analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected. GCP includes review and approval (or provision of a favorable opinion) by an independent ethics committee (IEC) before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject (or a subject's legally authorized representative, if the subject is unable to provide informed consent) before initiating a study. GCP does not require informed consent in life-threatening situations when the IEC reviewing the study finds, before initiation of the study, that informed consent is not feasible and either that the conditions present are consistent with those described in § 50.23 or § 50.24(a) of this chapter, or that the measures described in the study protocol or elsewhere will protect the rights, safety, and well-being of subjects; and

(ii) FDA is able to validate the data from the study through an onsite inspection if the agency deems it necessary.

(2) Although FDA will not accept as support for an IND or application for marketing approval a study that does not meet the conditions of paragraph (a)(1) of this section, FDA will examine data from such a study.

(3) Marketing approval of a new drug based solely on foreign clinical data is governed by § 314.106 of this chapter.

(b) *Supporting information.* A sponsor or applicant who submits data from a foreign clinical study not conducted under an IND as support for an IND or application for marketing approval must submit to FDA, in addition to information required elsewhere in parts 312, 314, or 601 of this chapter, a description of the actions the sponsor or applicant took to ensure that the research conformed to GCP as described in paragraph (a)(1)(i) of this section. The description is not required to duplicate information already submitted in the IND or application for marketing approval. Instead, the description must provide either the following information or a cross-reference to another section of the submission where the information is located:

(1) The investigator's qualifications;

(2) A description of the research facilities;

(3) A detailed summary of the protocol and results of the study and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records;

(4) A description of the drug substance and drug product used in the study, including a description of the components, formulation, specifications, and, if available, bioavailability of the specific drug product used in the clinical study;

(5) If the study is intended to support the effectiveness of a drug product, information showing that the study is adequate and well controlled under § 314.126 of this chapter;

(6) The name and address of the IEC that reviewed the study and a statement that the IEC meets the definition in § 312.3 of this chapter. The sponsor or applicant must maintain records supporting such statement, including records of the names and qualifications of IEC members, and make these records available for agency review upon request;

(7) A summary of the IEC's decision to approve or modify and approve the study, or to provide a favorable opinion;

(8) A description of how informed consent was obtained;

(9) A description of what incentives, if any, were provided to subjects to participate in the study;

(10) A description of how the sponsor(s) monitored the study and ensured that the study was carried out consistently with the study protocol; and

(11) A description of how investigators were trained to comply with GCP (as described in paragraph (a)(1)(i) of this section) and to conduct the study in accordance with the study protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained. Any signed written commitments by investigators must be maintained by the sponsor or applicant and made available for agency review upon request.

(c) *Waivers.* (1) A sponsor or applicant may ask FDA to waive any applicable requirements under paragraphs (a)(1) and (b) of this section. A waiver request may be submitted in an IND or in an information amendment to an IND, or in an application or in an amendment or supplement to an application submitted under part 314 or 601 of this chapter. A waiver request is required to contain at least one of the following:

(i) An explanation why the sponsor's or applicant's compliance with the requirement is unnecessary or cannot be achieved;

(ii) A description of an alternative submission or course of action that satisfies the purpose of the requirement; or

(iii) Other information justifying a waiver.

(2) FDA may grant a waiver if it finds that doing so would be in the interest of the public health.

(d) *Records.* A sponsor or applicant must retain the records required by this section for a foreign clinical study not conducted under an IND as follows:

(1) If the study is submitted in support of an application for marketing approval, for 2 years after an agency decision on that application;

(2) If the study is submitted in support of an IND but not an application for marketing approval, for 2 years after the submission of the IND.

Dated: April 21, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9200 Filed 4–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 24, and 27

[Docket No. TTB–2007–0006; T.D. TTB–70; Re: T.D. TTB–31 and Notice No. 51]

RIN 1513–AB00

Certification Requirements for Imported Natural Wine (2005R–002P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is adopting as a final rule, without changes, the temporary regulations implementing the certification requirements regarding production practices and procedures for imported natural wine. These requirements were adopted in section 2002 of the Miscellaneous Trade and Technical Corrections Act of 2004 as an amendment to section 5382 of the Internal Revenue Code of 1986.

DATES: *Effective Date:* This final rule is effective on May 28, 2008.

FOR FURTHER INFORMATION CONTACT: Jennifer Berry, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Rulings Division, P.O. Box 18152, Roanoke, VA 24014; telephone 540–344–9333.

SUPPLEMENTARY INFORMATION:

Background

The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for

the administration of Chapter 51 of the Internal Revenue Code of 1986 (IRC) which includes provisions relating to the taxation of wine. Section 5382(a) of the IRC (26 U.S.C. 5382(a)) sets forth standards regarding what constitutes proper cellar treatment of natural wine.

