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