through Friday, except on Federal holidays.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning December 10, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved or any studies of animal safety required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to veterinary prescription use of the drug in dogs for the control of clinical signs associated with cognitive dysfunction syndrome.

The agency has determined under 21 CFR 25.33(d)(1) 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.

List of Subjects in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.2098 is amended by redesignating paragraphs (d)(2) and (d)(3) as paragraphs (d)(1)(i) and (d)(1)(ii), respectively, and by adding paragraph (d)(2) to read as follows:

§ 520.2098 Selegiline hydrochloride tablets.

* * * * *

(d) *Conditions of use.* * * *

(2) *Dosage.* 0.5 to 1.0 milligram per kilogram of body weight once daily.

(i) *Indications for use.* For the control of clinical signs associated with canine cognitive dysfunction syndrome.

(ii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: January 6, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–739 Filed 1–12–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 5, 7, 13, and 19

[TD ATF–406 Re: Notice No. 815 and Notice No. 819]

RIN: 1512–AB34

Procedures for the Issuance, Denial, and Revocation of Certificates of Label Approval, Certificates of Exemption From Label Approval, and Distinctive Liquor Bottle Approvals (93F–029P)

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

ACTION: Final rule, Treasury decision.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is issuing regulations setting forth the procedures for the issuance, denial, and revocation of certificates of label approval (COLAs), certificates of exemption from label approval, and distinctive liquor bottle approvals. The denial and revocation regulations are new, whereas the issuance regulations merely amend current regulations. The new regulations also codify procedures for administratively appealing the denial or revocation of certificates of label approval, exemptions from label approval, or distinctive liquor bottle approvals.

DATES: These regulations are effective March 15, 1999.

ADDRESSES: Copies of the proposed regulation and written comments are available for public inspection during normal business hours at: ATF Reading Room, Office of Public Affairs and Disclosure, Room 6480, 650 Massachusetts Avenue, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Edward A. Reisman, Jr., Product Compliance Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW, Washington, DC 20226 (202–927–8140).

SUPPLEMENTARY INFORMATION:

Background

The Federal Alcohol Administration (FAA) Act, 27 U.S.C. 205(e), provides ATF, as the delegate of the Secretary of the Treasury, with authority to promulgate regulations with respect to the bottling, packaging, and labeling of distilled spirits, wine, and malt beverages in order to prohibit deception of the consumer, and provide the consumer with adequate information as to the identity and quality of the product.

In order to carry out such requirements, domestic bottlers and producers are prohibited from bottling distilled spirits, wines, or malt beverages, and importers are prohibited from removing bottled distilled spirits, wines, or malt beverages from customs custody unless they have in their possession a certificate of label approval covering such products, ''issued by the Secretary in such manner and form as he shall by regulations prescribe.'' 27 U.S.C. 205(e). The law provides an exemption from these requirements for products that are not to be sold, offered for sale, or shipped or delivered for shipment, or otherwise introduced, in interstate or foreign commerce.

The regulations implementing these statutory provisions provide that no person shall bottle or pack wine, distilled spirits, or malt beverages unless application is made to the Director and an approved certificate of label approval, ATF Form 5100.31, is issued. 27 CFR 4.50(a), 5.55(a), and 7.41. The regulations also provide that no bottled wines, distilled spirits, or malt beverages shall be released from customs custody for consumption unless an approved certificate of label approval, ATF Form 5100.31, is deposited with the appropriate customs officer at the port of entry. 27 CFR 4.40(a), 5.51(a), and 7.31(a).

A bottler of wine or distilled spirits who can show to the satisfaction of the Director that the product is not to be sold, offered for sale, or shipped or delivered for shipment or otherwise introduced in interstate or foreign commerce, must make application for exemption from the labeling requirements of the FAA Act on ATF Form 5100.31 in accordance with the instructions on the form. If the application is approved, a certificate of exemption from label approval will be issued on the same form. 27 CFR 4.50(b) and 5.55(b). Certificates of exemption from label approval are not issued for malt beverages.

Finally, the ATF Form 5100.31 is also used to obtain approval for distinctive liquor bottles, pursuant to the regulations appearing at 27 CFR 19.633(a). ATF's authority to regulate liquor bottles is derived from section 5301 of the Internal Revenue Code of 1986, 26 U.S.C. 5301. However, the approval of a distinctive liquor bottle also includes the approval of the label on that bottle, pursuant to the FAA Act.

Revocation of COLAs

ATF reviews approximately 60,000 applications for certificates of label approval, exemptions from label approval, and distinctive liquor bottle

approvals every year. Because errors occasionally occur in the approval process, there is a need for some type of revocation procedure.

Since the enactment of the FAA Act in 1935, ATF and its predecessor agencies have taken the position that the statutory authority to issue certificates of label approval includes the implied statutory authority to cancel or revoke the certificates if they were approved in error. However, there have never been formal procedures in the regulations for denial or revocation of certificates of label approval. Instead, ATF has utilized informal procedures for denials and revocations, where applicants or certificate holders who wished to contest a denial or revocation are given an opportunity to do so in writing, or through informal meetings with Bureau officials.

The certificate of label approval was never intended to convey any type of proprietary interest to the certificate holder. On the contrary, Paragraph 1 of Form 5100.31 provides that ''This certificate is issued for ATF use only. This certificate does not constitute trademark protection.'' Paragraph 2 of this form reminds applicants that the ''certificate does not relieve any person from liability for violations of the Federal Alcohol Administration Act.'' The certificate of label approval is a statutorily mandated tool used to help ATF in its enforcement of the labeling requirements of the FAA Act.

ATF's informal procedures for revocation of COLAs were subject to challenge in the Federal District Court for the Northern District of California. In *Cabo Distributing Co.* v. Brady, 821 F. Supp. 601 (N.D. Cal. 1992), the court set aside ATF's revocation of labels for ''Black Death'' vodka on several grounds. The court held that there was no express statutory or regulatory authority for the Bureau to cancel certificates of label approval, and that the Bureau had implied authority to reverse its actions only in limited circumstances. The court thus concluded that ''[w]ithout statutory authority or regulatory authority, the BATF cannot cancel a certificate of label approval.'' 821 F. Supp. at 612. The court also held that the Bureau's informal procedures for revoking the ''Black Death'' certificates of label approval had not afforded the certificate holders their constitutional right to procedural due process. 821 F. Supp. at 612.

AFT does not agree with the court's decision on either of these two holdings. ATF believes that a right to cancel certificates of label approval is implied from the authority granted by the statute to the Secretary to issue certificates of label approval ''in such manner and form as he shall by regulations prescribe * * *'' The statute explicitly authorizes ATF, as a delegate of the Secretary, to issue regulations governing the procedure for the issuance of certificates of label approval. There is also implicit statutory authority to issue regulations governing the procedures for denying and revoking certificates of label approval.

Furthermore, ATF believes that the procedures that it has been using for revoking certificates of label approval, although not codified in the regulations, have provided certificate holders with due process of law. However, ATF determined that rulemaking was appropriate in order to clarify its authority and procedures for revocation of label approvals.

Notice of Proposed Rulemaking

On September 13, 1995, ATF published a notice of proposed rulemaking (Notice No. 815, 60 FR 47506–47512) to solicit public comment on regulations setting forth procedures for the issuance, denial, and revocation of certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals. The comment period closed on December 12, 1995, and was reopened until February 21, 1996, by notice dated January 22, 1996 (Notice No. 819, 61 FR 1545–1546).

Notice No. 815 proposed to make existing regulations covering issuance of certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals more specific and proposed new regulations to codify existing informal procedures for denial of applications and revocation of certificates. The notice also proposed the codification of procedures for administratively appealing the denial or revocation of certificates of label approval, exemptions from label approval, and distinctive liquor bottle approvals. In the notice, ATF restated its position that the proposed regulations would afford applicants and certificate holders due process of law, and that the codification of these procedures in the regulations would eliminate any question as to ATF's authority to revoke certificates of label approval, exemptions from label approval, and distinctive liquor bottle approvals.

Under current regulations, the authority to approve certificates of label approval, exemptions from label approval, and distinctive liquor bottle applications rests with the Director and has been delegated to the labeling specialists in the Product Compliance Branch. The proposed regulations described the process of approval, denial, and administrative appeal in a new part 13. Proposed revisions to parts 4, 5, 7, and 19 added cross-references to the new part 13.

With respect to revocations of certificates of label approval, certificates of exemption from label approval, or distinctive liquor bottle approvals, and administrative appeals of such actions, the proposed regulations set forth a procedure based on ATF's informal practices.

