact or have other substantial consequences on the wine industry, and we note in this regard that no specific data were provided to support these general statements.

As we stated in Notice No. 78, the proposals we made were intended to strengthen the AVA program. As one commenter pointed out, the regulations for the establishment of AVAs are over 20 years old. Although these regulations may have been initially successful in getting the AVA program “off the ground,” the regulations have not been updated to address a number of procedural and substantive issues or the problems with AVA petitions that have arisen over the years. At the time of publication of Notice No. 78, some of the AVA issues or petition problems encountered by TTB were as follows:

• Petitions to create an AVA were incomplete for numerous reasons.
• Petitions to expand an existing AVA where the acreage to be added to the existing AVA has no viticulture and where no significant viticulture is planned in the near future.
• Petitions to expand an existing AVA for the purpose of including adjacent viticultural acreage, with no evidence that the expansion area has any geographical features in common with the existing AVA.
• Petitions where the proposed AVA name conflicted with the brand names on existing labels.

Based on the issues and problems outlined above, we believe that the AVA program has not operated as well as some of these commenters suggest, and that the current part 9 regulations do not provide sufficient clarity and transparency regarding the AVA petition and approval process and regarding the manner in which TTB exercises its authority in that process. The part 9 proposals set forth in Notice No. 78 make a radical departure from the current regulatory standards but rather were a necessary elaboration on those standards in order to clarify existing petition requirements and existing TTB authority regarding the processing of AVA petitions. Since the comment period closed on this proposal on March 20, 2008, TTB has continued to process AVA petitions and to publish proposed and final regulatory actions with respect to petitions submitted. However, TTB continues to encounter the issues and problems described above and therefore, TTB believes that the need for the proposed regulations remains.

With regard to the comments opposing the proposed Calistoga viticultural area, which was the subject of Notice No. 77, these comments are outside the scope of this rulemaking and were addressed in a separate final rulemaking action specific to Notice No. 77 (see T.D. TTB–83, 74 FR 64602, December 8, 2009). With regard to the comments concerning the specific topics of “nesting” and the proposed “grandfather provision,” we received a number of other comments concerning these proposals. We discuss these additional comments and provide a response to all the comments received on these specific issues below.

Other Comments in General Opposition

Fifteen other commenters generally opposed the proposed revisions, without detailing that opposition to any specific provision or issue. For example, the Wine Institute commented, “TTB already has the ability to deal with complex issues and unanticipated controversies fairly * * * TTB can issue policy statements, guidance documents, and manuals on AVA establishment with interpretive and procedural guidelines * * * Wine Institute believes that these alternatives are preferable than the proposed regulatory changes, which could lead to unintended consequences.” This commenter added that TTB has a 27-year record of successful AVA rulemaking, is acting under what appears to be “an artificial sense of urgency,” and should continue to use the existing regulations. Other commentators asserted that the proposed provisions “have far reaching consequences” or are “inconsistent with fair and sound practices.” that “consumers will not be protected under the proposed regulations,” or that “the current regulations do a good job.”

TTB Response

As explained in detail in Notice No. 78, TTB and Treasury believed that there were valid reasons for proposing the regulatory changes. The new TTB regulatory proposals were crafted after much deliberation within TTB and
Treasury regarding: (1) Our duty to protect the consumer under the FAA Act; (2) our desire to be fair to, and to protect the economic interests of, all stakeholders; and (3) the long-term viability and credibility of the AVA program. We disagree with the suggestion that these regulations were developed in haste without substantial consideration as to their overall impact on the AVA program. Moreover, these general statements in opposition were not accompanied by any supporting data. Finally, as regards the use of other alternatives such as policy statements, guidance, or manuals, these alternatives are not binding on either the public or TTB and therefore are inadequate substitutes for regulatory action.

Comments on Specific Issues

The remaining 144 comments addressed one or more of the following issues:

- Whether a minimum percentage of landmass should be involved in viticultural activities for proposed AVAs;
- Whether the establishment of a smaller AVA within a larger AVA should prevent the use of the larger AVA name;
- Whether the establishment of a smaller AVA within a larger AVA (“nesting”) should be eliminated;
- Whether the proposed new part 4 grandfather provision, or an alternative grandfather approach, should be adopted, and if so, what type of dispelling information is appropriate;
- Whether the procedural provisions proposed for part 9 should be adopted; and
- Whether the statements of viticultural significance proposed for part 9 are appropriate.

Below are comment summaries and TTB responses by issue.

Comments on Minimum Percentage of Landmass

Proposed § 9.12(a)(1), which concerns name evidence, stated that the name identified for the proposed AVA “must be currently and directly associated with an area in which viticulture exists.” Also, proposed § 9.14(b)(2)(i) stated as one of the reasons for withdrawing a proposal, the fact that the extent of viticulture within the proposed boundary “is not sufficient to constitute a grape-growing region as specified in § 9.11(a).” However, in the proposed regulatory texts we did not specify a minimum requirement for viticultural activities.

As noted above, in the “comments invited” section of Notice No. 78, TTB asked whether there should be a requirement that a specified percentage of the landmass of the proposed AVA be involved in viticultural activities. Eight comments specifically addressed this question—two in favor and six in opposition.

One commenter in favor of such a standard wrote:

“The need for more reflective AVAs grows exponentially as the U.S. wine market expands into the global market.”

