

concern to FDA, we believe that wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems and approaches to come into complete compliance with 21 CFR part 203.

FDA is issuing this PDMA CPG as a level 1 guidance consistent with FDA's good guidance practices (21 CFR § 10.115).

We note that guidance documents are not binding on FDA or industry, and, under appropriate circumstances, the agency may initiate regulatory action, including criminal prosecution, for violations of the pedigree requirements.

C. Guidance for Industry: Prescription Drug Marketing Act Pedigree Requirements Questions and Answers

We are also issuing the PDMA Q & A, which represents FDA's current thinking on several issues regarding the PDMA pedigree requirements. It addresses numerous questions that FDA received as comments to the PDMA CPG docket, as well as through e-mail and other communications, regarding the PDMA pedigree requirements. The questions and answers in the guidance address issues pertaining to manufacturers, wholesale distributors, pharmacies, and other entities affected by the PDMA pedigree requirements.

FDA is issuing the PDMA Q & A as a level 1 guidance consistent with FDA's good guidance practices (21 CFR § 10.115). Given that the relevant PDMA pedigree provisions will go into effect as of December 1, 2006, FDA is implementing the PDMA Q&A immediately, in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)), because the agency has determined that prior public input is not feasible or appropriate. As noted, the pedigree requirements set forth in §§ 203.3(u) and 203.50, which had been stayed on several occasions, will apply to prescription drug products as of December 1, 2006. Promptly clarifying FDA's current thinking on the questions in the guidance should facilitate industry's compliance with the PDMA pedigree requirements.

Under § 10.115(g), FDA is opening a docket on the PDMA Q & A, and we invite interested persons to submit comments and questions. FDA intends to review the comments and questions and to revise the PDMA Q & A when appropriate, using the question and answer format in the PDMA Q & A guidance. For purposes of transparency, efficiency, and clarity, the agency believes that, at the present time, it is important to maintain FDA's written responses to the significant questions

concerning the PDMA pedigree requirements in a single guidance document that is periodically updated as the agency receives and responds to additional questions. We also intend to use the following four indicators to help users of the guidance identify future additions or revisions: (1) The updated guidance will be identified as a revision of the previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the guidance, or prior answers that have been in any way modified, will be identified as such in the body of the guidance.

The PDMA CPG and PDMA Q & A guidance represent the agency's current thinking on issues related to the PDMA pedigree requirements. The guidances do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

An electronic version of the PDMA CPG is available on the Internet at <http://www.fda.gov/ora> under "Compliance Reference". An electronic version of the PDMA Q & A guidance is available at <http://www.fda.gov/pdma>.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the PDMA Q & A guidance or PDMA CPG at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the guidance may be seen in the Division of Dockets management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-9211 Filed 11-13-06; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 635

[FHWA Docket No. FHWA-2006-23552]

RIN 2125-AF18

Construction and Maintenance

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is revising its regulations in 23 CFR part 635 subpart D to address Section 5514 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU). This law requires the FHWA to ensure that States provide for competition with respect to the specification of alternative types of culvert pipes. These revisions will ensure that States provide for competition in the specification of alternative types of culvert pipes.

DATES: *Effective Date:* December 15, 2006.

FOR FURTHER INFORMATION CONTACT: For technical information: Mr. Gerald Yakowenko, Office of Program Administration (HIPA), (202) 366-1562. For legal information: Mr. Michael Harkins, Office of the Chief Counsel (HCC-30), (202) 366-4928, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document and all comments received by the U.S. DOT Dockets, Room PL-401, may be viewed through the Docket Management System (DMS) at <http://dms.dot.gov>. It is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of this Web site.

An electronic copy of this document may be downloaded from the **Federal Register's** home page at <http://www.archives.gov> and the Government Printing Office's Web page at <http://www.access.gpo.gov/nara>.

Background

Section 5514 of the SAFETEA-LU (Pub. L. 109-59; Aug. 10, 2005), titled "Competition for Specification of Alternative Types of Culvert Pipes," requires the Secretary of Transportation to ensure that States provide for competition with respect to the

specification of alternative types of culvert pipes through requirements that are commensurate with competition requirements for other construction materials.

The FHWA's policies in 23 CFR part 635 subpart D—General Material Requirements support the competitive bidding principles in Section 112 of Title 23 U.S. Code by providing for the broadest consideration of materials to encourage competition. Where alternative products are judged to be of satisfactory quality and equally acceptable on the basis of engineering and economic analysis, the FHWA requires equal consideration in the specification of materials.

