

approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agency believes only a small number of firms will be affected by this rule when finalized, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Request for Comments

Interested persons may, on or before April 13, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 892 be amended as follows:

PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 892.1990 is added to subpart B to read as follows:

§ 892.1990 Transilluminator for breast evaluation.

(a) *Identification.* A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700–1050

nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases or abnormalities.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval (PMA) or notice of completion of a product development protocol (PDP) is required.* The effective date of the requirement for premarket approval has not been established. See § 892.3.

Dated: December 23, 1994.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-971 Filed 1-12-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 5, and 7

[Notice No. 804; Re Notice No. 803]

RIN: AB32

Alteration of Labels on Containers of Distilled Spirits, Wine, and Beer (CRD-94-8)

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

ACTION: Corrected Notice of Proposed Rulemaking.

SUMMARY: On January 4, 1995, the Bureau of Alcohol, Tobacco and Firearms (ATF) published a notice of proposed rulemaking (Notice No. 803, 60 FR 411) in the **Federal Register**. Because the notice contained errors which could cause confusion to the public, ATF is reprinting the entire corrected text here, in this correction notice, as it should have appeared in Notice No. 803. The original text of Notice No. 803 should be disregarded; instead, all interested parties should refer to the reprinted text in this document. ATF is extending the comment period accordingly to allow 60 days from the date of this correction notice.

ATF is proposing to amend the regulations in 27 CFR Parts 4, 5, and 7 which implement section 105(e) of the Federal Alcohol Administration Act of 1935, which makes it unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand or label on wine, distilled spirits, or malt beverages held for sale in interstate or foreign commerce or after shipment therein. The proposed amendments will

eliminate a requirement that persons obtain ATF approval before relabeling wine and malt beverage products. Instead, persons who intend to relabel wine, malt beverage, or distilled spirits products would be required to notify ATF, in writing, of their intent to relabel. The proposed amendments will make it unlawful to relabel a distilled spirits, wine, or malt beverage container if the effect of such action is to remove from the container or label any information required by ATF regulations, or a product identification code placed on the product by the producer for tracing purposes.

DATES: Written comments must be received on or before March 14, 1995.

ADDRESSES: Send written comments to: Chief, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, DC 20091-0221. [Attn: Notice No. 804.]

FOR FURTHER INFORMATION CONTACT: Daniel J. Hiland, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202-927-8210)

SUPPLEMENTARY INFORMATION:

Background

Several producers and importers of alcoholic beverages have complained to the Bureau of Alcohol, Tobacco and Firearms (ATF) that product identification code markings placed on containers and labels of wines and distilled spirits by producers for tracing purposes are being removed or mutilated after the product has left the producer's premises. Such alterations of labels or packages have been permitted in foreign trade zones and Customs bonded warehouses, because ATF regulations do not specifically address such activities, and because product identification codes are not mandatory information under ATF regulations. However, the effect of such action is to make it impossible for the producers to rely on production codes to trace mislabeled, adulterated, or unsafe products.

Federal Alcohol Administration Act

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. § 205(e), authorizes ATF to prescribe regulations relating to the packaging, marking, branding, labeling, and size and fill of containers as will prohibit deception of the consumer with respect to such products or the quantity thereof.

In order to prevent the sale or shipment or other introduction of

distilled spirits, wine, or malt beverages in interstate or foreign commerce which are not bottled, packaged, or labeled in compliance with the regulations, the FAA Act requires that prior to bottling distilled spirits, wines, or malt beverages, the producer or bottler must obtain a certificate of label approval covering the product. Similarly, the law provides that no person shall remove bottled distilled spirits, wines, or malt beverages from Customs custody for consumption in bottles, for sale or any other commercial purpose, without having first obtained a certificate of label approval covering the product.

Thus, the certificate of label approval requirement ensures that mislabeled distilled spirits, wines, or malt beverages cannot be introduced in interstate or foreign commerce. To ensure that products with proper labels were not altered once such products had been removed from bond, section 205(e) further provides as follows:

It shall be unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand, or label upon distilled spirits, wine, or malt beverages held for sale in interstate or foreign commerce or after shipment therein, except as authorized by Federal law or except pursuant to regulations of the Secretary of the Treasury authorizing relabeling for purposes of compliance with the requirements of this subsection or of State law.