In response to Notice 815, ATF received comments from the following organizations:

Government Liaison Services, Inc.;

Presidents' Forum of the Beverage Alcohol Industry (Presidents' Forum);

American Brandy Association (ABA);

Wine Institute;

Fédération Internationale des Vins et Spiriteux (FIVS);

Fédération des Exportateurs de Vins & Spiriteux de France (FEVS);

National Assocaition of Beverage Importers, Inc. (NABI). Five importers, Remy Amerique, Inc., Austin Nichols & Co. Inc., Dribeck Importers, Inc., Guinness Import Company, Kobrand Corporation, and two associations, The Scotch Whisky Association and the Associación de Criadores Exportadores de Sherry, wrote to endorse the comments of NABI;

The Distilled Spirits Council of the U.S. (DISCUS). Jim Beam Brands Co., a distiller, wrote to express agreement with the DISCUS comments;

Beer Institute filed comments on behalf of its senior members: The Anheuser Busch Companies, Miller Brewing Company, Coors Brewing Company, Stroh Brewery Company, and G. Heileman Brewing Company;

Ropes & Gray filed comments on behalf of the Institut Nationale des Appellations d'Origine (INAO) of France, an entity responsible for protecting French appellations of origin;

The U.S. Department of Commerce transmitted comments from the European Commission (EC); and

The Embassy of Mexico Trade Office forwarded comments from Mexico's Dirección General De Normas concerning labeling of tequila and mezcal. This last comment suggests regulatory changes that are beyond the scope of Notice Number 815, but may be considered as part of a future rulemaking.

Analysis of Comments

The majority of the commenters expressed support for ATF's effort to promulgate regulations covering issuance, denial, and revocation of certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, though most had comments on specific proposals.

Proposals and Comments on Application, Approval and Denial

In Notice No. 815, ATF set forth proposed regulations describing in detail the steps in applying for a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, including issuance of approved certificates, denial of applications, and appeal of such denials. A number of comments addressed specific items in these proposed regulations.

In its comment, Government Liaison Services, Inc. expressed concern at the use of the word ''send'' in proposed § 13.11, which they interpreted to preclude hand delivery of applications for label approval. A clarifying change is made to this section, now designated as § 13.21. ATF did not intend to prohibit hand-delivered applications.

In the proposed rule, ATF described the approval process, including the noting of any qualifications to the approval in the appropriate space on the form. The proposed rule further provided that if an application is denied for any reason, the applicant is sent an ATF Form 5190.1, ''ATF F 5100.31 Correction Sheet,'' with the reasons for the denial briefly noted on the form. The proposed regulations afforded the applicant an opportunity to file an administrative appeal of the denial of an application for a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, with the Chief, Labeling Section, Product Compliance Branch, who would make a final decision on the denial of the application.

Government Liaison Services, Inc., the President's Forum, NABI and DISCUS all commented that the initial correction notice and informal discussion of technical issues arising from the application that often occurs between applicants and ATF representatives should be kept separate from a formal appeal process. DISCUS, in its comment, noted ''these informal consultations and contacts have served and do serve the interests of all parties, with commensurate savings in expenditures and manpower for both the government and the industry.''

In practice, applicants and ATF representatives often informally resolve issues related to a qualified approval or a denied application. ATF does not wish to create the impression that all qualifications or denials must be formally appealed. Accordingly, we have added a new subsection § 13.25(b) to confirm that the applicant has the option of pursuing informal resolution of a labeling issue by requesting an informal conference with the Product Compliance Branch Specialist or the Chief, Product Compliance Branch.

Government Liaison Services, Inc. also noted that the proposed regulations did not incorporate ATF's practice of allowing voluntary withdrawal of applications. A new § 13.22 has been added to cover withdrawal of applications.

Beer Institute, DISCUS and Government Liaison Services, Inc. questioned ATF's proposal to authorize the Chief of the Labeling Section to make final decisions on appeals of denials of applications for certificates of label approvals, exemptions from label approvals and distinctive liquor bottles. They suggested review by either a higher level officials within the Alcohol and Tobacco Programs Division or by someone outside the Division. Pursuant to these comments, a second level of appeal has been added in § 13.27 for qualifications or denials of applications for label approval. The final rule provides that the first appeal will be decided by the Chief, Product Compliance Branch, and the second appeal will be decided by the Chief, Alcohol and Tobacco Programs Division.

Appeal of Qualifications

The final rule expands the formal and informal resolution and appeal procedures for denials to include resolution of disagreements concerning qualifications on approved certificates. For these purposes, a qualification is treated like a partial denial, since it limits the use of the COLA.

Comments on Revocation and Appeal

With respect to revocations of certificates of label approval, certificates of exemption from label approval, or distinctive liquor bottle approvals, the proposed regulations divided revocations into two categories, revocation of specific labels and revocation by operation of law or regulation. The two types of revocation will be discussed separately in this background material.

The proposed regulations on revocation of specific approvals gave the Chief, Product Compliance Branch, authority to issue a notice of proposed revocation and gave the certificate holder 45 days to present written arguments as to why the revocation should not occur. In the proposed rule, the Chief, Product Compliance Branch, was authorized to decide whether to revoke the certificate. If a label or distinctive liquor bottle approval were revoked, the certificate holder would have 45 days to file a written appeal with the Chief, Alcohol and Tobacco Programs Division. In the proposed rule, the decision of the Chief, Alcohol and Tobacco Programs Division, was the final decision of the Bureau.

ATF's Authority To Revoke Label Approvals

Most commenters who addressed the issue agreed that ATF had authority to revoke certificates of label approval, although there was disagreement on the circumstances where revocation would be appropriate. DISCUS argued, however, that in the absence of a specific statutory provision authorizing revocations of approved labels, ATF lacked authority to take such actions.

ATF does not agree that it lacks statutory authority to revoke certificates of label approval. Many courts have recognized ''an implied authority in other agencies to reconsider and rectify errors even though the applicable statute and regulations do not expressly provide for such reconsideration.'' *Gun South, Inc.* v. *Brady*, 877 F.2d 858, 862 (11th Cir. 1989). For example, in concluding that the Interstate Commerce Commission could order a refund to correct a prior error, the Supreme Court stated that ''[a]n agency, like a court, can undo what is wrongfully done by virtue of its order.'' *United Gas Improvement Co.* v. *Callery Properties*, 382 U.S. 223, 229 (1965). *See also Kudla* v. *Modde*, 537 F. Supp. 87, 89 (E.D. Mich. 1982) (''[t]he power of the state to require a license implies the power of the state to revoke a license which has been improperly issued.''), *aff'd without opinion*, 711 F.2d 1057 (6th Cir. 1983); *Century Arms, Inc.* v. *Kennedy*, 323 F. Supp. 1002, 1016–17 (D. Vt. 1971), (''we are aware of no licenses which once granted, can never be taken away.''), *aff'd*, 449 F.2d 1306 (2d Cir. 1971), *cert. denied*, 405 U.S. 1065 (1972).

As we explained in the notice, it is ATF's position that its statutory authority to issue regulations governing the issuance of COLAs also includes the implied authority to issue regulations setting forth procedures for the denial and revocation of such COLAs. The single comment opposed to this position did not provide a persuasive basis for concluding otherwise.

Due Process Issues

The American Brandy Association (ABA), Beer Institute, Wine Institute, NABI and DISCUS submitted comments suggesting that ATF's approval of a certificate of label approval (COLA) does create a property right subject to the protection of due process of law.

ATF has always maintained that its informal procedures concerning the

denial and revocation of COLAs were sufficient to provide procedural due process to the applicant or certificate holder. Procedural due process imposes constraints on governmental decisions which deprive individuals of ''liberty'' or ''property'' interests within the meaning of the Due Process Clause of the Fifth Amendment. The Supreme Court has recognized that ''due process is flexible and calls for such procedural protections as the particular situation demands.'' *Morrissey* v. *Brewer,* 408 U.S. 471, 481 (1972).

In determining whether an administrative procedure accords due process, three factors are considered:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Mathews v. *Eldridge,* 424 U.S. 319, 334 (1976).

ATF recognizes that brand names and other terms on labels may be significant elements in the marketing of an alcohol beverage. However, even assuming that a certificate represents a property interest, we believe that the procedures set forth in the final rule minimize the risk of an erroneous deprivation of the interest of the industry member. The procedures adopted in the final rule ensure that certificate holders are given prior written notice of a proposed revocation; the opportunity to meet with agency officials to discuss the issues; and the opportunity to present written arguments or evidence before the agency takes final action to revoke a label.