Notice of Proposed Rulemaking (NPRM)

The FHWA published a NPRM on April 17, 2006, at 71 FR 19667. We proposed to delete 23 CFR 635.411, paragraph (d) and re-designate paragraphs (e) and (f) as (d) and (e) respectively. We also proposed to delete Appendix A to subpart D—"Summary of Acceptable Criteria for Specifying Types of Culvert Pipes" in its entirety.

Appendix A to subpart D of 23 CFR part 635 was officially included in the FHWA's regulations on September 30, 1974. Appendix A contained the requirements concerning the specification, number and types of culvert pipes specified on Federal-aid highway construction projects. These requirements were intended to encourage competition and lower the cost of culvert pipes by encouraging the consideration of alternate culvert pipe materials in certain drainage installations.

When Appendix A was codified in 1974, the universe of available culvert materials was very limited and the State DOT's experience with new culvert materials was equally limited. From a practical viewpoint, the culvert materials market consisted of two materials—reinforced concrete pipe and corrugated steel pipe (either plain galvanized or asphalt coated). At that time, the State DOTs were also limited by existing national materials specifications for these materials and it was difficult for new culvert manufacturers to enter the public transportation construction marketplace. Over the next thirty years, the competitive market changed significantly and American Association of State Highway and Transportation Officials (AASHTO) materials specifications are now available for various culvert materials such as: acrylonitrile butadiene styrene pipe, reinforced concrete pipe, corrugated

aluminum pipe, corrugated steel pipe (with coatings of zinc, aluminum, asphalt or polymers), poly-vinyl chloride pipe and high-density polyethylene pipe.

In order to implement the provisions of section 5514 of SAFETEA-LU and be consistent with the long-standing policy of ensuring the consideration of the largest number of appropriate alternatives that lead to the lowest overall life cycle cost, the FHWA proposed to delete Appendix A to subpart D of 23 CFR part 635. The deletion of Appendix A will eliminate the specific requirement for the consideration of alternative types of culverts for certain drainage installations. By doing so, the selection and specification of culvert types will be governed by the same regulatory policy for all other materials in 23 CFR 635.411, thus ensuring competition in the selection of pipes.

Summary Discussion of Comments Received in Response to the NPRM

The following discussion provides an overview of the comments received in response to the NPRM, and the FHWA's actions to resolve and address the issues raised by the respondents.

Profile of Respondents

We received responses from twenty-three entities. The respondents included: three State (DOTs), four associations, three consulting engineering firms, three firms involved with the manufacturing of culverts, and ten individuals. The four associations included: Uni-Bell PVC Pipe Association, the Plastic Pipe Institute, the American Concrete Pipe Association and the National Corrugated Steel Pipe Association. We classified the American Association of State Highway and Transportation Officials (AASHTO) as a State DOT because they represent State DOT interests. The AASHTO provided a consolidated response to the NPRM on behalf of its member States. Two State DOTs also provided their comments individually.

Analysis of NPRM Comments and FHWA Response

Fourteen commenters expressed support for the proposed changes in the NPRM. No commenter objected to the proposed changes in the NPRM. Nine commenters did not approve or disapprove of the proposed changes, but provided commentary for consideration in drafting the final rule.

Supporting the Need for Change

Nine commenters including: Chevron Philips Chemical Company LP,

Advanced Drainage Systems, Inc., the Plastic Pipe Institute, ExxonMobil Chemical Company, Mr. Daniel J. Kuroter, Mr. Andrew P. Thomas, Clough Harbour & Associates LLP, Honorable Deborah Pryce and Jim Goddard stated that Appendix A to subpart D is outdated and does not reflect the realities in today's highly competitive culvert marketplace.

We agree with this concern. The availability of different culvert materials and the State DOTs' experience with these materials has changed significantly since Appendix A was codified in 1974. This is one of the reasons why we elected to delete Appendix A. It is no longer necessary to have an FHWA requirement concerning the minimum number of alternative culvert specifications that are necessary for certain drainage installations.

Many respondents expressed concerns regarding interpretations of Appendix A that have limited competition. The ADR and Associates and Mr. Andy Beard stated that some contracting agency interpretations of Appendix A led to non-competitive situations—exactly the opposite of what the FHWA intended. They indicated that such interpretations stifle competition by allowing highway project managers to ignore the wide range of culvert alternatives that currently exist.

Mr. Daniel J. Kuroter, Mr. Andrew P. Thomas, and Clough Harbour & Associates LLP stated that the current regulations do not promote competition and are too frequently interpreted in ways that restrict competition. Advanced Drainage Systems, Inc. indicated that they have encountered certain States that routinely and arbitrarily restricted competition in the selection of drainage products.