TTB believes that the proposed regulatory language concerning this issue should be adopted without change. As stated in Notice No. 78, one of the key reasons for proposing changes to these regulations is to maintain the integrity of the AVA program, and requiring a sufficient amount of viticulture within a proposed AVA is necessary in order to ensure that designation of the AVA has meaning. For example, we do not believe that if a grape grower plants five acres of grapes in an area encompassing 10,000 square miles, that amount of viticulture is sufficient to justify the designation of an AVA. On the other hand, for several reasons TTB does not believe it is appropriate to establish a specific percentage of landmass as a requirement for establishing an AVA. First, TTB recognizes that often the reason that petitioners seek AVA designations is to assist in the marketing of their wines, and we are concerned that a requirement of landmass might overly favor established areas. Second, although establishing by regulation a precise minimum percentage standard would provide an easy, mechanical method for TTB to decide whether sufficient viticulture exists in the proposed AVA, we believe that such an across-the-board, penalizing the establishment of new vineyards.”

One commenter argued that the objective of the AVA program is to allow vintners and consumers to attribute a given quality, reputation, or other characteristic of wine made from grapes grown in an area to its geographic origin. This person further stated that the “percentage of landmass is not compatible with the objective, nor does it in any way help the smaller wine producing areas at all.”

A commenter on behalf of Triassic Legacy Vineyards wrote:

“The promise of an appellation to entice wine enthusiasts to purchase the wines is a major factor in encouraging landowners to make the huge investment of time energy and money to become growers and vintners. I respectfully request that the concept of requiring that an AVA have some percentage of total area under viticulture be abandoned.

Finally, a commenter on behalf of Tablas Creek Vineyard stated:

“While density of a plantation is a factor in determining the importance of an AVA, that density should be measured against the available planting acres in the appellation and not the simple total geographic area. The economic importance of grape/wine production to the area should also be noted.”

TTB Response

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TTB Response

TTB believes that the proposed regulatory language concerning this issue should be adopted without change. As stated in Notice No. 78, one of the key reasons for proposing changes to these regulations is to maintain the integrity of the AVA program, and requiring a sufficient amount of viticulture within a proposed AVA is necessary in order to ensure that designation of the AVA has meaning. For example, we do not believe that if a grape grower plants five acres of grapes in an area encompassing 10,000 square miles, that amount of viticulture is sufficient to justify the designation of an AVA. On the other hand, for several reasons TTB does not believe it is appropriate to establish a specific percentage of landmass as a requirement for establishing an AVA. First, TTB recognizes that often the reason that petitioners seek AVA designations is to assist in the marketing of their wines, and we are concerned that a minimum percentage of landmass requirement might overly favor established areas. Second, although establishing by regulation a precise minimum percentage standard would provide an easy, mechanical method for TTB to decide whether sufficient viticulture exists in the proposed AVA, we believe that such an across-the-board, penalizing the establishment of new vineyards.”

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mechanical rule could operate to the detriment of the AVA program by discounting the possibility of future expansion of viticulture within the area. We believe that where it might appear that the amount of acreage devoted to viticulture is too small in comparison to the size of the proposed AVA, other relevant factors could exist (such as the number of vineyards established and how they are dispersed within the proposed AVA), which could lead to the conclusion that the extent of viticulture within the proposed AVA is sufficient. TTB recognizes that the lack of dispersed viticulture in a proposed AVA could warrant a closer review of the sufficiency of the distinguishing geographical features and name evidence provided in the petition, but these issues should be reviewed on a case-by-case basis.

TTB also recognizes that the regulations require the boundaries to be delineated based upon certain distinguishing features, such as climate, geology, soils, physical features, and elevation, in addition to the name of the area. For example, a watershed or ridge-line may provide the best marker to delimit the area. Sometimes those features that are common to the area may far exceed the actual grape-growing then occurring. Therefore, grape-growing areas and boundaries based on geographic features are unlikely to be exactly alike. The proposed regulatory texts were intended to underscore the fundamental principle behind every AVA petition, that is, that viticulture already exists within the boundary proposed for the new AVA, and we believe that the texts achieve that result. Finally, we agree with the suggestion that we also consider the economic importance of grape/wine production to the area as part of the analysis of the sufficiency of viticulture in the proposed AVA. An area may be known to consumers as a grape-growing region whether or not grape/wine production is important to the overall economy of the area, and, accordingly, we do not believe adding this consideration would be appropriate.

Comments on Whether Approval of a Smaller AVA Should Prevent Use of a Larger Surrounding AVA Name and Whether Nesting of AVAs Should Be Eliminated

In proposed §9.12(b), which concerns AVAs within AVAs, we stated:

consistent with the existing AVA and explains how the proposed AVA is sufficiently distinct from the existing AVA and therefore appropriate for separate recognition. If the petition proposes the establishment of a new AVA that is larger than, and encompasses all or more existing AVAs, the evidence submitted under paragraph (a) of this section must include information addressing whether, and to what extent, the attributes of the proposed AVA are consistent with those of the existing AVAs. In any case, the AVA would be created entirely within another AVA, whether by the establishment of a new, larger AVA or by the establishment of a new AVA within an existing AVA, the petition must dispel any apparent inconsistency or explain why it is acceptable. When a smaller AVA has name recognition and features that so clearly distinguish it from a larger AVA that surrounds it, TTB may determine in the course of the rulemaking that it is not part of the larger AVA and that wine produced from grapes grown within the smaller AVA would not be entitled to use the name of the larger AVA as an appellation of origin or in a brand name.

As noted above, in the “comments invited” section of Notice No. 78, TTB asked whether in some or all cases the establishment of a smaller AVA located within the boundaries of a larger AVA should result in a prohibition against the use of the larger AVA name on wine labels. Twenty-four commenters specifically address this question—two in favor of such a prohibition and 22 opposed to it.