There have been suggestions that an evidentiary hearing, complete with an Administrative Law Judge and the right to cross-examine witnesses, is the appropriate model for a revocation proceeding. However, none of the commenters explained why a written review procedure involved a risk of erroneous deprivation of the certificate holder's property interests, or why an evidentiary hearing would shed further light on the issue of whether a label is in compliance with the regulations. *See Doolin Sec. Sav. Bank* v. *FDIC,* 53 F.3d 1395, 1403 (4th Cir. 1995), *cert. denied* 516 U.S. 973 (1995) (finding that an agency was not required to provide an evidentiary hearing where the plaintiff did not ''offer sufficient evidence demonstrating that an oral hearing would allow it to present evidence * * * that it could not present in the written review procedure'' and the ''determination did not involve credibility assessments, which would benefit from an oral hearing with the presentation of witnesses'').

Thus, the comments provided no basis for concluding that the additional procedural safeguards provided by an evidentiary hearing would be of value. However, such hearings would certainly impose additional administrative burdens on the agency. After evaluating the factors set forth in *Mathews* v. *Eldridge,* it is clear that due process does not require a formal evidentiary hearing before the agency revokes a certificate of label approval. As the Supreme Court noted in the case, ''the judicial model of an evidentiary hearing is neither a required, nor even the most effective, method of decisionmaking in all circumstances.'' 424 U.S. at 348. This is especially true where, as here, judicial review of the final agency determination is available in the United States District Court pursuant to the Administrative Procedure Act (APA). *See* 27 U.S.C. 205(e); 5 U.S.C. 702. *See also Doolin,* 53 F.3d at 1405 (''This opportunity for judicial review of FDIC reclassification determinations therefore supports our conclusion that the FDIC's risk classification review procedures satisfy due process''). Accordingly, the final rule does not provide for evidentiary hearings in connection with the revocation of certificates.

Level of Appeal

Some commenters suggested that the impact of a revocation on the industry member warrants review at a higher level than the ATF officials designated in the proposed rule. A number of commenters, including Beer Institute, suggested that the officials designated in the proposed rule to hear appeals are in day-to-day contact with the persons making the initial decisions and may even have participated in making those initial decisions. As previously noted, some commenters even suggested that appeals of revocations should be heard by an Administrative Law Judge.

The APA, 5 U.S.C. 554, generally requires that an independent hearing officer preside at formal adjudicatory hearings ''in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing.'' Section 554 also requires the separation of investigatory and decisionmaking functions for this type of formal adjudication.

The Federal Alcohol Administration Act does not provide that proceedings regarding labels must be ''determined on the record after opportunity for an agency hearing.'' Accordingly, proceedings regarding the approval or denial of a label do not constitute formal adjudicatory proceedings under the APA. *See Joseph E. Seagram & Sons, Inc.* v. *Dillon,* 344 F.2d 497 (D.C. Cir. 1965). Similarly, there is no statutory requirement that appeals of denials or revocations be determined on the record after opportunity for an agency hearing. Since these proceedings are not formal adjudications, there is no legal requirement that such appeals be heard by an independent hearing officer or Administrative Law Judge.

Nonetheless, ATF recognizes that many industry members believe that fairness dictates that appeals should be heard at a high enough level to ensure some division between the initiation of revocation proceedings and the final appeal. In response to these comments, we have revised the final rule to designate higher level officials to make revocation decisions and hear appeals. The Chief, Product Compliance Branch, will issue a notice of proposed revocation, but the decision whether or not to revoke a certificate will be made by the Chief, Alcohol and Tobacco Programs Division. Any appeal of such a revocation will be decided by the Assistant Director, Alcohol and Tobacco.

Time Limits for Initiating Revocation Proceedings

As noted above, many commenters suggested limitations on ATF's authority to rescind label approvals. Several commenters suggested setting a time within which ATF must begin revocation proceedings. For example, Beer Institute suggested a 30-day period during which ATF could revoke labels to correct agency administrative errors without a formal administrative hearing, and then ''an outer limit of one year'' on any other revocation. Wine Institute suggested that any time limit (they suggested five years) should be measured from ''relatively wide and bona fide distribution'' of a product, rather than from approval of a label.

It has been ATF's experience that in some cases, errors in the label approval process are not detected right away. For example, a label may be approved for a product that is not placed on the market for some time. ATF believes that the placement of an artificial time constraint on its ability to take revocation action would not further the statutory purpose of protecting the consumer from misleading labels. Accordingly, the final rule does not set forth such a time limit.

Standard of Proof for Revocation

The American Brandy Association and DISCUS suggested that the standard for revocation should be based on ''clear and convincing evidence'' that a label is not in compliance with law or regulations. However, the comment did not provide a legal basis for imposing such a standard.

Under the APA, an agency action (including an informal adjudication such as a denial or revocation of a certificate) shall be set aside by a reviewing court if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. 706(2)(A). Even an agency's action in a formal adjudicatory proceeding (which this is not) will be set aside by a reviewing court only if it is ''unsupported by substantial evidence.'' 5 U.S.C. 706(2)(E). there is no requirement that an agency establish ''clear and convincing evidence'' to justify its actions.

The standard of review set forth in the APA provides sufficient protection to applicants and certificate holders wishing to contest agency actions. Accordingly, this comment was not adopted.

Judicial Review

ATF is modifying the final rule to clarify that the administrative remedies available within ATF must be exhausted prior to application to the Federal courts for review. Accordingly, §§ 13.26, 13.27 and 13.44 are amended to reflect this requirement.

Effect of Revocation

There were several comments and questions concerning the effect of revocation of a certificate. In response, we have added a new § 13.73 to clarify this issue. Section 13.73 provides that, as of the effective date of the revocation, a revoked certificate may not be used to bottle or pack distilled spirits, wine or malt beverages; to remove such products from the place where they were bottled or packed; or to remove such products from customs custody for consumption.

Use-Up Period

A number of commenters suggested a longer ''use-up'' period for revoked labels. We have revised the section covering this issue, now designated as § 13.72, to allow 60 days from the date of the initial revocation of the certificate. Some commenters also did not understand that the proposed regulations provided that a timely appeal would stay the effective date of a revocation of a certificate (other than a revocation by operation of law or regulations). Accordingly, § 13.72 now incorporates the material on the effect of an appeal on the date of revocation, which was originally proposed in § 13.50(b).

Revocations by Operation of Law or Regulation

With respect to revocations by operation of law or regulation, the proposed rule did not require ATF to issue a notice of proposed revocation prior to notifying a certificate holder of the revocation of a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval. The proposed rule stated that in these cases, the burden of ensuring that affected labels were in compliance with the new requirements imposed by statute or regulation was on the certificate holder, not ATF.

The proposed rule provided that if ATF determined that a label or bottle which was not in compliance with the new statutory or regulatory requirements was still being used, the Chief, Product Compliance Branch, would issue a letter notifying the certificate holder that the certificate had been revoked by operation of law or regulation. If the certificate holder wished to challenge the application of the law or regulation to the particular label or bottle, the holder would appeal the decision, in writing, to the Chief, Alcohol and Tobacco Programs Division.

In its comment, DISCUS expressed its opinion that ATF should individually notify holders whose labels are revoked by operation of law, that ATF should never require submission of new COLAs to show compliance with any new requirement in the law, and further expressed the opinion that COLAs may not be revoked by operation of regulation. ATF is not adopting any of these comments.

In the first instance, affected certificate holders will likely receive notice of a proposed or final change in regulations by the publication of such notice or regulation in the **Federal Register**. Changes in law usually will be accompanied by changes in regulations. Amendments to both the law and regulations affecting industry members will be published in the ATF Quarterly Bulletin. Thus, there can be no argument that industry members do not receive notice of such changes. In those instances, ATF believes the responsibility for learning about the changes in the law and regulations and making appropriate changes to labels properly rests with the certificate holders.

Second, ATF reserves the right to decide, based on the facts and circumstances of each change in regulations, whether to require certificate holders to file new applications to show compliance with new requirements or to excuse holders of approved certificates from filing new applications, no longer as labels are modified appropriately.

Finally, on the issue of ATF's authority to revoke labels by operation of regulations, we believe this is part of our general authority to promulgate regulations and to revoke labels, which was discussed earlier in this preamble. Changes in the labeling regulations usually affect all future labeling activities, regardless of when a certificate of label approval was originally issued for a particular label. Such changes to the regulations will usually set forth specifically whether existing certificates of label approval must be surrendered, and new certificates obtained. In the event that an individual change to the labeling regulations is accompanied by a ''grandfathering'' provision for previously approved certificates of label approval, the regulation will so provide.