Regulations which implement these provisions of the FAA Act, as they relate to wine, distilled spirits, and malt beverages, are set forth in title 27, Code of Federal Regulations (CFR), parts 4, 5, and 7, respectively. These regulations provide for relabeling in certain circumstances.

Sections 4.30 and 7.20 provide that someone wanting to relabel must receive prior permission from the Regional Director (Compliance). Section 5.31 does not currently require prior approval for the relabeling of distilled spirits, as long as such relabeling is done in accordance with an approved certificate of label approval.

The regulations provide that distilled spirits, wines and malt beverages may be relabeled as authorized by Federal law. Such products may also be relabeled for purposes of compliance with the requirements of the regulations, or of State law. Finally, there may be added to wine and distilled spirits bottles, after removal from Customs custody, or prior to or after removal from bonded premises, without application for permission to relabel, a label identifying the wholesale or retail distributor thereof, and containing no reference whatever to the characteristics of the product.

Customs Bonded Warehouses and Foreign Trade Zones

The statutory prohibition against the alteration or mutilation of distilled spirits, wine, or malt beverage labels applies to all products held for sale in interstate or foreign commerce. The terms of the statute thus apply to nontaxpaid domestic and imported products held for storage or manipulation in a Customs bonded warehouse or foreign trade zone.

However, since domestic nontaxpaid alcoholic beverages bottled for exportation are exempt from the certificate of label approval requirement, and certificates of label approval are not required for imported alcoholic beverages until they are withdrawn from Customs custody for consumption in the United States, ATF has previously taken the position that relabeling activities could occur in a Customs bonded warehouse or foreign trade zone without prior ATF approval. ATF regulations authorize the relabeling of alcoholic beverages in Customs custody in order to bring such products in compliance with a certificate of label approval prior to withdrawal for consumption. However, current regulations do not specifically set forth the limitations on other types of relabeling activities in Customs bonded warehouses or foreign trade zones. In general, ATF saw no need to scrutinize labeling activities involving such products unless and until they were withdrawn from Customs custody for consumption in the United States.

While ATF has not required that persons relabeling alcoholic beverages in Customs bonded warehouses or foreign trade zones obtain prior approval, such activities are subject to regulation by the United States Customs Service ("Customs"). Because the current regulations do not clarify the scope of the prohibition against alteration of labels, there has been considerable confusion as to what types of labeling activities are authorized in a Customs bonded warehouse or foreign trade zone.

ATF has taken the position that there are restrictions as to the removal of mandatory information from domestic nontaxpaid distilled spirits, wines, and malt beverages. Pursuant to parts 19, 24, and 25, such products must be marked with certain mandatory information, which is necessary to protect the revenue, and to ensure the tracing of the product in the event of diversion. Thus, it has been ATF's policy that such mandatory information may not be removed from products, regardless of the fact that they are in a Customs

bonded warehouse or foreign trade zone awaiting exportation. However, this policy is not set forth in the current regulations.

ATF is thus proposing to amend the regulations in parts 4, 5, and 7 to clarify that the prohibition against alteration or mutilation of labels applies to products held in a foreign trade zone or customs bonded warehouse. The proposed amendments will specify the type of relabeling activities permissible for both domestic nontaxpaid alcoholic beverages and imported alcoholic beverages stored in a Customs bonded warehouse or foreign trade zone. Since current regulations do not authorize removal of domestic nontaxpaid malt beverages to Customs bonded warehouses pending exportation, the relabeling of malt beverages in Customs bonded warehouses is not discussed.

The proposed regulations will provide that relabeling of distilled spirits, wines, and malt beverages in Customs bonded warehouses or foreign trade zones can be accomplished without giving notice to ATF, as long as such relabeling is done under the supervision of Customs officials, in compliance with Customs requirements, and does not involve the removal from the label or package of information made mandatory by ATF regulations. The proposed language concerning the supervision of Customs officials and compliance with Customs requirements is not intended to impose any new requirements; instead, this language merely recognizes current requirements under Customs regulations. See 19 C.F.R. 19.11 and 146.51.