One of the two commenters in favor asserted that more than one AVA on one wine label is inherently contradictory to the regulations in proposed §9.12(b). This commenter further stated that nesting “weakens consumer understanding of AVAs.” Though opposed to the concept of nesting, this commenter stated that it is unfair to change the regulations by not allowing wine producers to put both the sub-AVA and larger AVA on its wine labels. This commenter suggested that TTB allow wine producers to use sub-AVAs in conjunction with “political appellations.”

The other commenter in favor of such a prohibition expressed concern that some small AVAs within larger AVAs “are not based on oenological, environmental, topographical or historical differences but are intended for an egotistical or economical basis, only.” For this reason, this commenter supported the proposed changes regarding the establishment of an AVA within another AVA.

Of the 22 comments in opposition to the proposed regulatory text, many of them pointed out that an AVA within a larger AVA makes sense, helps to better identify and define the wine, is already part of the existing AVA program (many businesses established and built themselves up based on this concept), and coincides with other countries’ practices. For example, one commenter stated that “more than three-fourths of all existing AVAs are located inside another AVA * * * AVAs within AVAs help consumers both better understand viticultural distinctions that may exist within a larger AVA and gain information about the origin and thus value of a particular wine.”

Commenters who opposed this proposal also asserted that it is always better for the consumer to have more information about where a wine comes from. Some pointed out the use of the larger, and therefore probably more well-known, AVA name aids the consumer in determining where the sub-AVA is located.

A commenter on behalf of Premier Pacific Vineyards stated that the proposals in Notice No. 78 “will have tangible negative effects on wine consumers and the industry.” This commenter further stated, “Not allowing producers to list all the information on the wine’s origin by limiting the description to a small AVA without providing the often more familiar larger AVA, removes useful information from the consumer. Changing the rules in a way that makes the origin of wine and labeling more confusing or less descriptive represents a disservice to the consumer.”

The president of Appellation St. Helena, which represents 60 wineries and 7 vineyards, stated that this provision is “a huge step backward” and that it “flies in the face of all of the other great wine growing regions worldwide that go to great lengths to encourage detailed naming of specific places.”

A commenter affiliated with the University of California, Davis, wrote that the “concept of hierarchical classification, or nesting finer-scale places within coarser-scale places, is both global and almost ubiquitous.” Further, as an analogy to different levels for specifying AVAs, several commenters discussed the classification system of dogs. These commenters wrote that a Yorkie is a Terrier which is a dog. They further stipulated that no one will refute the fact that though a Yorkie is not the same as all terriers and a Terrier is not the same as all dogs, they are all in fact dogs and therefore share similar characteristics.

With regard to the companion issue of whether the nesting of AVAs should be eliminated, TTB received 36 comments, all in opposition. Many of these commenters share the belief that nesting
exists, rather than a situation in which
distinguishable geographical features
growing regions based on similar yet
AVA in which it lies. TTB agrees that
nesting should not be prohibited, and
comments received asserting that
''for creating an AVA.
limit overlaps that do not meet the tests
result in distinctive grapes and wine.
defining geographic areas (AVAs) that
the TTB's goal of identifying and
telecopying AVAs are consistent with
''nested or
''this structure.

A commenter on behalf of the
PRAVAC argued that “every appellation
system in the world utilizes geographic
nesting to specify the origin of wines,
and consumers worldwide are already
familiar with this concept.” This
commenter further stated that “nesting
itself is fundamental to the existence of
a meaningful appellation system * * *
TTB must not enact rules that threaten
this structure.”

A commenter on behalf of Premier
Vineyards wrote that “nested or
telecopying AVAs are consistent with
the TTB’s goal of identifying and
defining geographic areas (AVAs) that
have unique geographic features that
result in distinctive grapes and wine.”
However, another commenter on behalf
of Sonoma County Vintners stated that
“this does not mean that TTB should not
limit overlaps that do not meet the tests
for creating an AVA.”

TTB Response

TTB believes there is merit in the
comments received asserting that
nesting should not be prohibited, and
that recognition of a smaller AVA
should not by definition prohibit the
use of the viticultural name of the larger
AVA in which it lies. TTB agrees that
consumer interests are served by greater
specificity within a hierarchy, where a
tue hierarchy exists.

However, TTB notes that a
deetermination that a hierarchy of grape-
growing regions based on similar yet
distinguishable geographical features
exists, rather than a situation in which
an entirely different grape-growing
region lies within another grape-
growing region, must be based on the
facts related to the geographical features
presented in the AVA petition under
consideration. The comments received
in response to Notice No. 78 do not
convince us that the mere fact that a
proposed AVA would be located within
an existing AVA is sufficient to allow
the use of either the existing AVA name
or the proposed AVA name, at the sole
discretion of the vintner.

For example, if an existing AVA is
defined as being a large valley and its
distinguishing geographical features are
those that are found on the valley floor,
it may be appropriate to approve a
proposed AVA described as being situated
in whole or in part on the same
valley floor within the existing AVA if
the proposed AVA shares some of the
geographical features with the existing
AVA but at the same time has other
definitive geographical features that are
sufficiently distinctive as to warrant its
own AVA designation. On the other
hand, if within that large valley AVA
there is a mountain on which a
petitioner proposes to establish a new
AVA above the 500-foot elevation line,
the evidence provided in the petition
might demonstrate that the
distinguishing features of the proposed
AVA bear no relationship to those of the
valley floor. In the latter case, the new
petition has demonstrated that this is
not a hierarchical situation involving
some sharing of common features but
rather is a proposal to establish an
entirely different AVA. In such a case,
TTB believes it may be inappropriate
to take a regulatory action that could cause
consumers mistakenly to conclude that
wine produced from grapes grown
within the petitioned-for AVA has the
same characteristics as wine produced
from grapes grown in the existing AVA.