Time Limits for Appeals

Several commenters, including Beer Institute, DISCUS, FEVS and NABI, asked ATF to set a time limit for its own actions in response to appeals. DISCUS, in its comment, suggested that ''[c]onsistent with the tenet of administrative efficiency, we believe that it is appropriate that the Bureau be required to issue its written decision concerning a COLA denial within 15 days from the receipt of the applicant's appeal of the denial.'' DISCUS made similar recommendations with respect to deadlines for ATF action on decisions after a COLA holder disputes a notice of proposed revocation and appeals a revocation. Beer Institute made the following suggestion: ''* * * we propose that ATF adopt a 45-day period to render decisions on appeals of denials of COLA applications.'' With respect to revocations, they recommend that decisions ''be made within 30 days'' after a formal appeal by the holder of the COLA.

Pursuant to the comments received on this issue, ATF has added a time limit provision to each of the regulatory sections covering initial approvals, appeals of denials of certificates, decisions whether or not to revoke a certificate, and appeals of revocations. ATF does not believe that the time periods suggested by the comments provide sufficient time for the unusual labeling cases that may require extensive agency review. Accordingly, the final rule provides that ATF must

generally act within 90 days of receiving an application or appeal. However, the regulations provide that, if an applicant or certificate holder requests an informal conference as part of an appeal, as authorized in §13.71, the 90-day period will begin 10 days after the date of the conference to allow for consideration of any written arguments, facts or evidence submitted after the conference. Further, ATF may exercise an option to extend this period one time for an additional 90 days, based on unusual circumstances.

It should be emphasized that ATF's current customer service standards call for action on initial label applications within 9 calendar days; the allowance of 90 days in the regulations does not reflect any intention to lengthen the average period of time for label review. Instead, the regulation merely places an outside limit on the unusual labeling cases that may require additional fact-finding, consultation with other agencies, or extensive review within the agency. A new §13.75 has been added to clarify the beginning date of this time limit.

Formal Third-Party Involvement in the Label Process

The INAO comment suggested that ATF should recognize the rights of third parties with respect to certificates of label approval. Once example given by the INAO was where ''a label may contain a brand, fanciful name, class, type or other designation that is identical or substantially similar to a term, such as an appellation of origin, which is protected under U.S. treaties, agreements, laws or regulations.'' The INAO suggested that in such a case, ATF should implement procedures to ensure that the country of origin was contacted regarding the use of the term on the label.

In appropriate situations, ATF will contact the country of origin for more information regarding whether the use of a labeling term would violate the laws of the country. Accordingly, ATF does not believe it is necessary to codify such procedures in the regulations.

The INAO also suggested that ATF should implement a system to publish approved labels, perhaps similar to the *Official Gazette* of the Patent and Trademark Office. Their comment suggested that such a procedure would enable concerned third parties to receive timely notice of approved labels, and, in the case of an erroneous approval, will enable the third party to bring the error to ATF's attention promptly.

Certificates of label approval or exemption from label approval, and approvals of distinctive containers, become public information upon approval, and can be viewed at the ATF Library or requested by mail under the Freedom of Information Act. ATF is also working to make these public records more readily available through electronic means. We hope to make the approved label database available on the Internet in the next year or two; we believe that this will provide affected third parties ample opportunity to inspect approved labels. Thus, we do not see a need for publishing approved labels on a regular basis.

However, in response to this comment, the final regulations contain a new § 13.61, which codifies ATF's policy concerning publicity of information contained in applications for certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, and the resulting approvals or administrative actions. The regulations also codify ATF's longstanding policy that pending and denied applications for label approval are treated as proprietary information and are not released to the public without the consent of the submitter.

The INAO and FEVS requested ATF to consider new procedures that would allow third parties to intervene in proceedings concerning the denial or revocation of a label. The INAO suggested that if a proposed revocation of such a label were appealed by the certificate holder, the third party should have an opportunity during the appeal process to submit material in support of revocation.

The INAO correctly noted that ATF currently reviews complaints concerning approved labels where a third party believes that the label is in violation of the regulations. However, the INAO suggested that this policy be codified, so that the public would be aware of its existence. We concur with the suggestion to codify ATF's policy and informal practice concerning review of third party complaints, and accordingly have added a new § 13.62 to the final rule. However, the regulation does not provide for any formal role for third parties during a revocation proceeding. ATF believes that it may be appropriate in certain cases to seek the opinions of third parties regarding whether a particular label is misleading to consumers; however, we believe that this is best determined on a case-by-case basis.

Service of Notices

In proposed § 13.55, ATF stated that notices of denial, proposed revocation and revocation will be served by first class mail or by personal delivery. NABI and several other commenters stated that service by mail should be by registered mail, return receipt requested. This section has been renumbered as § 13.76 in the final rule and modified to require proof of service of notices of proposed revocation or revocation, either a postal return receipt or equivalent written acknowledgment obtained from the addressee by a commercial delivery service or a report of hand delivery by an ATF official. The final rule does not require proof of service for notices of denial of applications, since applicants may not use a label until an approved certificate is received.

Informal Conferences

In proposed § 13.40(a), ATF reserved the right to decide whether to grant an informal conference to discuss a denial or revocation of a certificate. Several commenters suggested that such a conference should be granted as a matter of right, and cited 27 CFR 70.418, which states that any person may have a conference concerning ''any matter arising in connection with such person's operations'' upon request. In the final rule, the paragraph, now designated as § 13.71, is revised to show that a conference will be granted upon request.

Proposed paragraph (b) of that section stated that no transcript would be made of a conference, if one was held, and that any arguments, facts or evidence on which an applicant or certificate holder wishes to rely, should be incorporated in a written submission. A number of commenters expressed the opinion that there should be a formal record made of such a conference. ATF disagrees. As noted above, proceedings regarding label approvals are not required by statute to be conducted on the record after an agency hearing; accordingly this is not a formal adjudicatory proceeding. The regulations clarify that the conference is an informal means of clarifying issues or discussing alternative solutions, not an administrative hearing. The written submission of the applicant or certificate holder and the written response of ATF will form the official administrative record of such proceedings.

Comments Regarding Imported Products

The EC commented that ''establishing a mandatory procedure concerning certificates of label approval * * * would appear to be disproportionate to the pursued objective'' (of preventing consumer deception). The EC said

further that they ''would, therefore, deem this regulation as having the effect of creating unnecessary obstacles to European exports unless the U.S. authorities can show that this proposal is not more trade-restrictive than necessary to fulfill the pursued objective and explain the justification for this technical rule in terms of these Articles. * * *'' (Article 2.2 and Article 5.1.2 in connection with Article 2.5 of the Agreement on Technical Barriers to Trade).

The final regulations do not create any unnecessary obstacles to European exports to the United States; on the contrary, the regulations will provide all applicants and certificate holders with more detailed and specific information about the label approval process. The regulations also set forth specific avenues of appeal for applicants and certificate holders. Domestic and imported products are treated with parity under both the proposed and final regulations. Accordingly, ATF does not agree that the regulations create unnecessary obstacles to imported products.

In its comments, FEVS asked that ATF ensure equal treatment of domestic and foreign goods in the final rule, but did not identify any specific changes to be made. As noted above, ATF is not aware of any provision in the proposed rule or this final rule that treats domestic and imported products differently.

NABI noted that importers of beer are subject to suspension or revocation of their basic permits for FAA Act violations, including labeling violations, while domestic brewers are not required to obtain a basic permit under the FAA Act. However, this distinction flows directly from the statute and is not subject to change through regulations. Furthermore, brewers may be subject to other sanctions for violations of the FAA Act. Thus, no changes were made to the final rule as a result of these comments.

Unrelated Labeling Issues

Government Liaison Services, Inc. expressed concerns about ATF's day-to-day handling of applications for certificates of label approval, exemption from label approval, and distinctive liquor bottles. They requested that ATF make changes in areas such as training, workflow, recordkeeping, and communication of policy decisions. Similar concerns were raised in the DISCUS and INAO comments.

These issues are beyond the scope of this rulemaking document. Nonetheless, ATF is committed to improving the day-to-day administration of its label approval system. ATF is addressing these issues through partnership meetings with the regulated industry, and through internal restructuring efforts.