Product Identification Codes

The complaints about the mutilation of product identification codes in Customs bonded warehouses and foreign trade zones brought to the surface an issue which ATF had previously been considering—whether lot identification numbers or product identification codes should be made mandatory information on consumer packages of alcoholic beverages. Such codes are not currently required under the regulations. Instead, labels on domestic distilled spirits, wines, and malt beverages are merely required to list the name and address of the bottler. For imported products, the name and address of the importer is required information on the label.

Obviously, these requirements provide enough information so that if a product is mislabeled, adulterated, or poses a health hazard, it is possible to determine the source of the product. However, this does not allow either ATF or the producer to trace a particular

consumer package back to a bottling line or production shift.

Current regulations in parts 19, 24 and 25 promulgated pursuant to the Internal Revenue Code require certain markings on cases of distilled spirits, wines, and malt beverages. Cases of distilled spirits and wines must be marked with serial numbers. These markings are required in order to protect the revenue, and to facilitate tracing in the event of the diversion of nontaxpaid goods. However, case markings have limited value in tracing consumer packages such as bottles and cans. Once the product is removed from the case, those markings are obviously of no value in tracing the product.

The purpose of product identification codes (i.e., lot identification numbers, bottling dates, freshness dates, etc.) on labels or packages of products is to facilitate the tracing of a product for safety, compliance or quality control issues. For example, if an alcoholic beverage product is found to have been tampered with, or contaminated, any type of code which would enable the tracing of the product back to the bottling line or production batch would be extremely valuable in determining how the tampering or contamination occurred, and in allowing the producer to make an informed decision as to the extent of the problem, and the need for product recalls.

For this reason, ATF believes that product identification codes are useful as a consumer protection measure. Safety, labeling and quality control problems often come to light by virtue of consumer complaints or market place testing of products by ATF. In such instances, case markings will generally be of no avail. However, the use of product identification codes can help to readily identify the hazardous or defective product, and, in the event that a health hazard exists, assist in a speedier and more orderly recall of these products from the marketplace.

The use of lot identification numbers has already been mandated by the Council of the European Communities, in Council Directive 89/396/EEC, dated June 14, 1989. In view of the fact that many European countries now require such markings, and many large producers in the United States voluntarily place such codes on product labels or containers, ATF raised the issue of mandatory product identification codes at an industry meeting held in Washington, D.C. on July 26, 1994.

The purpose of raising this issue with industry members was to gather information on current industry practices regarding product

identification codes. ATF has learned that many domestic and foreign producers of alcoholic beverages voluntarily place product identification codes or lot identification numbers on the labels or containers of wines, distilled spirits, and malt beverages. Typically, the label or container of the product will be marked with a code indicating the batch from which the product was made, a bottling date, a production shift code, or some other type of mark which will enable the producer to trace the consumer package to a specific production batch or bottling line.

While large producers are more likely to have their own system of product codes, small producers often find that such a system is unnecessary, because their own records will enable them to do any necessary tracing. At the industry meeting, questions were raised as to whether it was necessary to impose a product identification code requirement on small producers.

Rather than impose a mandatory product identification code requirement on all producers, ATF is proposing to leave the decision as to whether to place product identification codes on consumer packages to the producer. At this time, we believe that the consumer is adequately protected by the information required under the current regulations.

However, in order to allow producers to efficiently develop a system in which they can ensure the tracing of their own products, we believe that the voluntary placement of product identification codes on consumer packages by producers should be protected by regulation. This will address the specific problem currently faced by producers—the removal of product identification codes by distributors or other third parties.

If a producer believes that the only way it can efficiently trace products is to put product identification codes on the consumer packages, ATF does not believe it should allow the intent of the producer to be frustrated by third parties. It is the producer who will have to bear the costs of recalls if product identification codes have been obliterated by distributors. It is the consumer who will suffer if the obliteration of such marks makes it impossible to trace problems with contaminated products. Finally, such actions make it more difficult for ATF to trace problems with products already in the market place.

Thus, ATF is proposing an amendment to the regulations which will specifically prohibit the labeling or relabeling of products if the effect of

such action is to remove from labels or containers "product identification codes" placed on the label or container by the producer for tracing purposes. The term "product identification code" is defined to include any numbers, letters, symbols, dates, or other codes placed on the label or container by which the producer may be able to trace a product back to a particular production lot or batch, bottling line, or date of removal.