Based on our experience in reviewing
petitions for the establishment of AVAs,
we have found that in the vast majority
of cases petitioners who propose the
establishment of an AVA within an
existing AVA, and who provide
evidence that there are sufficiently
distinguishable geographical features in
the proposed AVA to warrant its
recognition, can also establish through
the evidence submitted that the
proposed AVA has some geographical
features that are sufficiently similar to
those of the existing AVA so as to allow
it still to be considered a part of the
existing AVA. In those very rare
instances in which no notable common
geographical features between the two
AVAs can be found, we believe TTB
permitting the use of both AVA names
for wine sourced from the grapes grown
within the proposed AVA could be
misleading to the consumer, and it
would not be appropriate for TTB to
take regulatory action which would
produce that result.

After careful consideration of the
comments submitted, TTB has
determined that it would be
inappropriate to adopt regulatory
language that prohibits future approvals
of AVAs that entirely surround or lie
entirely within, or that overlap, existing
AVAs, provided such approvals are
adequately justified through petition
evidence and rulemaking procedures.
TTB also believes that the decision as to
whether or not a proposed AVA that
entirely surrounds, lies entirely within,
or overlaps, an existing AVA should
prohibit label holders from using the
existing AVA name on the wine labels
as well should be made on a case-by-
case basis considering the evidence
submitted by the proposing AVA
petitioner. The regulatory language as
proposed in Notice No. 78 is consistent
with these principles and will afford
sufficient flexibility under the case-by-
case approach. TTB notes the intent of
the provisions dealing with AVAs
within AVAs is to apply it prospectively
to newly established areas only. AVAs
already established within AVAs will
not be affected by these provisions.

Comments on the New Part 4
Grandfather Provision

The text proposed in Notice No. 78 for
new § 4.39(i)(3) stated:

(3) Brand names that do not meet the
requirements of paragraph (i)(2) of this
section and that contain the name of a
viticultural area or other term of viticultural
significance established under part 9 of
this chapter on or after [INSERT EFFECTIVE
DATE OF FINAL RULE] may be used in
conjunction with information which the
appropriate TTB officer finds to be
sufficient to dispel the impression that the
graphic area suggested by the brand name is
indicative of the origin of the wine, provided
that the brand name:

(i) Was in use in an existing certificate of
label approval issued prior to the
5-year period immediately preceding receipt of
the perfected petition for establishment of
the viticultural area; and

(ii) Was in actual commercial use on labels
for at least 3 years during that 5-year period.

As noted above, in the “comments
invited” section of Notice No. 78, TTB
asked whether the use of a grandfather
provision to avoid conflicts between an
established brand name and the
establishment of a proposed AVA is
appropriate. Of the 191 comments
received, 107 comments specifically
addressed this issue—92 in favor of using
such a grandfather provision and 105
opposed to its use.
A commenter on behalf of Compliance Service of America, whose services include the preparation and filing of AVA petitions, stated in favor of the grandfather provision. “It is understandable the TTB sees this problem and its effect more completely than many industry members, because TTB has been forced to find the solutions for the competing interests of the parties.” This commenter further stated, “The problem of conflicts between new AVAs and existing brands continues to exist and is becoming even more prevalent as more AVAs are created. With the growth of the US wine industry and the proliferation of AVAs, conflicts will only become more frequent, and will continue to be devastating to wineries that have literally put the viticultural area on the map.” This commenter cited the petitioned-for Eola Hills AVA as an example, pointing out that Eola Hills Winery developed the region as a grape-growing region and essentially created the viticultural significance of the name Eola Hills. The commenter asserted that the establishment of the AVA would have had an adverse impact on the use of the winery’s brand name and noted that the problem was narrowly avoided by adding a modifier to the AVA name so that the AVA name established is Eola-Amity Hills.

A commenter representing Calistoga Partners, L.P., also in favor of the grandfather provision, wrote:

We believe that TTB’s proposed rulemaking in Notice No. 78 is fundamentally a fair resolution of the potential conflicts between the rights of brand owners who had brand names in actual commercial use based on existing certificates of label approval and the rights of those who wish to establish a new AVA, and represents a reasonable compromise that we would strongly support.

Most of the 105 commenters who opposed the grandfather provision wrote that they believe the proposed provision would allow misleading, confusing, and/or deceptive wine labels in the marketplace and thereby harm consumers. Many of these commenters further asserted that the grandfather provision will have far reaching consequences that will degrade the integrity of the AVA system. A number of these commenters specifically referred to the issues discussed in Notice No. 77, regarding the proposed establishment of a Calistoga viticultural area, as an example of problems that a grandfather provision can create.

The president of the Washington Wine Institute wrote that the grandfather proposals put forth in Notice No. 78 “are not sufficient to protect against deceptive labeling and consumer misunderstanding; in fact, they are a step backwards from both industry and governmental efforts to provide consumers with accurate and comprehensible information about the wine in the bottle.”

The commenter on behalf of the PRAVAC wrote:

Current law applies two different sets of labeling rules for the industry: One set of rules applies to geographic brands used in COLAs issued prior to July 7, 1986, and a different set—the labeling rules set forth in the current regulations—governs every other geographic brand in the U.S. marketplace.