Regulatory Flexibility Act

It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation will give ATF specific regulatory authority to issue, deny or revoke certificates of label approval, exemptions from label approval, and distinctive liquor bottle approvals. The regulation will not increase recordkeeping or reporting requirements. Accordingly, a regulatory flexibility analysis is not required because the final rule is not expected (1) to have significant secondary or incidental effects on a substantial number of small entitles; or (2) to impose, or otherwise cause a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866. Accordingly, this rule is not subject to the analysis required by this Executive Order.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(j), and its implementing regulations, 5 CFR part 1320, do not apply to this document because no requirement to collect information is imposed.

Drafting Information

The principal author of this document is Marjorie D. Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms. However, other personnel of ATF participated in developing this document.

List of Subjects in

27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, Wine.

27 CFR Part 5

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

27 CFR Part 7

Advertising, Beer, Consumer protection, Customs duties and inspection, Imports, Labeling.

27 CFR Part 13

Administrative practice and procedure, Alcohol and alcoholic beverages, Appeals, Applications, Certificates of label approval, Certificates of exemption from label approval, Denials, Distinctive liquor bottle approvals, Informal conferences, Labeling, Revocations.

27 CFR Part 19

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations, Claims, Chemicals, Customs duties and inspection, Electronic fund transfers, Excise taxes, Exports, Gasohol, Imports, Labeling, Liquors, Packaging and containers, Puerto Rico, Reporting and recordkeeping requirements, Research, Security measures, Spices and flavorings, Surety bonds, Transportation, Virgin Islands, Warehouses, Wine.

Authority and Issuance

Chapter I of Title 27, Code of Federal Regulations, is amended as follows:

PART 4—LABELING AND ADVERTISING OF WINE

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

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

Par. 2. Section 4.40 is amended to add paragraph (d) to read as follows:

§ 4.40 Label approval and release.

* * * * *

(d) *Cross reference.* For procedures regarding the issuance, denial, and revocation of certificates of label approval, as well as appeal procedures, see part 13 of this chapter.

Par. 3. Section 4.50 is amended to add paragraph (c) to read as follows:

§ 4.50 Certificates of label approval.

* * * * *

(c) *Cross reference.* For procedures regarding the issuance, denial, and revocation of certificates of label approval, and certificates of exemption from label approval, as well as appeal procedures, see part 13 of this chapter.

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

Par. 4. The authority citaiton for part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805, 27 U.S.C. 205.

Par. 5. Section 5.46 is amended to revise paragraph (d) to read as follows:

§ 5.46 Standard liquor bottles.

* * * * *

(d) *Exceptions.*—(1) *Distinctive liquor bottles.* The headspace and design requirements in paragraphs (b) and (c) of this section do not apply to liquor bottles that are specifically exempted by the Director, pursuant to an application filed by the bottler or importer.

(2) *Cross reference.* For procedures regarding the issuance, denial and revocation of distinctive liquor bottle approvals, as well as appeal procedures, see part 13 of this chapter.

Par. 6. Section 5.51 is amended to add paragraph (e) to read as follows:

§ 5.51 Label approval and release.

* * * * *

(e) *Cross reference.* For procedures regarding the issuance, denial, and revocation of certificates of label approval, as well as appeal procedures, see part 13 of this chapter.

Par. 7. Section 5.55 is amended to add paragraph (d) to read as follows:

§ 5.55 Certificates of label approval.

* * * * *

(d) *Cross reference.* For procedures regarding the issuance, denial, and revocation of certificates of label approval and certificates of exemption from label approval, as well as appeal procedures, see part 13 of this chapter.

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

Par. 8. The authority citation for part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 9. Section 7.31 is amended to add paragraph (d) to read as follows:

§ 7.31 Label approval and release

* * * * *

(d) *Cross reference.* For procedures regarding the issuance, denial, and revocation of certificates of label approval, as well as appeal procedures, see part 13 of this chapter.

Par. 10. Section 7.41 is revised to read as follows:

§ 7.41 Certificates of label approval.

(a) *Requirement.* No person shall bottle or pack malt beverages, or remove malt beverages from the plant where bottled or packed unless application is made to the Director, and an approved certificate of label approval, ATF Form 5100.31, is issued by the Director.

(b) *Cross reference.* For procedures regarding the issuance, denial, and revocation of certificates of label approval, as well as appeal procedures, see part 13 of this chapter.

PART 13—LABELING PROCEEDINGS

Par. 11. Part 13 is added to read as follows:

Subpart A—Scope and Construction of Regulations

Sec.
13.1 Scope of part.

Subpart B—Definitions

13.11 Meaning of terms.

Subpart C—Applications

13.21 Application for certificate.
13.22 Withdrawal of applications.
13.23 Notice of denial.
13.25 Appeal of qualification or denial.
13.26 Decision after appeal of qualification or denial.
13.27 Second appeal of qualification or denial.

Subpart D—Revocations of Specific Certificates

13.41 Authority to revoke certificates.
13.42 Notice of proposed revocation.
13.43 Decision after notice of proposed revocation.
13.44 Appeal of revocation.
13.45 Final decision after appeal.

Subpart E—Revocation by Operation of Law or Regulation

13.51 Revocation by operation of law or regulation.
13.52 Notice of revocation.
13.53 Appeal of notice of revocation.
13.54 Decision after appeal.

Subpart F—Miscellaneous

13.61 Publicity of information.
13.62 Third-party comment on certificates.
13.71 Informal conferences.
13.72 Effective dates of revocations.
13.73 Effect of revocation.
13.74 Surrender of certificates.
13.75 Evidence of receipt by ATF.
13.76 Service on applicant or certificate holder.
13.81 Representation before ATF.
13.91 Computation of time.
13.92 Extensions.

Authority: 27 U.S.C. 205(e), 26 U.S.C. 5301 and 7805.

Subpart A—Scope and Construction of Regulations

§ 13.1 Scope of part.

The regulations in this part govern the procedure and practice in connection with the issuance, denial, and revocation of certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals under 27 U.S.C. 205(e) and 26 U.S.C. 5301. The regulations in this part also provide for appeal procedures when applications for label approval, exemptions from label approval, or distinctive liquor bottle approvals are denied, when such applications are approved with qualifications, or when these applications are approved and then subsequently revoked.

Subpart B—Definitions

§ 13.11 Meaning of terms.

Where used in this part and in forms prescribed under this part, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof, terms shall have the meaning ascribed in this subpart. Words in the plural form shall include the singular, and vice versa, and words importing the masculine gender shall include the feminine. The terms ''include'' and ''including'' do not exclude things not enumerated that are in the same general class.

Act. The Federal Alcohol Administration Act.

Applicant. The permittee or brewer whose name, address, and basic permit number, or plant registry number, appears on an unapproved ATF F 5100.31, application for a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval.

Assistant Director, Alcohol and Tobacco. The ATF official responsible for deciding an appeal of a revocation of a certificate of label approval, a certificate of exemption from label approval, or a distinctive liquor bottle approval, under this part.

ATF. The Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury, Washington, DC 20226.

Brewer. Any person who brews beer (except a person who produces only beer exempt from tax under 26 U.S.C. 5053(e)) and any person who produces beer for sale.

Certificate holder. The permittee or brewer whose name, address, and basic permit number, or plant registry number, appears on an approved ATF F 5100.31, certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval.

Certificate of exemption from label approval. A certificate issued on ATF F 5100.31 which authorizes the bottling of wine or distilled spirits, under the condition that the product will under no circumstances be sold, offered for sale, shipped, delivered for shipment, or otherwise introduced by the applicant, directly or indirectly, into interstate or foreign commerce.

Certificate of label approval. A certificate issued on ATF F 5100.31 that authorizes the bottling or packing of wine, distilled spirits, or malt beverages,

or the removal of bottled wine, distilled spirits, or malt beverages from customs custody for introduction into commerce, as long as the project bears labels identical to the labels affixed to the face of the certificate, or labels with changes authorized by the certificate.

Chief, Alcohol and Tobacco Programs Division. The ATF official responsible for issuing revocations of certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, under this part. This official is also responsible for deciding certain appeals of denials of applications for certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, under this part.

Chief, Product Compliance Branch. The ATF official responsible for deciding first appeals of denials of applications for certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, under this part. This official is also responsible for proposing revocation of certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, under this part.

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of the Treasury, Washington, DC.

Distilled spirits. Ethyl alcohol, hydrated oxide of ethyl, spirits of wine, whisky, rum, brandy, gin, and other distilled spirits, including all dilutions and mixtures thereof for nonindustrial use. The term ''distilled spirits'' does not include mixtures containing wine, bottled at 48 degrees of proof or less, if the mixture contains more than 50 percent wine on a proof gallon basis.