Under the proposed regulations, if it is necessary for anyone but the producer to remove the original label from the product, the product identification code must be put back on the new label. ATF believes that this proposal will adequately address the problem before us, without imposing an undue burden on any part of the industry. Most importantly, it will ensure that an important consumer protection mechanism voluntarily placed on consumer packages by manufacturers will not be thwarted.

Although ATF is not proposing to require product identification codes on labels or packages, it is the opinion of the Bureau that such codes are useful, and should be encouraged. If at any time we find that the lack of such codes is hampering the exercise of our consumer protection function, we may wish to reconsider this option.

Products Bottled for Exportation

Although products which are bottled for exportation are not required to be covered by certificates of label approval, ATF believes that the prohibition on alteration of labels applies to such products. The alteration or mutilation of required information on labels, as well as product identification codes, would hamper ATF's efforts in tracing the illegal diversion of nontaxpaid alcoholic beverages which were intended for exportation. One of the purposes of the FAA Act was to aid in the collection of taxes on distilled spirits, wines, and malt beverages. Thus, we have authority under the FAA Act to extend these provisions to products which are intended to be exported.

Elimination of Prior Approval Requirement

The proposed amendments to parts 4, 5, and 7 relating to the relabeling of wine, distilled spirits, and malt beverages would also resolve an inconsistency in the present regulations. Currently, persons who wish to relabel wine and malt beverages are required to make written application and receive approval from ATF prior to relabeling these products. However, persons who wish to relabel distilled spirits are not

required to receive prior approval from ATF, as long as the distilled spirits products are relabeled in accordance with an approved label.

The proposed amendments would eliminate the requirement to receive approval from the regional director prior to relabeling wine and malt beverages. Instead, any persons who wished to relabel wine, malt beverages, or distilled spirits would be required to notify the Director, in writing, of their intent to relabel. This letterhead notice must be accompanied by duplicate copies of the old and new labels, together with a written statement of the reasons for relabeling, the quantity and location of the product to be relabeled, and the name and address of the person conducting the relabeling activities.

ATF believes that the proposed amendment will eliminate the inconsistencies in the current regulations, while still enabling the tracing of products in the event of a safety hazard or a compliance issue. Since the requirement for prior approval is being eliminated, the proposed amendments will provide that the notice should be sent to the Director, rather than the regional director. This proposal will increase efficiency in the Bureau's tracing of labels, since copies of certificates of label approval are maintained at Bureau headquarters.

As previously noted, the proposed regulations will provide that ATF does not need to be notified of the relabeling of alcoholic beverage products in Customs bonded warehouses or foreign trade zones, as long as all other requirements are met.

Miscellaneous

ATF is also proposing to add to section 7.20 a provision which is already found in slightly different forms in sections 4.30 and 5.31. This provision authorizes, without any notice requirement, the addition of a label identifying the wholesale or retail distributor, or identifying the purchaser or consumer, as long as the label contains no reference whatever to the characteristics of the product. The proposed regulations will standardize this provision for wines, distilled spirits, and malt beverages.

Furthermore, the notice procedure in all three sections is also standardized for the sake of consistency. Although the current regulations in sections 4.30 and 7.20 do not specifically condition approval for relabeling on the existence of a certificate of label approval for the new labels, such a policy has always been enforced by ATF. The proposed regulations will require submission of

evidence of label approval for label changes.

Executive Order 12866

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

Regulatory Flexibility Act

It is hereby certified that this regulation will not have a significant impact on a substantial number of small entities. This notice requests comments on a proposal to make it unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand or label on wine, distilled spirits, or malt beverages held for sale in interstate or foreign commerce or after shipment therein, including products held in a foreign trade zone or Customs bonded warehouse, if the effect of such action is to remove mandatory information required by ATF regulations, or to remove a product identification code placed on the label or container by the producer for tracing purposes. The proposal would also impose a notice requirement on the relabeling of distilled spirits, wine, and malt beverages, while eliminating the prior approval requirement previously imposed by the wine and malt beverage regulations. This proposal does not mandate new labeling requirements, but merely protects and preserves mandatory information already required under the regulations, and product identification codes which a producer voluntarily chooses to put on the product. Thus, the proposal should not have a significant economic impact on a substantial number of small entities.