While not a perfect solution, at least these two groups are easily identifiable and not subject to change. The number of grandfathered brands with misdescriptive names is finite, thus limiting the chances for consumer deception.

This commenter further stated that the proposed changes to the regulations would create three sets of labeling rules: (1) For brands on COLAs issued prior to July 7, 1986; (2) for geographic brands used on COLAs issued at least 5 years prior to the date on which a petition for a conflicting AVA is “perfected” that also have been used in commerce for at least 3 of those 5 years; and (3) for brands on COLAs that do not fall into either of the preceding categories. This commenter added that “this solution is inadvisable.” This commenter also provided an example of a name conflict involving a petitioned-for AVA within the Paso Robles AVA, the proposed El Pomar District AVA, which was resolved with the owners of the potentially conflicting COLAs by their consenting to the use of the proposed AVA name prior to submission of the petition.

The president of the industry trade association Wine America, wrote:

The grandfathering clause would allow already existing geographic brand names that contain a reference to a new AVA to continue to be used as long as they were on a COLA approved at least 5 years before filing of an AVA petition and have been in actual commercial use for at least three years of those five years. This change in regulation is driven by concern that petitioners may propose AVAs to limit competition to the detriment of established businesses.

This commenter added that this proposal “creates consumer confusion, it undermines the value of the appellation for wineries properly using the appellation, and we believe the TTB has sufficient authority to resolve such conflicts through other means.”

The president of the board of directors for the Napa Valley Vintners trade association raised concern on the issue, stating:

This proposed rule requiring five years of ownership of COLA and three years of use in commerce is contrary to TTB’s consumer protection mandate set under the FAA Act. It has no basis in, and is contrary to, recognized trademark and unfair competition law and does not comport with the provisions of Article 23 of the Agreement on Trade-Related Aspects of Intellectual Property Rights. As mandated by the FAA Act, TTB’s primary function in the regulation of wine labeling is to protect consumers by ensuring that they are not misled. The proposed grandfather rule in Notice No. 78 is contrary to this Congressional mandate.

Many of the commenters indicated that they believe the current regulations in existence for more than 20 years are fair to all concerned and do not believe it is fair to change this provision now because industry members have been playing by these rules for 20 plus years. Several commenters pointed to TTB’s regulations, which prohibit the use of misleading and deceptive labeling. Other commenters pointed out that TTB has the responsibility to protect the public from misleading labels.

One commenter further asserted that the grandfather provisions are not in line with the FAA Act. This commenter pointed to the TTB regulations that outline the label revocation procedure set forth in 27 CFR part 13, subpart D. In discussing the establishment of this procedure, this commenter stated that TTB made the following observation, “Paragraph 1 of Form 5100.31 [Application for and Certification/ Exemption of Label/Bottle Approval] does not constitute trademark protection.”

A commenter on behalf of the International Trademark Association wrote:

[The] proposal advocated by TTB fails to properly consider the principle of “first in time, first in right” priority and the fact that U.S. trademark and unfair competition laws recognize the establishment of rights in trademarks and geographical indications based on use and consumer recognition without the necessity of any type of registration. Accordingly, the grandfather proposal advocated in NPRM No. 78, and effectively applied in NPRM No. 77, does not ensure that the valid rights of either trademark owners or the users of geographical indications or the interest of consumers, will be protected.

As noted above, in the “comments invited” section of Notice No. 78, TTB asked whether it would be more appropriate to adopt an alternative to the grandfather provision that would apply to brand names that have longstanding commercial use under one or more existing or fictitious label approval without specifying a time period. Four commenters specifically
responded to this question—all in opposition to the use of such an alternative.

Also as noted above, in the “comments invited” section of Notice No. 78, TTB asked for comments on what type of dispelling information would prevent consumers from being misled as to the origin of the wine when a grandfather provision applies as well as for other comments for a requirement on dispelling information. Twenty-two commenters specifically responded to this comment solicitation, all in opposition to using dispelling information to avoid misleading consumers.

Several of these commenters stated that disclaimers will not be effective in avoiding the misleading of consumers when consumers are purchasing wine from a wine list in a restaurant or online. For example, the Napa Chamber of Commerce believes that “disclaimers hidden on back labels do not help consumers make informed choices when choosing from a wine list.” In addition, the president of Duckhorn Wine Company stated that “additional wording on the label to help clarify the origin of wines * * * will not dispel confusion as most consumers will not see the label before they order wine in a restaurant or purchase wine online.” Another commenter wrote, “Consumers purchasing wine via mail-order or the Internet * * * purchase wine with brand names that include wine region names with the belief that the wine is from the region identified in the brand name.”

Some commenters provided references to studies that indicate that dispelling information is not effective in avoiding consumer deception or confusion. One commenter stated that “more frequently courts have found disclaimers to be ineffective,” and that “[t]his judicial skepticism over disclaimers is supported by the scholarly literature” such as the article by Jacob Jacoby and George Szybillo entitled “Why Disclaimers Fail.” The commenter noted that “disclaimers generally are not likely to be effective because the information provided does not automatically translate into the desired effect, i.e., comprehension.” This commenter also added that “using a disclaimer or other dispelling label information to suggest that wine with a misleading geographic brand name is not from the place identified * * * will be ineffective because consumers will neither read nor absorb the disclaimer information in the retail purchase environment.”