Distinctive liquor bottle. A liquor bottle of distinctive shape or design.

Distinctive liquor bottle approval. Approval issued on ATF F 5100.31 that authorizes the bottling of distilled spirits, or the removal of bottled distilled spirits from customs custody for introduction into commerce, as long as the bottle is identical to the photograph affixed to the face of the form.

Interstate or foreign commerce. Commerce between any State and any place outside that State, or commerce within any Territory or the District of Columbia, or between points within the same State but through any place outside that State.

Liquor bottle: A bottle made of glass or earthenware, or of other suitable material approved by the Food and Drug Administration, which has been designed or is intended for use as a container for distilled spirits for sale for beverage purposes, and which has been determined by the Director to protect the revenue adequately.

Malt beverage. A beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of malted barley with hops, or their parts, or their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates, or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption.

Permittee. Any person holding a basic permit under the Federal Alcohol Administration Act.

Person. Any individual, partnership, joint stock company, business trust, association, corporation, or other form of business enterprise, including a receiver, trustee, or liquidating agent and including an officer or employee of any agency of a State or political subdivision thereof.

Product Compliance Branch Specialist. An ATF official responsible for reviewing initial applications for certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, under this part, with authority to issue approvals, qualified approvals, or denials of such applications for certificates.

United States. The several States and Territories and the District of Columbia; the term ''State'' includes a Territory and the District of Columbia; and the term ''Territory'' means the Commonwealth of Puerto Rico.

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 the Act.

Wine. Wine as defined in section 610 and section 617 of the Revenue Act of 1918 (26 U.S.C. 3036, 3044, 3045) and other alcoholic beverages not so defined, but made in the manner of wine, including sparkling and carbonated wine, wine made from condensed grape must, wine made from other agricultural products than the juice of sound, ripe grapes, imitation wine, compounds sold as wine, vermouth, cider, perry, and sake; in each instance only if containing not less than 7 percent, and not more than 24 percent of alcohol by volume, and if for nonindustrial use.

Subpart C—Applications

§ 13.21 Application for certificate.

(a) *Form of application.* An applicant for a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, must send or deliver signed duplicate copies of ATF Form 5100.31, ''Application For And Certification/Exemption Of Label/Bottle Approval'' to the Product Compliance Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226. If the application complies with applicable laws and regulations, a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval will be issued. If the approval is qualified in any manner, such qualifications will be set forth in the appropriate space on the form.

(b) *Time period for action on application.* Within 90 days of receipt of an application, the Product Compliance Branch must notify the applicant whether the application has been approved or denied. The Product Compliance Branch may extend this period of time once by an additional 90 days if it finds that unusual circumstances require additional time to consider the issues presented by an application. If the Product Compliance Branch extends the period, it must notify the applicant by letter, along with a brief explanation of the issues presented by the label. If the applicant receives no decision from the Product Compliance Branch within the time periods set forth in this paragraph, the applicant may file an appeal as provided in § 13.25 of this part.

§ 13.22 Withdrawal of applications.

A person who has filed an application for a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, may withdraw such application at any time before ATF takes action on the application.

§ 13.23 Notice of denial.

Whenever an application for a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval is denied, a Product Compliance Branch Specialist must issue to the applicant a notice of denial on ATF Form 5190.1, entitled ''ATF F 5100.31 Correction Sheet,'' briefly setting forth the reasons why the label or bottle is not in compliance with the applicable laws or regulations. The applicant may then submit a new application for approval after making the necessary corrections.

§ 13.25 Appeal of qualification or denial.

(a) *Form of appeal.* If an applicant for a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval wishes to appeal the qualified approval or denial of an application, the applicant may file a written appeal with the Chief, Product Compliance Branch, within 45 days after the date of the notice of qualification or denial. The appeal should explain why the applicant believes that the label or bottle is in compliance with applicable laws and regulations. If no appeal is filed within 45 days after the date of the notice of qualification or denial, the notice will be the final decision of ATF.

(b) *Informal resolution.* Applicants may choose to pursue informal resolution of disagreements regarding correction sheets or qualifications by requesting an informal conference with the Specialist or the Chief, Product Compliance Branch. However, formal administrative appeals must comply with the provisions of paragraph (a) of this section.

§ 13.26 Decision after appeal of qualification or denial.

(a) *Decision.* After considering any written arguments or evidence presented by the applicant, the Chief, Product Compliance Branch, must issue a written decision to the applicant. If the decision is that the qualified approval or denial should stand, a copy of the application, marked ''appeal denied,'' must be returned to the applicant with an explanation of the decision and the specific laws or regulations relied upon in qualifying or denying the application. If the decision is that the certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle application should be approved without qualification, the applicant should resubmit ATF Form 5100.31 and the certificate will be issued.

(b) *Time limits for decision.* Within 90 days of receipt of an appeal, the Chief, Product Compliance Branch, must notify the appellant whether the appeal has been granted or denied. If an applicant requests an informal conference as part of an appeal, as authorized in § 13.71, the 90-day period will begin 10 days after the date of the conference to allow for consideration of any written arguments, facts or evidence submitted after the conference. The Chief, Product Compliance Branch, may extend this period of time once by an additional 90 days if he or she finds that unusual circumstances require additional time to consider the issues presented by an appeal. If the Chief, Product Compliance Branch, extends the period, he or she must notify the applicant by letter, briefly explaining the issues presented by the label. If the appellant receives no decision from the Chief, Product Compliance Branch, within the time periods set forth in this paragraph, the appellant may appeal as provided in § 13.27.

(c) *Judicial review.* Prior to applying to the Federal courts for review, an applicant must first exhaust his or her administrative remedies, including the appeal rights set forth in this section and § 13.27.

§ 13.27 Second appeal of qualification or denial.

(a) *Form of Appeal.* The decision of the Chief, Product Compliance Branch, may be appealed in writing to the Chief, Alcohol and Tobacco Programs Division. If the decision is that the qualified approval or denial was correct, a copy of the application, marked ''appeal denied,'' must be returned to the applicant, with an explanation of the decision and the specific laws or regulations relied upon in qualifying or denying the application. If the decision is that the certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle application should be approved without qualification, the applicant may resubmit ATF Form 5100.31 and the certificate will be issued.

(b) *Time limits for decision.* Within 90 days of receipt of an appeal, the Chief, Alcohol and Tobacco Programs Division, must notify the appellant whether the appeal has been granted or denied. If an applicant requests an informal conference as part of an appeal, as authorized in § 13.71, the 90-day period will begin 10 days after the date of the conference to allow for consideration of any written arguments, facts or evidence submitted after the conference. The Chief, Alcohol and Tobacco Programs Division, may extend this period of time once by an additional 90 days if he or she finds that unusual circumstances require additional time to consider the unique issues presented by an appeal. If the Chief, Alcohol and Tobacco Programs Division, extends the time period, he or she must notify the applicant by letter, briefly explaining the issues presented by the label. The decision of the Chief, Alcohol and Tobacco Programs Division, shall be the final decision of ATF.

(c) *Judicial review.* An appeal to the Chief, Alcohol and Tobacco Programs Division is required prior to application to the Federal courts for review of any denial or qualification of an application.

Subpart D—Revocations of Specific Certificates

§ 13.41 Authority to revoke certificates.

Certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals, previously approved on ATF Form 5100.31, may be revoked by the Chief, Alcohol and Tobacco Programs Division, upon a finding that the label or bottle at issue is not in compliance with the applicable laws or regulations.

§ 13.42 Notice of proposed revocation.

Except as provided in § 13.51, when the Chief, Product Compliance Branch, determines that a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval has been issued for a label or bottle that is not in compliance with the laws or regulations, he or she must issue to the certificate holder a notice of proposed revocation. The notice must set forth the basis for the proposed revocation and must provide the certificate holder with 45 days from the date of receipt of the notice to present written arguments or evidence why the revocation should not occur.

§ 13.43 Decision after notice of proposed revocation.

(a) *Decision.* After considering any written arguments or evidence presented by the certificate holder, the Chief, Alcohol and Tobacco Programs Division, must issue a decision. If the decision is to revoke the certificate, a letter must be sent to the holder explaining the revocation of the certificate, and the specific laws or regulations relied upon in determining that the label or bottle was not in conformance with law or regulations. If the decision is to withdraw the proposed revocation, a letter of explanation must be sent.