Accordingly, a regulatory flexibility analysis is not required because the proposal, if promulgated as a final rule, is not expected: (1) To have significant secondary or incidental effects on a substantial number of small entities, 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.

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. 3504(h).

Comments on the collection of information should be directed to the

Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Bureau of Alcohol, Tobacco and Firearms, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to: Reports Management Officer, Information Programs Branch, Room 3450, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226.

The collections of information in this regulation are in 27 CFR 4.30, 5.31, and 7.20. These sections require that persons who wish to alter approved labels must notify ATF. This information is required by the Bureau of Alcohol, Tobacco and Firearms to ensure that alterations of labels are done in compliance with the regulations. The likely respondents are businesses or other for-profit institutions, including small businesses or organizations. This information collection requirement is included in OMB Control Number 1512-0092, which covers the relabeling of distilled spirits, wines, and beer. The estimated total number of label approvals issued annually under Control Number 1512-0092 is 54,601. Based on an estimated average time of 30 minutes to complete the application for label approval, the total annual burden associated with Control Number 1512-0092 is 27,300 hours. We estimate that ATF will receive about 180 notices of intent to relabel distilled spirits, wines, and malt beverages every year.

The amendments proposed in this document will not change the estimated number of 54,601 responses, because any person wanting to relabel an alcoholic beverage product is already required to obtain a certificate of label approval. The requirement for filing a notice with the Director will not change the estimated average time of 30 minutes to complete the application for a certificate of label approval, because only about 180 of the 54,601 responses will involve relabeling. The additional time required for those 180 responses is not significant enough to affect the estimated average time of 30 minutes to complete the application for label approval. Thus, the total burden estimate associated with Control Number 1512-0092 is not affected by the amendments proposed in this document.

Public Participation

ATF requests comments from all interested persons concerning the amendments proposed by this notice. Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same

consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date. ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting the comment is not exempt from disclosure.

Any interested person who desires an opportunity to comment orally at a public hearing on the proposed amendments to the regulations should submit his or her request, in writing, to the Director within the 60-day comment period. The Director, however, reserves the right to determine, in light of all circumstances, if a public hearing is necessary.

Disclosure

Copies of this notice and the written comments will be available for public inspection during normal business hours at: ATF Public Reading Room, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC 20226

Drafting Information

The principal author of this document is Daniel J. Hiland, Alcohol and Tobacco Programs Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 4

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

27 CFR Part 5

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

27 CFR Part 7

Advertising, Consumer Protection, Customs duties and inspection, Imports, Labeling.

Issuance

Title 27, Chapter I, is proposed to be amended as follows:

PART 4—LABELING AND ADVERTISING OF WINE

Paragraph 1. The authority citation for 27 CFR Part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. Section 4.30(b) is revised, and new paragraphs (c) and (d) are added to read as follows:

§ 4.30 General.

* * * * *

(b) *Alteration of labels.* (1) It shall be unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand, or label upon wine held for sale in interstate or foreign commerce or after shipment therein, including wine held in Customs bonded warehouses or foreign trade zones, except as authorized by Federal law, or as provided for in this section.

(2) *Relabeling.* (i) Persons may engage in additional labeling or relabeling of wine in containers for purposes of compliance with the requirements of this subpart or of State law only if the new labels are covered by certificates of label approval, and the relabeling will not result in the removal from the container or label of a product identification code placed on the container or label by the producer for tracing purposes. For purposes of this section, the term "product identification code" includes any numbers, letters, symbols, dates, or other codes placed on the label or container by which the producer may be able to trace a product back to a particular production lot or batch, bottling line, or date of removal.

(ii) Persons who wish to relabel in accordance with paragraph (b)(2)(i) of this section must give prior written notice to the Director of their intent to relabel. A notice of intent to relabel wine shall be accompanied by two complete sets of the old labels and two complete sets of any proposed new labels, together with a statement of the reasons for relabeling, the quantity and the location of the wine, and the name and address of the person conducting the relabeling activity. In addition, persons desiring to relabel wine must provide evidence that they have applied for and received a certificate of label approval, ATF F 5100.31, covering such products.