On December 3, 2004, the President signed into law the Miscellaneous Trade and Technical Corrections Act of 2004, Public Law 108–429, 118 Stat. 2434 (''the Act''), which revised section 5382(a) of the IRC to accommodate two new provisions. The first new provision was paragraph (1)(B), which provides that, in the case of wine produced and imported subject to an international agreement or treaty, proper cellar treatment of natural wine includes those practices and procedures acceptable to the United States under the agreement or treaty. The second new provision was paragraph (3), which sets forth a new certification requirement regarding production practices and procedures for imported natural wine produced after December 31, 2004.

Under section 5382(a)(3) the Secretary of the Treasury shall accept the practices and procedures used to produce wine in another country if, at the time of importation of the wine, one of the following conditions is met:

- The Secretary has on file or is provided with a certification from the government of the producing country, accompanied by an affirmed laboratory analysis, that the practices and procedures used to produce the wine constitute proper cellar treatment under regulations prescribed by the Secretary;
- The Secretary has on file or is provided with a certification required by an international agreement or treaty covering proper cellar treatment, or the wine is covered by an international agreement or treaty covering proper cellar treatment that does not require a certification; or
- In the case of an importer that owns or controls or that has an affiliate that owns or controls a winery operating under a basic permit issued by the Secretary, the importer certifies that the practices and procedures used to produce the wine constitute proper cellar treatment under regulations prescribed by the Secretary.

In addition, for purposes of the certification requirement, section 5382(a)(3) defines ''affiliate'' as having the meaning contained in section 117(a)(4) of the Federal Alcohol Administration Act (27 U.S.C. 211(a)(4)), and as including ''a winery's parent or subsidiary or any other entity in which the winery's parent or subsidiary has an ownership interest.''

Temporary Rule and Notice of Proposed Rulemaking

On August 24, 2005, TTB published in the **Federal Register** (70 FR 49479) a temporary rule, T.D. TTB–31, which implemented the above described certification requirements by amending 27 CFR parts 4, 24, and 27. In conjunction with the publication of T.D. TTB–31, TTB published a notice of proposed rulemaking, Notice No. 51, in the **Federal Register** (70 FR 49516) on August 24, 2005, referencing and inviting comments on T.D. TTB–31. The comment period closed October 24, 2005.

Comments and TTB Analysis

TTB received four comments during the comment period. Below, we summarize and respond to the four comments.

Comment

The Embassy of Switzerland commented that requiring certification for shipments of limited quantities could create impediments to the introduction of new products. It therefore urged TTB to exempt from certification shipments of limited quantities and non-commercial shipments intended for trade fairs or exhibits.

TTB Response

The implementing regulations include an exemption for importations of commercial samples of natural wine. Under 27 CFR 27.140(b)(2)(ii)(C), commercial samples include sales samples, samples for trade shows, and samples imported for laboratory analysis. We believe this provision addresses the commenter's concern regarding shipments for trade shows and exhibits. We also believe that 27 CFR 27.140(b)(2)(ii)(B), which exempts importations of a personal, non-commercial nature, could apply to many of the shipments of limited quantities mentioned by the commenter.

Comment

The National Association of Beverage Importers, Inc. (NABI), in its comment, stated that TTB did not define the word ''importer'' in the temporary regulations, making it unclear who must retain a copy of the certification. It stated that in the industry, ''importer'' could mean either the ''authorized importer'' or the ''importer of record.'' According to NABI, the ''authorized importer'' is authorized by the foreign supplier to import the supplier's wine into the U.S., whereas the ''importer of record'' is the importer that physically imports the wine (sic), usually using a certificate of label approval (COLA) owned by the authorized importer. NABI therefore asked which type of importer must maintain a copy of the certification in their records. NABI believes that the COLA owner should be required to retain the certification. NABI also requested clarification regarding wine that is a blend of wines from multiple suppliers, asking if the importer must obtain certifications for all the wines used in a blend or only for the finished wine.

TTB Response

''Importer'' is defined in § 27.140 of the implementing regulations as ''any person importing wine who must obtain a permit as provided in § 27.55.'' Under § 27.55, any person who intends to engage in the business of importing wines must obtain a permit from TTB. If a COLA holder is also the actual importer, that COLA holder would have to both obtain a permit and retain the certification, a copy of which is sufficient for this purpose. TTB believes the regulations are sufficiently clear on this point.

With regard to NABI's second point, we note that the certification requirement applies to the wine that is imported into the United States, that is, the certification is required only for the finished wine if that is the wine that is imported. If the component wines were imported into the United States for blending here, then the certification requirement would apply to each of the component wines that is imported. If the wine is blended before importation, a certificate is required only for the finished, blended wine. We believe the regulatory language is also sufficiently clear on this point.