(b) *Time limits for decision.* Within 90 days of receipt of written arguments or evidence from the certificate holder, the Chief, Alcohol and Tobacco Programs Division, shall notify the appellant of his or her decision. If a certificate holder requests an informal conference as part of an appeal, as authorized in § 13.71, the 90-day period will begin 10 days after the date of the conference to allow for consideration of any written arguments, facts or evidence submitted after the conference. The Chief, Alcohol and Tobacco Programs Division, may extend this period of time once by an additional 90 days if he or she finds that unusual circumstances require additional time to consider the issues presented by a proposed revocation. If the Chief, Alcohol and Tobacco

Programs Division, extends the time period, he or she must notify the applicant by letter, along with a brief explanation of the issues under consideration.

§ 13.44 Appeal of revocation.

(a) *Filing of appeal.* A certificate holder who wishes to appeal the decision of the Chief, Alcohol and Tobacco Programs Division, to revoke a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, may file a written appeal with the Assistant Director, Alcohol and Tobacco, setting forth why the holder believes that the decision of the Chief, Alcohol and Tobacco Programs Division, was erroneous. The appeal must be filed with the Assistant Director, Alcohol and Tobacco within 45 days after the date of receipt of the decision of the Chief, Alcohol and Tobacco Programs Division.

(b) *Judicial review.* An appeal to the Assistant Director, Alcohol and Tobacco, is required prior to application to the Federal courts for review of any revocation of a certificate.

§ 13.45 Final decision after appeal.

(a) *Issuance of decision.* After considering any written arguments or evidence presented by the certificate holder or the holder's representative, the Assistant Director, Alcohol and Tobacco, must issue a final decision. If the decision is to revoke the certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, a letter must be issued explaining the basis for the revocation, and the specific laws or regulations relied upon in determining that the label or bottle was not in conformance with law or regulations. If the decision is to withdraw the proposed revocation, a letter explaining the decision must be sent.

(b) *Time limits for decision.* Within 90 days of receipt of an appeal, the Assistant Director, Alcohol and Tobacco, must notify the holder whether the appeal has been granted or denied. If a certificate holder requests an informal conference as part of an appeal, as authorized in § 13.71, the 90-day period will begin 10 days after the date of the conference to allow for consideration of any written arguments, facts or evidence submitted after the conference. The Assistant Director, Alcohol and Tobacco, may extend this period of time once by an additional 90 days if he or she finds that unusual circumstances require additional time to consider the issues presented by an appeal. If the Assistant Director, Alcohol and Tobacco, extends the period, he or she must notify the holder by letter, briefly explaining the issues presented by the label. The decision of the Assistant Director, Alcohol and Tobacco, will be the final decision of the Bureau.

Subpart E—Revocation by Operation of Law or Regulation

§ 13.51 Revocation by operation of law or regulation.

ATF will not individually notify all holders of certificates of label approval, certificates of exemption from label approval, or distinctive liquor bottle approvals, that their approvals have been revoked if the revocation occurs by operation of law or regulation. If changes in labeling or other requirements are made as a result of amendments or revisions to the law or regulations, the certificate holder must voluntarily surrender all certificates that are no longer in compliance. The holder must submit applications for new certificates in compliance with the new requirements, unless ATF determines that new applications are not necessary. If a new application is unnecessary, it is the responsibility of the certificate holder to ensure that labels are in compliance with their requirements of the new regulations or law.

§ 13.52 Notice of revocation.

If ATF determines that a certificate holder is still using a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval that is no longer in compliance due to amendments or revisions in the law or regulations, the Chief, Product Compliance Branch, will notify the certificate holder in writing that the subject certificate has been revoked by operation of law or regulations, with a brief description of the grounds for such revocation.

§ 13.53 Appeal of notice of revocation.

Within 45 days after the date of receipt of a notice of revocation by operation of law or regulations, the certificate holder may file a written appeal with the Chief, Alcohol and Tobacco Programs Division. The appeal should set forth the reasons why the certificate holder believes that the regulation or law at issue does not require the revocation of the certificate.

§ 13.54 Decision after appeal.

(a) *Issuance of decision.* After considering all written arguments and evidence submitted by the certificate holder, the Chief, Alcohol and Tobacco Programs Division, must issue a final decision regarding the revocation by operation of law or regulation of the certificate. If the decision is that the law or regulation at issue requires the revocation of the certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, a letter must be issued explaining the basis for the revocation, and citing the specific laws or regulations which required the revocation of the certificate. If the decision is that the law or regulation at issue does not require the revocation of such certificate, a letter explaining the decision must be sent to the certificate holder. The decision of the Chief, Alcohol and Tobacco Programs Division, will be the final decision of ATF.

(b) *Time limits for decision.* Within 90 days of receipt of an appeal, the Chief, Alcohol and Tobacco Programs Division, must notify the holder whether the appeal has been granted or denied. If a certificate holder requests an informal conference as part of an appeal, as authorized in § 13.71, the 90-day period will begin 10 days after the date of the conference to allow for consideration of any written arguments, facts or evidence submitted after the conference. The Chief, Alcohol and Tobacco Programs Division, may extend this period of time once by an additional 90 days if he or she finds that unusual circumstances require additional time to consider the issues presented by an appeal. If the Chief, Alcohol and Tobacco Programs Division, extends the period, he or she must notify the holder by letter, briefly explaining the issues presented by the label. The decision of the Chief, Alcohol and Tobacco Programs Division, will be the final decision of ATF.

Subpart F—Miscellaneous

§ 13.61 Publicity of information.

(a) *Pending and denied applications.* Pending and denied applications for certificates of label approval, certificates of exemption from label approval, or distinctive liquor bottle approvals are treated as proprietary information, unless the applicant or certificate holder provides written authorization to release such information.

(b) *Approved applications.* The Chief, Product Compliance Branch, shall cause to be maintained in the ATF Library for public inspection, a copy of each approved application for certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval. These documents may be viewed during business hours at

650 Massachusetts Avenue, NW, Washington, DC 20226.

(c) *Revoked certificates.* If an approved certificate is subsequently revoked, the record of the approved application will remain on file for public inspection, but the index will be annotated to show it was revoked.

(d) *Further disclosure of information on denied or revoked certificates.* If an applicant whose application is pending or has been denied, or a holder of a revoked certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, issues public statements concerning ATF action in connection with such application or certificate, then ATF may issue a statement to clarify its position or correct any misstatements of fact, including a disclosure of information contained on the application or certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval.

§ 13.62. Third-party comment on certificates.

When a third party (such as foreign government, another Federal agency, a State agency, an industry association, a competitor of a certificate holder, a consumer or consumer group, or any other interested person) wishes to comment on an approved certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, such comments should be submitted in writing to the Chief, Product Compliance Branch. The Chief, Product Compliance Branch, will review the subject of the comment. If the comment raises an issue that is outside the scope of ATF's statutory or regulatory authority, or the Chief, Product Compliance Branch, determines that the certificate is in compliance with applicable law and regulations, the commenter will be informed that no further action will be taken. If the Chief, Product Compliance Branch, determines that the commenter has raised a valid issue that ATF has authority to address, then the Chief, Product Compliance Branch, will initiate appropriate action. The Chief, Product Compliance Branch, may, in his or her discretion, notify the commenter as to the action being taken by ATF with respect to the certificate.

§ 13.71 Informal conferences.

(a) *General.* As part of a timely filed written appeal of a notice of denial, a notice of proposed revocation, or a decision of the Chief, Alcohol and Tobacco Programs Division, to revoke a certificate, an applicant or certificate holder may file a written request for an informal conference with the ATF official deciding the appeal, or that official's delegate.

(b) *Informal conference procedures.* The deciding official, or such official's delegate, and the applicant or certificate holder will agree upon a date for an informal conference. The informal conference is for purposes of discussion only, and no transcript shall be made. If the applicant or certificate holder wishes to rely upon arguments, facts, or evidence presented at the informal conference, he or she has 10 days after the date of the conference to incorporate such arguments, facts, or evidence in a written submission to the deciding official.

§ 13.72 Effective dates of revocations.

(a) *Effective dates.*—(1) *Revocation of specific certificates.* A written decision to revoke a certificate becomes effective 60 days after the date of the decision.

(2) *Revocation by operation of law or regulation.* If a certificate is revoked by operation of law or regulation, the revocation becomes effective on the effective date of the change in law or regulation with which the certificate does not comply, or if a separate label compliance date is given, on that date.