Finally, as noted above, in Notice No. 78 TTB proposed a 5-year/3-year standard for applying the proposed new grandfather provision in § 4.39(i) when it is not possible otherwise to limit the adverse impact on established brand names when a new AVA is approved. In order for the grandfather provision to apply to a brand name, the COLA for the label carrying that brand name must have been issued at least 5 years prior to the receipt of the perfected petition for establishment of the new AVA. Additionally, the label in question must have been in actual commercial use for at least 3 years during that 5-year period.

A few commenters specifically opposed this provision. The commenter on behalf of the International Trademark Association wrote, “This 5-year COLA/3-year in use rule is arbitrary and capricious and does not reflect any recognized standard for the acquisition of trademark rights and does not protect the rights of trademark owners.”

TTB Response

The comments in opposition to the addition of a new grandfather provision to § 4.39(i), in part, have caused us to reassess our proposal. In response to the two comments favoring the grandfather provision, as noted below, in almost all cases in which a potential conflict has arisen between a proposed new AVA name and a brand name used on a label, our predecessor agency and we have been able to find a mutually satisfactory solution that would permit the establishment of the AVA without the least negative impact on current label holders while also protecting consumers. We believe that we will continue to be able to resolve future conflicts this way without need for a new grandfather provision. We recognize that there may be the rare case in which a mutually satisfactory solution cannot be found. In such cases we believe that a case-by-case resolution is a better approach than to create a new grandfather provision as a default resolution. Moreover, we believe that adoption of the new grandfather provision as proposed could lead to over-reliance on it, thus unnecessarily increasing the use of labels that must carry dispelling information, and could increase the risk of consumer confusion. Accordingly, we have determined not to adopt the new grandfather provision proposed in Notice No. 78. We reserve reconsideration of this issue in the future should circumstances warrant.

In the past, when a conflict has arisen between an existing approved label and a proposed AVA name, TTB or its predecessor agency, the viticultural area petitioners, and/or the affected label holders usually have been able to satisfy the conflicting parties and the needs of both legal and business entities. However, we believe it is preferable for all of the parties involved in the case to arrive at a mutually acceptable resolution. This approach has worked well in the past, unless the parties were not cooperative.

TTB has been able to resolve the issue without need for a new grandfather provision under § 4.39(i).

We have also in some cases designated new AVAs that limit the use of existing labels when the affected label holders have indicated that they understood the restrictive effect and did not object to the designation (e.g., “Lake Chelan” AVA, T.D. TTB–76, published in the Federal Register at 74 FR 19409 on April 29, 2009), in another case we withdrew the proposal to establish the AVA for insufficient name evidence while acknowledging the principle that an established brand name could be a factor in deciding not to establish a proposed AVA because it would create consumer confusion (see Notice No. 84, published in the Federal Register at 73 FR 34902 on June 19, 2008, withdrawing the “Tulocay” AVA proposal). In the recent “Calistoga” AVA case, we resolved the issue by providing a three-year transitional period to afford the affected brand name holders time to adjust their business models to the new AVA rule (see T.D. TTB–83, published in the Federal Register at 74 FR 64602 on December 8, 2009). In all of these cases, TTB and its predecessor agency, most often with the cooperation of the affected parties, have been able to resolve the issue without the need for a new grandfather provision under § 4.39(i).

We believe it is preferable for all the parties who would be affected by AVA rulemaking to resolve any conflicts through solutions that protect the interests of, and are acceptable to, all concerned parties, including consumers, rather than to rely on TTB to resolve the issue through rulemaking. We continue to believe that most conflicts can be resolved in such a manner. As such,
TTB will continue to seek resolution of these conflicts on a case-by-case basis. As to the comments regarding dispensing information that would have been required as part of a grandfathering standard under the proposed rule, we continue to believe that dispensing information is appropriate and effective in certain situations, but because we are not adopting a grandfathering standard with a dispensing information requirement in this final rule, we do not need to respond further to these comments. Regarding the comment that our regulatory proposal would be in conflict with international agreements and trademark rights, the decision not to include a grandfather provision in this final rule makes it unnecessary to address the comment in this rulemaking.

Finally, we have decided not to adopt any of the other proposed editorial-type changes to §4.39(i) because any change may result in unintended debate and confusion as to its interpretation.

**Comments on Whether the Part 9 Procedural Provisions Should Be Adopted**

In Notice No. 78, TTB proposed amendments to the part 9 text to clarify the rules for preparing, submitting, and processing AVA petitions. A few commenters specifically addressed these changes, stating that while they are not opposed to the proposed procedural changes, they do not see them as necessary. Other commenters stated that the current regulations work well for the industry and consumers, and one commenter specifically mentioned that the “Draft AVA Manual” developed by TTB as a useful document in preparing an AVA petition.

**TTB Response**

TTB has determined that the proposed regulatory provisions in question should be adopted without change. TTB proposed these regulatory changes based on what we have learned over the years in reviewing and acting on AVA petitions. We will strengthen the process through providing more effective guidance to the public by including details in our regulations on how to petition for the establishment or modification of an AVA and on what evidence is necessary to support a petition, and by clearly stating the evidence is necessary to support a modification of an AVA and on what to petition for the establishment or modify an existing area, but these regulations would not impose additional associated costs because the specific data that petitioners would rely on to develop these explanations under these revised regulations are already a part of the data set required of petitioners under existing rules. As noted in Notice No. 78 and in this final rule document, the regulatory amendments do not impose new standards but rather represent a codification of longstanding administrative authority and practice. Therefore, no regulatory flexibility analysis is required.

