



DEPARTMENT OF THE TREASURY
BUREAU OF ALCOHOL, TOBACCO AND FIREARMS

Washington, DC 20226

Rec'd 9/12/02
16
801000:CEC

August 30, 2002

Ms. Linda A. Skladany
Senior Associate Commissioner for External Relations
Food and Drug Administration
5600 Fishers Lane (HF-10)
Rockville, MD 20857

RE: Public Law 107-88, Docket Nos. 02N-0276,
02N-0277, and 02N-0278

Dear Ms. Skladany,

This letter responds to your request for comments regarding Title III, Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-88, (the Act of 2002). The Act is directed at protecting the safety and security of the nation's food and drug supply and requires in relevant part that the Food and Drug Administration (FDA) impose certain registration, recordkeeping, and notice requirements to effect its purpose. The Bureau of Alcohol, Tobacco and Firearms (ATF) regulates the alcohol beverage industry and imposes many of the same requirements upon the industry that are required under the Act of 2002. This letter identifies these requirements and encourages collaboration between our respective agencies to avoid duplication of efforts and undue burden upon the alcohol industry.

Background

As background, section 305 of the Act of 2002 (Docket No. 02N-0276) requires the registration of domestic and foreign food facilities. The registration must contain information necessary to notify the Secretary of Health and Human Services (HHS) of the name and address of each facility, trade names under which the

02N-0276

WWW.ATF.TREAS.GOV

C23

EXHIBIT No.2

address of each facility, trade names under which the facility conducts business and, when the Secretary of HHS deems necessary, the general food category.

Section 306 of the Act of 2002 (Docket No. 02N-0277) requires the promulgation of regulations to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food, which records would be kept for no more than two years. This section would authorize the Secretary of HHS to have access to these records when there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Finally, section 307 of the Act of 2002 (Docket No. 02N-0278) requires that the owner, importer, or consignee provide prior notice of imported food shipments. The notice must identify the article, the manufacturer and shipper, the grower (if known within the time within which notice is required under regulations), the country of origin, the country from which the article is shipped, and the anticipated port of entry. Providing this notice is a condition of the article's admission into the United States.

ATF-Enforced Statutory Requirements

Registration of the Industry Member

The Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 203, and implementing regulations in title 27 C.F.R., imposes many of the same requirements as those imposed under the Act of 2002. Specifically, like the registration requirements in the Act of 2002, the FAA Act and implementing regulations provide that it shall be unlawful, except pursuant to a basic permit issued by the Secretary of the Treasury, to engage in the business of importing, wholesaling, producing, blending, or rectifying alcohol beverages. The FAA Act and implementing regulations identify the limited class of persons entitled to a basic permit and condition the permit upon compliance with all Federal laws relating to alcohol. 27 U.S.C. 204. This requirement is intended to protect the integrity of

the industry by ensuring that only those persons who are likely to comply with the law enter the industry.

The basic permit approval process entails a multi-layered investigation of the permit applicant, involving verification of citizenship or business visas issued by the Immigration and Naturalization Service, review of the applicant's business structure to discover any hidden ownership, and investigation of investors and owners through multiple criminal databases to discover criminal histories and/or affiliations.

In addition to ensuring the integrity of the regulated industry, the permit requirement, along with labeling requirements identifying the bottler or importer, and other required records under the Internal Revenue Code of 1986 (IRC)¹ (discussed below), facilitates the tracing of product to the responsible party (permittee) in cases of a problem with the product. See, e.g., 27 C.F.R. 1.20-1.22, 4.35a, and 24.300, et seq.² In the case of imported products, while the foreign producer is not registered with ATF, the importer is routinely required to produce letters from the foreign supplier about the product as part of the application process.

We would also point out that State liquor control boards also require that persons engaged in the alcohol beverage business obtain a State license, and impose similar application standards, for engaging in business in this industry. An E A registration requirement for domestic and foreign facilities producing alcohol beverages would appear to be

¹The IRC and implementing regulations require that persons wishing to establish operations as a distilled spirits plant (DSP), bonded winery (BW), or brewer must also qualify to engage in such operations. See, e.g., 27 C.F.R. Part 19 (DSP), Subpart G; 27 C.F.R. Part 24, Subpart D (BW); and 27 C.F.R. Part 25, Subpart G (Brewery). The regulations establish a rigorous application process, to allow ATF to evaluate the applicant's likelihood to comply with the law.