(3) *Labels identifying wholesale or retail distributor.* There may be added to the container, after removal from customs custody, or prior to or after removal from the premises where bottled or packed, without notice to ATF, a label identifying the wholesale or retail distributor thereof or identifying the purchaser or consumer, and containing no references whatever to the characteristics of the products.

(c) *Customs bonded warehouses.* (1) Domestic wines which have been removed without payment of tax for transfer to a Customs bonded warehouse pending exportation may be relabeled without notice to ATF, as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements,

and the effect of the relabeling is not to remove from the container or label any markings which are required under part 24 of this chapter, or any product identification code placed on the container or label by the producer for tracing purposes.

(2) Imported wines held in a Customs bonded warehouse may be relabeled without notice to ATF, as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements, and the effect of the relabeling is not to remove from the container or label any product identification code placed on the container or label by the producer for tracing purposes. As provided in § 4.40, imported beverage wine in containers shall not be released from Customs custody for consumption without a certificate of label approval.

(d) *Foreign trade zones.* (1) Domestic wines which have been withdrawn without payment of tax for deposit in a foreign trade zone pending exportation may be relabeled without notice to ATF as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements, and the effect of the relabeling is not to remove from the container or label any markings required by Part 24 of this chapter, or any product identification code placed on the container or label by the producer for tracing purposes.

(2) Imported wines which have been entered into a foreign trade zone may be relabeled without notice to ATF, as long as such relabeling is done under Customs supervision and in compliance with Customs requirements, and the effect of such relabeling is not to remove from the label or container any product identification code placed on the label or container by the producer for tracing purposes. As provided in § 4.40, imported beverage wine in containers shall not be released from Customs custody for consumption without a certificate of label approval.

Par. 3. Section 4.80 is revised to read as follows:

§ 4.80 Exports.

With the exception of the regulations at § 4.30(b), (c), and (d), the regulations in this part shall not apply to wine exported in bond.

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

Par. 4. The authority citation for 27 CFR part 5 continues to read as follows:

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

Par. 5. Section 5.1 is revised to read as follows:

§ 5.1 General.

The regulations in this part relate to the labeling and advertising of distilled spirits. This part applies to the several States of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. With the exception of the regulations at § 5.31(b), (c), and (d), the regulations in this part do not apply to distilled spirits for export.

Par. 6. Section 5.31 (b) is revised, and new paragraphs (c) and (d) are added to read as follows:

§ 5.31 General.

* * * * *

(b) *Alteration of labels.* (1) It shall be unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand, or label upon distilled spirits held for sale in interstate or foreign commerce or after shipment therein, including distilled spirits held in Customs bonded warehouses or foreign trade zones, except as authorized by Federal law, or as provided in this section.

(2) *Relabeling.* (i) Persons may engage in additional labeling or relabeling of distilled spirits in containers for purposes of compliance with the requirements of this subpart or of State law only if the new labels are covered by certificates of label approval, and the relabeling will not result in the removal from the container or label of a product identification code placed on the container or label by the producer for tracing purposes. For purposes of this section, the term "product identification code" includes any numbers, letters, symbols, dates, or other codes placed on the label or container by which the producer may be able to trace a product back to a particular production lot or batch, bottling line, or date of removal.

(ii) Persons who wish to relabel in accordance with paragraph (b)(2)(i) of this section must give prior written notice to the Director of their intent to relabel. A notice of intent to relabel distilled spirits shall be accompanied by two complete sets of the old labels and two complete sets of any proposed new labels, together with a statement of the reasons for relabeling, the quantity and the location of the distilled spirits, and the name and address of the person conducting the relabeling activity. In addition, persons desiring to relabel distilled spirits must provide evidence that they have applied for and received a certificate of label approval, ATF F 5100.31, covering such products.

(3) *Labels identifying wholesale or retail distributor.* There may be added to

the bottle, after removal from customs custody, or prior to or after removal from bonded premises, without notice to ATF, a label identifying the wholesale or retail distributor thereof or identifying the purchaser or consumer, and containing no references whatever to the characteristics of the product.