**Paperwork Reduction Act**

The collection of information contained in this final regulation has been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507(d)) under control number 1513–0127. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The collection of information in this regulation is in 27 CFR 9.11 and 9.12. This information is required to petition TTB to establish a new AVA or to change an existing AVA. This information will be used to verify evidence sources and to determine whether the information is sufficient to begin the rulemaking process (that is, proceed to a notice of proposed rulemaking). The collection of information is required to obtain a benefit. The likely respondents are non-profit institutions and small businesses or organizations.

**Drafting Information**

Rita D. Butler of the Regulations and Rulings Division drafted this document.

**List of Subjects**

27 CFR Part 4

Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices, and Wine.

27 CFR Part 9

Wine.

27 CFR Part 70

Administrative practice and procedure, Claims, Excise taxes, Freedom of information, Law enforcement, Penalties, Reporting and recordkeeping requirements, and Surety bonds.

**Amendments to the Regulations**

For the reasons discussed in the preamble, TTB amends 27 CFR, chapter I, parts 4, 9, and 70, as follows:
PART 4—LABELING AND ADVERTISING OF WINE

1. The authority citation for part 4 continues to read as follows:

Authority: 27 U.S.C. 205, unless otherwise noted.

2. In § 4.25, paragraphs (e)(1)(i) and (e)(2) are revised to read as follows:

§ 4.25 Appellations of origin.

(a) Appropriate TTB officer. An officer or employee of the Alcohol and Tobacco Tax and Trade Bureau authorized to perform any functions relating to the administration or enforcement of this part by TTB Order 1135.9, Delegation of the Administrator’s Authorities in 27 CFR Part 9, American Viticultural Areas.

(b) Use of other terms. Any other term defined in the Federal Alcohol Administration Act and used in this part shall have the same meaning assigned to it by that Act.

PART 9—AMERICAN VITICULTURAL AREAS

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


4. A new § 9.0 is added before subpart A to read as follows:

§ 9.0 Scope.

The regulations in this part relate to American viticultural areas created under the authority of the Federal Alcohol Administration Act and referred to in § 4.25(e) of this chapter.

5. Subpart B is revised to read as follows:

Subpart B—AVA Petitions

§ 9.11 Submission of AVA petitions.

(a) Procedure for petitioner. Any person may submit an AVA petition to TTB to establish a grape-growing region as a new AVA, to change the boundary of an existing AVA, or to change the name of an existing AVA. The petitioner is responsible for including with the petition all of the information specified in § 9.12. The person submitting the petition is also responsible for providing timely and complete responses to TTB requests for additional information to support the petition.

(b) How and where to submit an AVA petition. The AVA petition may be sent to TTB using the U.S. Postal Service or a private delivery service. A petition sent via a private delivery service should be addressed to: Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Washington, DC 20220. A petition sent via a private delivery service should be directed to: Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, Suite 200E, 1310 G Street, NW., Washington, DC 20005.

(c) Purpose and effect of submission of AVA petitions. The submission of a petition under this subpart is intended to provide TTB with sufficient documentation to propose the establishment of a new AVA or to propose changing the name or boundary of an existing AVA. After considering the petition evidence and any other relevant information, TTB shall decide what action to take in response to a petition and shall so advise the petitioner. Nothing in this chapter shall, or shall be interpreted to, compel any Department of the Treasury official to proceed to rulemaking in response to a submitted petition.

§ 9.12 AVA petition requirements.

(a) Establishment of an AVA in general. A petition for the establishment of a new AVA must include all of the evidentiary materials and other information specified in this section. The petition must contain sufficient information, data, and evidence such that no independent verification or research is required by TTB.

1. Name evidence. The name identified for the proposed AVA must...
be currently and directly associated with an area in which viticulture exists. All of the area within the proposed AVA boundary must be nationally or locally known by the name specified in the petition, although the use of that name may extend beyond the proposed AVA boundary. The name evidence must conform to the following rules:

(i) **Name usage.** The petition must completely explain, in narrative form, the manner in which the name is used for the area covered by the proposed AVA.

(ii) **Source of name and name evidence.** The name and the evidence in support of it must come from sources independent of the petitioner. Appropriate name evidence sources include, but are not limited to, historical and modern government or commercial maps, books, newspapers, magazines, tourist and other promotional materials, local business or school names, and road names. Whenever practicable, the petitioner must include with the petition copies of the name evidence materials, appropriately cross-referenced in the petition narrative. Although anecdotal information by itself is not sufficient, statements taken from local residents with knowledge of the name itself is not sufficient, statements taken from local residents with knowledge of the name and its use may also be included to support other name evidence.

(2) **Boundary evidence.** The petition must explain in detail the basis for defining the boundary of the proposed AVA as set forth in the petition. This explanation must have reference to the name evidence and other distinguishing features information required under this section. In support of the proposed boundary, the petition must outline the commonalities or similarities within that boundary and must explain with specificity how those elements are different in the adjacent areas outside that boundary.

(3) **Distinguishing features.** The petition must provide, in narrative form, a description of the common or similar features of the proposed AVA affecting viticulture that make it distinctive. The petition must also explain with specificity in what way these features affect viticulture and how they are distinguished viticulturally from features associated with adjacent areas outside the proposed AVA boundary. For purposes of this section, information relating to distinguishing features affecting viticulture includes the following:

(i) **Climate.** Temperature, precipitation, wind, fog, solar orientation and radiation, and other climate information;

(ii) **Geology.** Underlying formations, landforms, and such geophysical events as earthquakes, eruptions, and major floods;

(iii) **Soils.** Soil series or phases of a soil series, denoting parent material, texture, slope, permeability, soil reaction, drainage, and fertility;

(iv) **Physical features.** Flat, hilly, or mountainous topography, geographical formations, bodies of water, watersheds, irrigation resources, and other physical features; and

(v) **Elevation.** Minimum and maximum elevations.