Mr. John Owen Hurd and Jim Goddard stated that Appendix A has allowed contracting agencies to circumvent the intent of the rules to encourage competition and specify only one pipe material if they so choose.

We appreciate the concerns of these respondents in asserting that some contracting agencies may have used Appendix A as an excuse for not fully considering all reasonable culvert alternatives. With the deletion of Appendix A, contracting agencies will no longer be able to cite Appendix A as their basis for not considering other culvert alternatives.

Other respondents suggested that the FHWA consider a revision, rather than a deletion of Appendix A. Honorable Deborah Pryce recommended that consideration be given to revising Appendix A to clarify the types and

numbers of alternative products that are required for consideration in various drainage applications. Advanced Drainage Systems, Inc. and the Plastic Pipe Institute stated that a proper revision of Appendix A might have been more effective in requiring competition; however, they recognized that the proposed deletion of Appendix A could accomplish the same goal as long as it is properly enforced at the State level.

We considered a revision rather than a deletion of Appendix A but elected not to do so for two reasons. First, Section 5514 requires the Secretary to “* * * ensure that States provide for competition with respect to the specification of alternative types of culvert pipes through requirements that are commensurate with competition requirements for other construction materials, as determined by the Secretary.” The FHWA does not have a specific policy requiring the specification, number and types of alternative materials for any other highway construction material. In all other areas of highway material specification, the contracting agency has the responsibility to consider all alternative products that are judged to be of satisfactory quality and equally acceptable on the basis of engineering and economic analyses. Thus, it is important to treat culvert materials the same as other materials by removing Appendix A. Second, the culvert materials industry is a highly competitive market and it would not be appropriate to limit the consideration of alternative materials through a revision of Appendix A.

Many of the respondents recommended that the FHWA take additional enforcement and compliance actions to ensure real competition. The ADR and Associates and Mr. Andy Beard recommend that we take additional enforcement steps to ensure that the final rule results in the promotion of real competition. Advanced Drainage Systems, Inc. and the Plastic Pipe Institute recommended that the FHWA provide appropriate communications and enforcement actions if it is to meet the intent of Congress. Other commenters such as Chevron Phillips Chemical Company LP, ADR and Associates, Mr. Andy Beard, ExxonMobil Chemical Company, Mr. Daniel J. Kuroter, Mr. Andrew P. Thomas, Clough Harbour & Associates LLP and Jim Goddard suggested that FHWA utilize appropriate incentives and penalties to ensure compliance.

We recognize the concerns of these respondents who believe that culvert material competition has been limited in certain segments of the Federal-aid

program. While the FHWA does not have the legal authority to utilize incentives to the States for enforcement purposes, the FHWA does have the authority to impose penalties if the FHWA determines that a State is not complying with Federal requirements. Pursuant to 23 CFR 1.36, the FHWA may withhold payment on a particular project, withhold approval of further projects, and take any other action the FHWA may deem appropriate. The FHWA will continue to exercise appropriate oversight over all Federal requirements and work with the States to ensure that these requirements are met.

Maintaining the Status Quo

Generally speaking, the AASHTO, two State DOT representatives and Ms. Lesly Tribelhorn were concerned that the final rule may require States to change their current State practices, thus limiting the flexibility they now have for culvert material selection.

The AASHTO agreed that the proposed deletion of Appendix A will eliminate specific requirements for the consideration of alternative types of culverts for certain drainage installations, thus making the selection of culvert materials subject to the same FHWA regulations as the selection of all other materials. The AASHTO believed that this would provide flexibility and allow for the application of engineering judgment in selection and design of drainage facilities. However, AASHTO noted that the proposed change failed to recognize the complexities associated with the analysis, design, detailing and bidding of multiple culvert type specifications.

The State of Rhode Island currently restricts the use of high-density polyethylene (HDPE) pipe to a maximum culvert diameter of 24 inches. The Rhode Island representative was concerned that the proposed changes would require a revision of its culvert material selection policy to consider the use of HDPE pipes for culvert installations greater than 24 inches. Similarly, a representative from the Iowa DOT indicated that it was not opposed to the proposed rule, however, it did not want the final rule to limit or restrict the State's ability to specify certain pipe materials in specific drainage installations.