(c) *Customs bonded warehouses.* (1) Domestic distilled spirits which have been removed without payment of tax for transfer to a Customs bonded warehouse pending exportation may be relabeled without notice to ATF, as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements, and the effect of the relabeling is not to remove from the container or label any markings which are required under part 19 of this chapter, or any product identification code placed on the container or label by the producer for tracing purposes.

(2) Imported distilled spirits held in a Customs bonded warehouse may be relabeled without notice to ATF, as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements, and the effect of the relabeling is not to remove from the container or label any product identification code placed on the container or label by the producer for tracing purposes. As provided in § 5.51, bottled distilled spirits shall not be released from Customs custody for consumption without a certificate of label approval.

(d) *Foreign trade zones.* (1) Domestic distilled spirits which have been withdrawn without payment of tax for deposit in a foreign trade zone pending exportation may be relabeled without notice to ATF as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements, and the effect of the relabeling is not to remove from the container or label any markings required by part 19 of this chapter, or any product identification code placed on the container or label by the producer for tracing purposes.

(2) Imported distilled spirits which have been entered into a foreign trade zone may be relabeled without notice to ATF, as long as such relabeling is done under Customs supervision and in compliance with Customs requirements, and the effect of such relabeling is not to remove from the label or container any product identification code placed on the label or container by the producer for tracing purposes. As provided in § 5.51, bottled distilled spirits shall not be released from

Customs custody for consumption without a certificate of label approval.

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

Par. 7. The authority citation for 27 CFR Part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 8. Section 7.20 is amended by revising paragraph (c), and adding new paragraphs (d) and (e) to read as follows:

§ 7.20 General.

* * * * *

(c) *Alteration of labels.* (1) It shall be unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand, or label upon malt beverages held for sale in interstate or foreign commerce or after shipment therein, including malt beverages held in Customs bonded warehouses or foreign trade zones, except as authorized by Federal law, or as provided in this section.

(2) *Relabeling.* (i) Malt beverages in containers may be relabeled for purposes of compliance with the requirements of this subpart or of State law only if the new labels are covered by certificates of label approval, and the relabeling will not result in the removal from the container or label of a product identification code placed on the container or label by the producer for tracing purposes. For purposes of this section, the term "product identification code" includes any numbers, letters, symbols, dates, or other codes placed on the label or container by which the producer may be able to trace a product back to a particular production lot or batch, bottling line, or date of removal.

(ii) Persons who wish to relabel in accordance with paragraph (c)(2)(i) of this section must give prior written notice to the Director of their intent to relabel. A notice of intent to relabel malt beverages shall be accompanied by two complete sets of the old labels and two complete sets of any proposed new labels, together with a statement of the reasons for relabeling, the quantity and the location of the malt beverages, and the name and address of the person conducting the relabeling activity. In addition, persons desiring to relabel malt beverages must provide evidence that they have applied for and received a certificate of label approval, ATF F 5100.31, covering such products.

(3) *Labels identifying wholesale or retail distributor.* There may be added to the bottle, after removal from customs custody, or prior to or after removal from bonded premises, without notice to ATF, a label identifying the wholesale or retail distributor thereof or

identifying the purchaser or consumer, and containing no references whatever to the characteristics of the product.

(d) *Customs bonded warehouses.* Imported malt beverages held in a Customs bonded warehouse may be relabeled without notice to ATF, as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements, and the effect of the relabeling is not to remove from the container or label any product identification code placed on the container or label by the producer for tracing purposes. As provided in § 7.31, no imported malt beverages in containers shall be released from Customs custody for consumption without a certificate of label approval.

(e) *Foreign trade zones.* (1) Domestic malt beverages which have been withdrawn without payment of tax for deposit in a foreign trade zone pending exportation may be relabeled without notice to ATF as long as such relabeling is done under the supervision of Customs officers, in compliance with all applicable Customs requirements, and the effect of the relabeling is not to remove from the container or label any markings required by Part 25 of this chapter or any product identification code placed on the container or label by the producer for tracing purposes.

(2) Imported malt beverages which have been entered into a foreign trade zone may be relabeled without notice to ATF, as long as such relabeling is done under Customs supervision and in compliance with Customs requirements, and the effect of such relabeling is not to remove from the label or container any product identification code placed on the label or container by the producer for tracing purposes. As provided in § 7.31, no imported malt beverages in containers shall be released from Customs custody for consumption without a certificate of label approval.