²While the regulations in that letter refer to wine, the regulatory scheme applies to both distilled spirits and wine. Regulations for beer are exempt from the permit requirement for brewers of malt beverages.

duplicative of existing registration requirements and unnecessary.

Recordkeeping

The recordkeeping requirements required under section 306 of the Act of 2002 are similar in nature and purpose to the recordkeeping requirements under the IRC, 26 U.S.C. chapter 52. The importer, wholesaler, producer, and blender of alcohol beverages are required to maintain records of production and importation. 27 CFR Part 24, Subpart O (wine); 27 CFR Part 19, Subpart W (distilled spirits); 27 CFR Part 25, Subpart U (beer); 27 CFR Part 251, Subpart I (imported distilled spirits, wine and beer). These record keeping requirements are intended to ensure that the tax due on the product is paid, or that the tax is not reimposed upon the product by virtue of the manner in which it is disposed. Therefore, required records track the product from the point of production or importation to its ultimate disposition. Thus, required records under the IRC already establish the immediate previous sources and the immediate subsequent recipients of the alcohol beverages, as is required by the Act of 2002. A requirement that the same or similar information be maintained under FDA regulations would be duplicative and unnecessary.

Prior Notice

As indicated above, section 307 of the Act of 2002 requires prior notice describing the article, the manufacturer and shipper; the grower (if known), the country of origin, and the country from which the article is shipped. This information is also required under regulations implementing the FAA Act. While there is no formal "prior notice" requirement under FAA Act regulations, the information collection is essentially the same and serves the same purpose.

In particular, the FAA Act requires that industry members apply for and obtain a certificate of label approval (COLA) covering the bottled product before the product is introduced into interstate or foreign commerce. The COLA, which is intended to ensure that

the product identifies the product in a non-deceptive way, must contain mandatory alcohol beverage label information, which includes the brand name of the product, the class and type designation, the alcohol content, the name and address of the bottler or packer (domestic product or imported bulk product bottled in the United States) or importer, and the country of origin. The COLA forms are valid indefinitely, provided the beverage content, label and importer remain the same.

Significantly, the Act of 2002 does not define "prior notice" and leaves the amount of time required to satisfy "prior notice" to be established by regulation. Since an approved COLA form must be submitted to Customs at the port of entry as a condition of releasing the product (see, e.g., 27 C.F.R. § 4.40), we believe the purpose of the prior notice requirement is fully satisfied. That is, the purpose of the prior notice requirement is to enable the Government to establish the identity and origin of the product prior to the product's importation into the country. The submission of the COLA forms as a condition to importation satisfies this purpose.

Other ATF Regulation of the Industry

In addition to the above, ATF conducts periodic testing of alcohol beverages and laboratory analyses, as appropriate, to ensure product integrity and compliance with applicable regulations. Numerous alcohol beverage products will not be issued COLA forms without first performing a product evaluation at the ATF Laboratory. ATF conducts occasional alcohol beverage samplings, both targeted and random, testing the integrity and regulatory compliance of alcohol beverage products on the market. ATF also investigates consumer complaints and, in consultation with the FDA, requests voluntary recalls of the product where a health concern is presented.

After attending the Constituent Roundtable: Interagencies meeting on August 6, 2002, I followed up with a telephone call to Ms. Leslye M. Fraser, (Associate Director for Regulations, Office of Regulations and Policy), to discuss the information

outlined in this memorandum and encourage the exchange of information and open dialogue between FDA and ATF, to avoid duplication of registration and recordkeeping requirements of our industry members. ATF believes that the requirements we currently impose on the alcohol beverage industry meet the requirements of P.L. 107-188. ATF recommends further discussion between our agencies to minimize duplication of efforts and unnecessary redundancy in regulating the alcohol beverage industry.

I hope that this information concerning ATF's mission and regulatory functions assists you in your regulations writing process. Should you require further assistance on this matter, please do not hesitate to contact me. I may be reached at the ATF Domestic and International Trade Division (202) 927-8100.

Sincerely yours,


Theresa M. Glasscock
Chief

Domestic and International Trade Division

Attachments

C: Leslye Fraser