Ms. Tribelhorn stated that there is a need to allow the States to use engineering judgment in the culvert selection process and contracting agencies should be allowed to use specific selection criteria without the FHWA requiring pipe alternatives in the bidding process. Ms. Tribelhorn

questioned whether the deletion of Appendix A would allow for this flexibility.

With the deletion of Appendix A, the FHWA's material selection policy will require the States to consider all available materials or products that are judged to be of satisfactory quality and equally acceptable on the basis of engineering and economic analyses. Where such products appear to be equal, alternative bidding practices must be used as required by 23 CFR 635.411(b). Where alternative products are determined to have different engineering and economic properties, contracting agencies may select a specific material or product based on life cycle cost criteria. In such cases, the contracting agency should document its material selection decision on a project or program basis as appropriate.

The AASHTO further stated that it is often necessary to specify a certain type of culvert on higher functional classification roadways where major disruptions of traffic would occur if repairs or replacements were needed. The AASHTO stated that existing Appendix A to Subpart D provided the authority to do this. It raised the concern that the proposed deletion of Appendix A would result in the States having to justify and seek FHWA's approval for such installations.

We disagree that the proposed change would result in additional work for the contracting agency (assuming that the agency is currently complying with the FHWA policy).

The AASHTO recommended that the FHWA insert the following language in 23 CFR 635.411(b), at the end of the second sentence—“This provision is not intended to displace the owner's or their Professional Engineers responsibility to determine acceptable materials based on local performance history or owner's policies on material use.” It appears that the intent of this recommendation is to give the contracting agency the discretion to waive the requirement for alternate material bidding of equally acceptable products for various reasons.

Mr. Jim Goddard commented that AASHTO's recommendation was written to permit those agencies still using single source, non-competitive standards to maintain the status quo. Mr. John Owen Hurd stated that AASHTO's recommendation would completely emasculate the intent of the proposed changes, permitting arbitrary selection of only one type of pipe material.

We disagree with the recommendation proposed by AASHTO. The existing provisions in 23 CFR part 411 provides contracting agencies with

sufficient flexibility to select materials or products that are of satisfactory quality and equally acceptable on the basis of engineering and economic analyses.

Other Comments

The National Corrugated Steel Pipe Association (NCSPA) noted its support for the intent of Section 5514 of SAFETEA-LU but provided specific recommendations regarding culvert type selection procedures. The NCSPA recommend that the FHWA require contracting agencies to set acceptable service life requirements and provide economic analyses of the alternates based on those requirements. The NCSPA believes that very few State DOT specifications have a service life requirement and the design methodology to adequately determine service life for all culvert alternatives in the varying environments. Furthermore, the NCSPA stated that under the current policy, the FHWA cannot be assured of proper life cycle cost analysis from each State DOT unless that State has specific service life requirements.

We agree with the intent of the comment; however, this topic is not appropriate for inclusion in this regulation. It would be more appropriate to address this issue in an AASHTO guide specification or AASHTO guideline as is currently done for other highway materials.

The American Concrete Pipe Association supported the proposed language in the NPRM, but recommended a revision to the first sentence in 23 CFR 635.411(b) to read as follows: "When there is available for purchase more than one nonpatented, nonproprietary material, semifinished or finished article or product that will fulfill the requirements for an item of work of a project and these available materials or products are proven to be of equal quality and material service life, perform the intended engineering function during the design life of the project, and equally acceptable on the basis of an engineering analysis and a present worth life cycle cost analysis, the PS&E for the project shall either contain or include by reference the specifications for each such material or product that is considered acceptable for incorporation in the work."

This revision would place more emphasis on life cycle costs rather than initial costs. We agree with the intent of this recommendation; however, we do not believe that the revision is necessary as contracting agencies already consider life cycle cost considerations in determining which materials are equally acceptable.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this final rule is not a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of Department of Transportation regulatory policies and procedures. We anticipate that the economic impact of this rulemaking will be minimal. These changes to the FHWA's Material or Product Selection policies are minor in nature. The deletion of Appendix A to subpart D of 23 CFR part 635 eliminates the specific requirement for the consideration of alternative types of culverts for certain drainage installations. Culvert pipes will be subject to the same selection policies as all other highway materials and products. This final rule will not adversely affect, in a material way, any sector of the economy. In addition, these changes will not interfere with any action taken or planned by another agency and will not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601-612) the FHWA has evaluated the effects of this final rule on small entities and has determined that the action will not have a significant economic impact on a substantial number of small entities. This final rule addresses material selection for States. As such, it affects only States and States are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, the Regulatory Flexibility Act does not apply and the FHWA certifies that this action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995, 109 Stat. 48). This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$128.1 million or more in any one year. Additionally, the definition of "Federal Mandate" in the Unfunded Mandates Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal

government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism)

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, and the FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this action does not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520.