Comment

The Wine Institute filed a comment disagreeing with the position taken by TTB in the temporary rule regarding self-certification, that is, that the statute does not allow self-certification by a winery when the winery owns or controls an importer rather than the other way around. The Wine Institute stated that a winery operating under a basic permit is the more qualified of the two entities to make this certification. The Wine Institute contends that TTB has the authority to infer that Congress did not intend to make this exclusion and that TTB should therefore revise the temporary regulations to allow a winery owning or controlling an importer to self-certify its imports.

TTB Response

TTB notes that the statutory language contained in 26 U.S.C. 5382(a)(3)(A)(iii)

very specifically refers only to an importer that owns or controls a winery or that has an affiliate that owns or controls a winery operating under a basic permit. The statutory language does not suggest that Congress intended the statute also to allow self-certification by a winery that owns or controls an importer or that has an affiliate to that owns or controls an importer. Accordingly, we do not believe Congress intended the interpretation suggested in this comment.

Comment

The Government of Canada submitted a comment requesting that certain types of Canadian wines—non-grape wines, cider, and wines containing less than 7 percent alcohol by volume—be exempt from the certification requirements. These wines are outside the scope of the ''Agreement on Mutual Acceptance of Oenological Practices'' (MAA) signed by several nations including Canada and the United States, which covers only natural grape wines that are at least 7 percent alcohol by volume, and are therefore subject to the certification requirements. Canada contends that an exemption would be justified because Canadian regulations require that fruit wines (other than cider) and wines containing less than 7 percent alcohol by volume must be produced in accordance with the same standards as wines covered by the MAA.

Canada also requested consideration of an exemption from the certification requirements for the importation of small quantities of non-grape natural wine from Canada in order to mitigate the potential economic impact on small exporters. Canada stated that because these wines are exported in limited quantities by small exporters the cost of complying with the requirements will be prohibitive and may shut these products out of the U.S. market. Finally, Canada requested that we delay the implementation of the certification requirements until the United States and Canada can reach an agreement on an import certification regime covering these wines.

TTB Response

We are unable to provide the two requested exemptions. The non-grape wines and other products described by Canada clearly fall within the certification requirements of the statute. The fact that they are produced in accordance with the same standards as wine covered by the scope of the MAA or are only exported in limited quantities cannot override the clear wording of the statute.

Regarding the request for a delay in the implementation date, TTB does not have the authority to change the implementation date of the certification requirements, which is prescribed by the statute.

TTB Finding

Based on the reasons set forth above and on the comments received, we believe it is appropriate to adopt the temporary rule as a final rule without change.

Regulatory Flexibility Act

We certify that this regulation will not have a significant impact on a substantial number of small entities. This regulation adopts without change a temporary rule that incorporated some reporting and recordkeeping requirements. It was previously concluded that those requirements were expected to be of minimal burden, and we have received no information that contradicts that previous determination. Therefore, no regulatory flexibility analysis is required. Additionally, pursuant to section 7805(f) of the Internal Revenue Code, we submitted the temporary rule to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact to small businesses. That office did not comment on the temporary rule.

Paperwork Reduction Act

The collections of information contained in this final regulation have been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) and assigned OMB control number 1513–0119. 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. This final rule restates the collection of information without substantive change.

Comments concerning suggestions for reducing the burden of the collections of information should be directed to Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, at any of these addresses:

- P.O. Box 14412, Washington, DC 20044–4412;
- 202–927–8525 (facsimile); or
- *formcomments@ttb.gov* (e-mail).

Executive Order 12866

This rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, it requires no regulatory assessment.

Drafting Information

The principal author of this document was Jennifer K. Berry, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau. Other personnel also participated in its development.

List of Subjects

27 CFR Part 4

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

27 CFR Part 24

Administrative practice and procedure, Claims, Electronic fund transfers, Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavoring, Surety bonds, Vinegar, Warehouses, Wine.

27 CFR Part 27

Alcohol and alcoholic beverages, Beer, Customs duties and inspection, Electronic funds transfers, Excise taxes, Imports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Wine.

The Regulatory Amendment

For the reasons stated in the preamble, the temporary rule published in the **Federal Register** at 70 FR 49479 on August 24, 2005, is adopted as a final rule without change.

Signed: January 2, 2008.

John J. Manfreda,

Administrator.

Approved: March 24, 2008.

Timothy E. Skud,

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

[FR Doc. E8–9173 Filed 4–25–08; 8:45 am]

BILLING CODE 4810–31–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2007–0510; FRL–8556–1]

Withdrawal of Federal Implementation Plans for the Clean Air Interstate Rule in 12 States

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is withdrawing Federal Implementation Plans (FIPs) for the