(4) **Maps and boundary description.**

(i) **Maps.** The petitioner must submit with the petition, in an appropriate scale, the U.S.G.S. map(s) showing the location of the proposed AVA. The exact boundary of the AVA must be prominently and clearly drawn on the maps without obscuring the underlying features that define the boundary line. U.S.G.S. maps may be obtained from the U.S. Geological Survey, Branch of Distribution. If the map name is not known, the petitioner may request a map index by State.

(ii) **Boundary description.** The petition must include a detailed narrative description of the proposed AVA boundary based on U.S.G.S. map markings. This description must have a specific beginning point, must proceed unbroken from that point in a clockwise direction, and must return to that beginning point to complete the boundary description. The boundary description must refer to easily discernable reference points on the U.S.G.S. maps. The proposed AVA boundary description may rely on any of the following map features:

(A) State, county, township, forest, and other political entity lines;

(B) Highways, roads (including unimproved roads), and trails;

(C) Contour or elevation lines;

(D) Natural geographical features, including rivers, streams, creeks, ridges, and marked elevation points (such as summits or benchmarks);

(E) Human-made features (such as bridges, buildings, windmills, or water tanks); and

(F) Straight lines between marked intersections, human-made features, or other map points.

(b) **AVAs within AVAs.** If the petition proposes the establishment of a new AVA entirely within, or overlapping, an existing AVA, the evidence submitted under paragraph (a) of this section must include information that both identifies the attributes of the proposed AVA that are consistent with the existing AVA and explains how the proposed AVA is sufficiently distinct from the existing AVA and therefore appropriate for separate recognition. If the petition proposes the establishment of a new AVA that is larger than, and encompasses, all of one or more existing AVAs, the evidence submitted under paragraph (a) of this section must include information addressing whether, and to what extent, the attributes of the proposed AVA are consistent with those of the existing AVA(s). In any case in which an AVA would be created entirely within another AVA, whether by the establishment of a new, larger AVA or by the establishment of a new AVA within an existing one, the petition must explain why establishment of the AVA is acceptable. When a smaller AVA has name recognition and features that so clearly distinguish it from a larger AVA that surrounds it, TTB may determine in the course of the rulemaking that it is not part of the larger AVA and that wine produced from grapes grown within the smaller AVA would not be entitled to use the name of the larger AVA as an appellation of origin or in a brand name.

(c) **Modification of an existing AVA.**

(1) **Boundary change.** If a petition seeks to change the boundary of an existing AVA, the petitioner must include with the petition all relevant evidence and other information specified for a new AVA petition in paragraphs (a) and (b) of this section. This evidence or information must include, at a minimum, the following:

(i) **Name evidence.** If the proposed change involves an expansion of the existing boundary, the petition must show how the name of the existing AVA also applies to the expansion area. If the proposed change would result in a decrease in the size of an existing AVA, the petition must explain, if so, the extent to which the AVA name does not apply to the excluded area.

(ii) **Distinguishing features.** The petition must demonstrate that the area covered by the proposed change has, or does not have, distinguishing features affecting viticulture that are essentially the same as those of the existing AVA. If the proposed change involves an expansion of the existing AVA, the petition must demonstrate that the area covered by the expansion has the same distinguishing features as those of the existing AVA and has different features from those of the area outside the proposed, new boundary. If the proposed change would result in a decrease in the size of an existing AVA, the petition must explain how the distinguishing features of the excluded area are different from those within the boundary of the smaller AVA. In all
cases the distinguishing features must affect viticulture.

(iii) Boundary evidence and description. The petition must explain how the boundary of the existing AVA was incorrectly or incompletely defined or is no longer accurate due to new evidence or changed circumstances, with reference to the name evidence and distinguishing features of the existing AVA and of the area affected by the proposed boundary change. The petition must include the appropriate U.S.G.S. maps with the proposed boundary change drawn on them and must provide a detailed narrative description of the changed boundary.

(2) Name change. If a petition seeks to change the name of an existing AVA, the petition must establish the suitability of that name change by providing the name evidence specified in § 9.11(a); or

(ii) The name, boundary, or distinguishing features evidence does not meet the standards for such evidence set forth in § 9.12; or

(iii) The petitioned-for action would be inconsistent with one of the purposes of the Federal Alcohol Administration Act or any other Federal statute or regulation or would be otherwise contrary to the public interest;

(3) Prepare a new NPRM for publication in the Federal Register setting forth a modified AVA action for public comment; or

(4) Take any other action deemed appropriate by TTB as authorized by law.

PART 70—PROCEDURE AND ADMINISTRATION

7. The authority citation for part 70 continues to read as follows:


8. Section 70.701 is amended by adding a sentence at the end of paragraph (c) to read as follows: “A petition to establish a new American viticultural area or to modify an existing American viticultural area is subject to the rules in part 9 of this chapter.”

Signed: October 1, 2010.

John J. Manfreda,
Administrator.

Approved: October 1, 2010.

Timothy E. Skud,
Deputy Assistant Secretary, (Tax, Trade, and Tariff Policy).

For further information, contact Kara Fontaine, National Revenue Center, Alcohol and Tobacco Tax and Trade Bureau (202–453–2103 or Kara.Fontaine@ttb.gov).

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for the administration and enforcement of chapters 51 and 52 of the Internal Revenue Code of 1986 (IRC). These