Par. 9. Section 7.60 is revised to read as follows:

§ 7.60 Exports.

With the exception of the regulations at § 7.20(c), (d) and (e), the regulations in this part shall not apply to malt beverages exported in bond.

Signed: January 10, 1995.

Daniel R. Black,

Acting Director.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 254

RIN 1010-AB81

Response Plans for Facilities Seaward of the Coast Line

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule to implement the Oil Pollution Act of 1990 (OPA) would establish requirements for spill-response plans for oil handling facilities seaward of the coast line, including associated pipelines. The proposed rule provides guidance to owners and operators for preparing and submitting these spill-response plans.

DATES: Comments must be received or postmarked by March 14, 1995.

ADDRESSES: All comments concerning this proposed rule should be mailed or hand-carried to the Minerals Management Service, Mail Stop 4700; 381 Elden Street; Herndon, Virginia 22070-4817, Attention: Chief, Engineering and Standards Branch.

FOR FURTHER INFORMATION CONTACT: John V. Mirabella or Lawrence Ake, Engineering and Standards Branch, telephone (703) 787-1600.

SUPPLEMENTARY INFORMATION: In August 1990, Congress passed the OPA containing various provisions to strengthen oil-spill prevention efforts and oil-spill response capability. The OPA included amendments to section 311 of the Federal Water Pollution Control Act (FWPCA). The President signed Executive Order (E.O.) 12777 on October 18, 1991 (56 FR 54757), to implement these new authorities. Section 2(b)(3) of E.O. 12777 delegated to the Secretary of the Interior (Secretary) those responsibilities under section 311(j)(1)(C) of the FWPCA, requiring the Secretary to establish procedures, methods, and requirements for equipment to prevent and contain discharges of oil and hazardous substances from offshore facilities, including associated pipelines. Under section 2(d)(3) of E.O. 12777, section 311(j)(5) of FWPCA, and section 4202(b)(4) of OPA, the Secretary is required to issue regulations requiring the owners or operators of offshore facilities, including associated pipelines, to prepare and submit response plans that ensure the availability of private spill-response personnel and equipment and to permit the operation of offshore facilities,

including associated pipelines, without approved response plans if certain conditions are met. Under section 2(e)(3) of E.O. 12777 and section 311(j)(6)(A) of FWPCA, the Secretary must require periodic inspections of containment booms and equipment used to remove discharges at offshore facilities, including associated pipelines. The Secretary has redelegated these responsibilities to the Director, MMS.

Under OPA and E.O. 12777, MMS is to administer these new requirements for all "offshore" facilities in, on, or under coastal waters of the territorial sea, rivers, lakes, and other navigable waters within the States and Territories of the United States or otherwise subject to U.S. jurisdiction including State submerged lands. The MMS negotiated a redelegation of its responsibilities for "offshore" facilities located landward of the coast line to other Federal agencies with existing inland regulatory capabilities and responsibilities. This redelegation was published in the **Federal Register** on February 28, 1994 (59 FR 9494). Accordingly, this proposed rule addresses only facilities seaward of the coast line.

The MMS believes that adequate spill-prevention regulations meeting the requirements of OPA currently exist for facilities in the Outer Continental Shelf (OCS) at 30 CFR part 250. In addition, all States with facilities seaward of the coast line have existing programs to prevent spills. For these reasons, MMS does not propose regulations to implement the spill-prevention requirements of section 311(j)(1)(c) of the FWPCA at this time. The proposed rule requires that plan submitters provide information on the prevention methods they must utilize during operations in State waters.

The MMS will work with States on compatible spill-prevention rules for facilities in State waters seaward of the coast line. The MMS has executed a Memorandum of Understanding (MOU) with the State of Texas General Land Office and is discussing MOU's with the States of Alaska, California, and Louisiana. Further coordination is planned with States to ensure that regulations are compatible. Commenters are urged to provide comments on the types of prevention rules that should be required.

During the preparation of this notice of proposed rulemaking, MMS participated with three other Federal agencies in the drafting of the National Preparedness for Response Exercise Program (PREP). The agencies (U.S. Coast Guard, Environmental Protection Agency, Research and Special Projects