(b) *Use of certificate during period of appeal.* If a certificate holder files a timely appeal after receipt of a decision to revoke a certificate from the Chief, Alcohol and Tobacco Programs Division, pursuant to § 13.45, the holder may continue to use the certificate at issue until the effective date of a final decision issued by the Assistant Director, Alcohol and Tobacco. However, the effective date of a notice of revocation by operation of law or regulations, issued pursuant to § 13.52, is not stayed pending the appeal.

§ 13.73 Effect of revocation.

On and after the effective date of a revocation of a certificate of label approval, certificate or exemption from label approval, or distinctive liquor bottle approval, the label or distinctive liquor bottle in question may not be used to bottle or pack distilled spirits, wine or malt beverages, to remove such products from the place where they were bottled or packed, or to remove such products from customs custody for consumption.

§ 13.74 Surrender of certificates.

On the effective date of a final decision that has been issued by the Chief, Alcohol and Tobacco Programs Division, or the Assistant Director, Alcohol and Tobacco, to revoke a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval, the certificate holder must surrender the original of the certificate to ATF for manual cancellation. Regardless of whether the original certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval has been manually canceled or not, the certificate is null and void after the effective date of the revocation. It is a violation of this section for any certificate holder to present a certificate of label approval, certificate of exemption from label approval, or distinctive liquor bottle approval to an official of the United States Government as a valid certificate after the effective date of the revocation of the certificate if the certificate holder has been previously notified that such certificate has been revoked by ATF.

§ 13.75 Evidence of receipt by ATF.

If there is a time limit on ATF action that runs from ATF's receipt of a document, the date of receipt may be established by a certified mail receipt or equivalent written acknowledgment secured by a commercial delivery service or by a written acknowledgment of personal delivery. In the absence of proof of receipt, the date the document is logged in by ATF will be considered the date of receipt.

§ 13.76 Service on applicant or certificate holder.

(a) *Method of service.* ATF must serve notices of denial on an applicant by first class mail, or by personal delivery. ATF must serve notices of proposed revocation and notices of revocation on a certificate holder by certified mail, return receipt requested, by a commercial delivery service that will provide an equivalent written acknowledgment from the recipient, or by personal delivery.

(b) *Date of receipt.* If there is a time limit on a certificate holder's action that runs from the holder's receipt of a document, the date of receipt may be established by a certified mail receipt, an equivalent written acknowledgment secured by a commercial delivery service, or by a written acknowledgment of personal delivery.

(c) *Person to be served.* When service is by mail or other commercial delivery service, a copy of the document must be sent to the applicant or certificate holder at the address stated in the application or at the last known address. If authorized by the applicant or certificate holder, the copy of the document may be mailed to a designated representative. If service is by personal delivery, a copy of the document must be delivered to the

certificate holder or to a designated representative. In the case of a corporation, partnership, or association, personal delivery may be made to an officer, manager, or general agent thereof, or to the attorney of record.

§ 13.81 Representation before ATF.

An applicant or certificate holder may be represented by an attorney, certified public accountant, or other person recognized to practice before ATF as provided in 31 CFR part 8 (Practice Before the Bureau of Alcohol, Tobacco and Firearms). The applicable requirements of 26 CFR 601.521 through 601.527 (conference and practice requirements for alcohol, tobacco, and firearms activities) shall apply.

§ 13.91 Computation of time.

In computing any period of time prescribed or allowed by this part, the day of the act, event or default after which the designated period of time is to run, is not counted. The last day of the period to be computed is counted, unless it is a Saturday, Sunday, or legal holiday, in which case the period runs until the next day that is not a Saturday, Sunday, or legal holiday. Papers or documents that are required or permitted to be filed under this part must be received at the appropriate office within the filing time limits, if any.

§ 13.92 Extensions.

An applicant or certificate holder may apply to the Chief, Product Compliance Branch, the Chief, Alcohol and Tobacco Programs Division, or the Assistant Director, Alcohol and Tobacco for an extension of any time limit prescribed in this part. The time limit may be extended if ATF agrees the request is reasonable.

PART 19—DISTILLED SPIRITS PLANTS

Par. 12. The authority citation for part 19 continues to read as follows:

Authority: 19 U.S.C. 81c, 1311; 26 U.S.C. 5001, 5002, 5004–5006, 5008, 5010, 5041, 5061, 5062, 5066, 5081, 5101, 5111–5113, 5142, 5143, 5146, 5171–5173, 5175, 5176, 5178–5181, 5201–5204, 5206, 5207, 5211–5215, 5221–5223, 5231, 5232, 5235, 5236, 5241–5243, 5271, 5273, 5301, 5311–5313, 5362, 5370, 5373, 5501–5505, 5551–5555, 5559, 5561, 5562, 5601, 5612, 5682, 6001, 6065, 6109, 6302, 6311, 6676, 6806, 7011, 7510, 7805; 31 U.S.C. 9301, 9303, 9306.

Par. 13. Section 19.633 is amended to add paragraph (c) to read as follows:

§ 19.633 Distinctive liquor bottles.

* * * * *

(c) *Cross reference.* For procedures regarding issuance, denial and revocation of distinctive liquor bottle approvals, as well as appeal procedures, see part 13 of this chapter.

Par. 14. Section 19.641 is revised to read as follows:

§ 19.641 Certificate of label approval or exemption.

(a) *Requirement.* Proprietors are required by 27 CFR part 5 to obtain approval of labels, or exemption from label approval, for any label to be used on bottles of spirits for domestic use and shall exhibit evidence of label approval, or of exemption from label approval, on request of an ATF officer.

(b) *Cross reference.* For procedures regarding the issuance, denial and revocation of certificates of label approval and certificates of exemption from label approval, as well as appeal procedures, see Part 13 of this chapter.

''(Sec. 201, Pub. L. 85–859, 72 Stat. 1356, as amended (26 U.S.C. 5201))

Signed: August 6, 1998.

John W. Magaw,

Director.

Approved: December 11, 1998.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 99–624 Filed 1–12–99; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 20

RIN 2900–AJ15

Board of Veterans' Appeals: Rules of Practice—Revision of Decisions on Grounds of Clear and Unmistakable Error

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Rules of Practice of the Board of Veterans' Appeals (Board) to implement the provisions of section 1(b) of Pub. L. No. 105–111 (Nov. 21, 1997), which permit challenges to Board decisions on the grounds of ''clear and unmistakable error'' (CUE). The amendments provide specific application procedures and establish decision standards based on case law. These changes implement the new statutory provisions, which permit a claimant to demand review by the Board to determine whether CUE exists in an appellate decision previously issued by the Board, with a right of review of such determinations by the U.S. Court of Veterans Appeals.

DATES: Effective Date: February 12, 1999.

FOR FURTHER INFORMATION CONTACT: Steven L. Keller, Chief Counsel, Board of Veterans' Appeals, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 565–5978.

SUPPLEMENTARY INFORMATION: The Board of Veterans' Appeals (Board) is an administrative body that decides appeals from denials of claims for veterans' benefits. There are currently 60 Board members, who decide 35,000 to 40,000 such appeals per year.

On May 19, 1998, the Department of Veterans Affairs (VA) published a notice of proposed rulemaking (NPRM) in the **Federal Register**. 63 FR 27534. We proposed to implement the provisions of section 1(b) of Pub. L. 105–111 (Nov. 21, 1997), which permits challenges to decisions of the Board of Veterans' Appeals (Board) on the grounds of ''clear and unmistakable error'' (CUE).

The public comment period ended on July 20, 1998. VA received 5 comments: 3 from veterans service organizations; one from a consortium of organizations, including veterans service organizations; and one from an individual. These comments are discussed below.

Based on the rationale set forth in the proposed rule and in this document, we adopt the provisions of the proposed rule as a final rule with changes explained below.

Subpart G, Rule 609(c)—Attorney Fees

Two commenters questioned Rule 609(c)(4)'s approach to attorney fees. That rule provides that the term ''issue,'' for purposes of charging a fee, would have the same meaning as ''issue'' in the context of a motion under subpart O. In other words, provided that the Board decision being challenged is associated with a notice of disagreement dated on or after November 18, 1988, and that the attorney was retained within one year of that decision, the attorney can be paid for services rendered in connection with a motion under subpart O.

The rule as proposed makes paid legal representation available to the maximum extent possible under existing law. For example, if we defined ''issue'' as meaning a challenge based on CUE, an attorney would never be able to charge for services in connection with a CUE motion because the Board would not have issued a final decision on the ''issue'' until after the CUE process was complete.

Two commenters suggested that we ignore the requirement that, in order for an attorney or agent to charge a fee, a