National Environmental Policy Act

The FHWA has analyzed this final rule for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4347) and has determined that this action will not have any effect on the quality of the environment.

Executive Order 12630 (Taking of Private Property)

This action will not affect the taking of private property or otherwise have taking implications under Executive Order 12630, Government Actions and Interface with Constitutionally Protected Property Rights.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

We have analyzed this final rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. The FHWA certifies that this action will not cause an environmental risk to health or safety that might disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this final rule under Executive Order 13175, dated November 6, 2000, and believes that this action will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal laws. This final action addresses material selection by the States for Federal-aid highway projects and will not impose any direct compliance requirements on Indian tribal governments. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

We have analyzed this action under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use Dated May 18, 2001. We have determined that it is not a significant energy action under that order because it is not a significant regulatory action under Executive Order 12866 and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 635

Grant programs—transportation, Highways and roads, Reporting and recordkeeping requirements.

Issued on: November 7, 2006.

J. Richard Capka,

Federal Highway Administrator.

■ In consideration of the foregoing, the FHWA proposes to amend part 635 of title 23, Code of Federal Regulations, as follows:

PART 635—CONSTRUCTION AND MAINTENANCE

■ 1. Revise the authority citation for part 635 to read as follows:

Authority: Sec. 5514 of Pub. L. 109–59, 119 Stat. 1144; 23 U.S.C. 101 (note), 109, 112, 113, 114, 116, 119, 128, and 315; 31 U.S.C. 6505; 42 U.S.C. 3334, 4601 et seq.; Sec.

1041(a), Pub. L. 102–240, 105 Stat. 1914; 23 CFR 1.32; 49 CFR 1.48(b).

§ 635.411 [Amended]

■ 2. Amend § 635.411 by removing paragraph (d) and redesignating paragraphs (e) and (f) as (d) and (e) respectively.

Appendix A to Subpart D [Removed]

■ 3. Amend 23 CFR part 635, subpart D by removing Appendix A to Subpart D.

[FR Doc. E6–19240 Filed 11–14–06; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY**Alcohol and Tobacco Tax and Trade Bureau****27 CFR Part 9**

[T.D. TTB–55]

RIN 1513–AB32

Los Carneros Viticultural Area; Technical Amendment (2006R–224P)

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 makes a technical amendment to its regulations to clarify the viticultural significance of the terms “Los Carneros” and “Carneros” in relation to the existing Los Carneros viticultural area.

DATES: *Effective Date:* November 15, 2006.

FOR FURTHER INFORMATION CONTACT: N. A. Sutton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 925 Lakeville St., No. 158, Petaluma, CA 94952; phone 415–271–1254.

SUPPLEMENTARY INFORMATION:**Background on Viticultural Areas***TTB Authority*

Section 105(e) of the Federal Alcohol Administration Act (the FAA Act, 27 U.S.C. 201 *et seq.*) requires that alcohol beverage labels provide consumers with adequate information regarding product identity and prohibits the use of misleading information on those labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out its provisions. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers these regulations.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and 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) contains the list of approved viticultural areas.

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 regulations. These 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.

Los Carneros Viticultural Area*Background*

The Bureau of Alcohol, Tobacco and Firearms (ATF), the predecessor agency of TTB, established the Los Carneros viticultural area effective on September 19, 1983, in T.D. ATF–142, published in the **Federal Register** on August 18, 1983 (48 FR 37365). The establishment of the Los Carneros viticultural area is codified, and its boundary is described, in the TTB regulations at 27 CFR 9.32.

The “Evidence of Name” discussion in the preamble of T.D. ATF–142 states that the names “Los Carneros” and “Carneros” are generally used interchangeably. The 1983 final rule document explains that ATF approved many labels over a period of more than ten years that simply used the name “Carneros.” Also, ATF noted that the Spanish word “los” translates to “the” in English. ATF therefore, in this specific case, determined that “Carneros” and “Los Carneros” are not different names, but rather are equivalent forms of the same name. Consequently, ATF concluded that either “Los Carneros” or “Carneros” should be allowed for use on labels and in advertising to refer to the Los Carneros viticultural area.

Currently, paragraph (a) of § 9.32, states, “The name of the viticultural area described in this section is ‘Los Carneros.’” To clarify that the “Los Carneros” and “Carneros” names both have the same and equal viticultural significance in the context of this