

April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0276: Food and Drug Administration/Bioterrorism Preparedness and Response Act of 2002/Registration Proposal

Dear Sir or Madam:

The undersigned are a coalition of trade associations representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States. On behalf of our respective members, we welcome the opportunity to submit this comment in response to the Food and Drug Administration's (FDA) notice of proposed rulemaking implementing the registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

We fully support a focused regulatory scheme to guard against a threatened or actual terrorist attack on the U.S. food supply. A focused scheme takes into account existing regulatory requirements that already are in effect, despite the fact that they may be implemented by various Federal agencies. Such a coordinated strategy makes both "government sense" and "business sense." Redundant regulation only serves to burden business and cause confusion, without any commensurate benefit in achieving our collective goal of a safe and secure food supply.

Existing Requirements for Beverage Alcohol Meet the Goals of the Act

For beverage alcohol, the directives of the Bioterrorism Act already are met and satisfied by the existing obligations imposed by the Department of Treasury's Tax and Trade Bureau (formerly the Bureau of Alcohol, Tobacco and Firearms). The statutory and regulatory requirements of the Tax and Trade Bureau (TTB) clearly demonstrate this point. Since the 1930s, TTB and its predecessor agencies have regulated the beverage alcohol industry in terms of both import and domestic trade.

TTB has a comprehensive set of regulations governing the production, manufacture, importation, and distribution of beverage alcohol products. All persons engaged in the business of producing, importing and distributing beverage alcohol products in the United States must obtain a permit from TTB or be registered with TTB. (See, e.g., Federal Alcohol Administration Act, 27 U.S.C. §§ 203-204.)

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Any applicant for a permit or registration with TTB is subject to an extensive background and financial investigations review. Foreign entities can import beverage alcohol products only through an entity that holds a Federal Basic Importer's Permit. These permit and registration requirements, which are discussed further below, clearly meet the objectives of the registration provisions of the Act. Among other things, they provide the requisite information and mechanisms to ensure prompt identification and recourse for any threats to our nation's food supply.

As a consequence, we urge FDA not to adopt a registration requirement that would duplicate regulations already in place and administered by TTB. A means to achieve this end is to include express language in the Bioterrorism Act's final registration rule recognizing that TTB's requirements satisfy the registration requirement under the Bioterrorism Act.

We submit that our proposed course of action also will achieve Commissioner McClellan's goals to implement the Act both effectively and efficiently. In that regard, Commissioner McClellan recently stated: "My goal here, as an economist by training and as a physician, is to make these regulations work as efficiently as possible. We have goals that we have to meet, but if [we] can do it at lower cost or more efficiently, it will reduce adverse effects." (Washington Post, April 1, 2003; Page E01.) Utilizing TTB's information network will produce the end results sought by Commissioner McClellan and intended by Congress.

We further urge FDA to reconsider its registration proposal in terms of whether the burden of a new, but duplicative, regulation outweighs its benefit for both government officials and members of the beverage alcohol industry. In that regard, FDA's burden estimate for information collection is inherently flawed because it does not take into account that beverage alcohol industry members would be required to satisfy two regulatory schemes with redundant dictates. To the same effect, FDA's burden estimates regarding cost, impact and other factors similarly are flawed.

Government Resources Should be Directed to Coordinate, Not Duplicate, Regulation

Coordination of action, not duplication of action, should be the keystone in implementing the provisions of the Bioterrorism Act. Congress recognized that the Act called upon the functions of other Federal agencies and appropriately directed these agencies to work together in forging a food safety and security strategy. To that end, Sections 302(c) and 314 of the Act contemplate, as well as direct, the Secretary of Health and Human Services to forge linkages with other Federal agencies to facilitate the implementation of the Act. Simply put, both the provisions of the Act and its legislative history envision a clear allocation of Federal agency activities as the most prudent and effective use of government resources.

Further, this clear allocation of responsible action among Federal agencies, such as TTB vis-à-vis its regulatory scheme governing beverage alcohol industry members, will best be achieved by utilizing the government procedures and processes already in place, irrespective of whether such regulatory schemes are implemented by FDA. This type of allocation of

government resources will most efficiently “develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply,” the stated purpose of Title III of the Act.

In addition to the regulatory structure TTB already has in place concerning members of the beverage alcohol industry, TTB regulators themselves are well suited to address the elevated threats of terrorism to our nation’s commercial infrastructure. Unlike officials of other Federal agencies, TTB has sworn law enforcement officers with a long history of collaboration with other levels of government. These TTB officials possess security clearances, relationships with other law enforcement authorities and access to information about their regulated community that likely surpasses that of other Federal agencies with authority over our nation’s food supply.

Further, communication systems between and among members of the beverage alcohol industry also are in place whereby distillers, brewers, vintners, and distributors (both private entities and State commercial enterprises), for example, have the ability to rapidly and effectively track product and exchange information.

In sum, since the requirements of TTB already achieve the desired objectives of the registration requirement of the Bioterrorism Act, it should be incumbent upon FDA to liaise with TTB to coordinate their actions, rather than unduly burden industry due to a lack of coordination. Any other course of action would impose unnecessary burdens upon regulators and the regulated community and thereby divert valuable time and resources away from government and industry efforts to protect the food supply from bioterrorist threats -- an objective that all of us fully support.

TTB’s Existing Requirements Governing the Beverage Alcohol Industry

Section 103 of the Federal Alcohol Administration Act (FAA Act) (27 U.S.C. § 203) and its implementing regulations in 27 C.F.R. 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 producing, importing or wholesaling beverage alcohol products. In order to protect the integrity of the industry by ensuring that only persons who are likely to comply with the law may be granted permits, Section 104 of the FAA Act (27 U.S.C. § 204) prohibits the issuance of a permit to:

- any person who has been convicted of a felony under Federal or State law within the prior five years;
- any person who has been convicted of a misdemeanor under Federal law relating to taxation within the prior three years;
- any person who, by reason of business experience, financial standing or trade connections, is not likely to commence operations within a reasonable period or to maintain such operations in conformity with Federal law; or



DEPARTMENT OF THE TREASURY
BUREAU OF ALCOHOL, TOBACCO AND FIREARMS

Washington, DC 20226

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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

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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 FDA 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 legal citations in this letter refer to wine, a similar regulatory scheme applies to both distilled spirits and malt beverages/beer as well (except that no permit is required 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