



**NATIONAL ASSOCIATION
OF BEVERAGE IMPORTERS, INC.**

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March 5, 2003

Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
New Executive Office Building
725 17th Street, N.W., Room 10235
Washington, D.C. 20503

ATTN: Stuart Shapiro
Desk Officer for FDA

RE: Docket No. 02N-0276

Dear Mr. Shapiro:

These Comments are submitted on behalf of the Members of the National Association of Beverage Importers, Inc., (NABI). NABI is a national trade association that represents the interests of importers of beer, wine, and distilled spirits. NABI Members are responsible for the importation of a major share of all alcohol beverages that are imported into the United States.

NABI Members welcome this opportunity to provide comments to the Office of Management and Budget (OMB). The Paperwork Reduction Act of 1995 subjects these proposed rules to review by OMB. We ask that OMB review these regulations as they relate to the collection of information and the burden on large and small businesses alike. We believe that FDA is proposing regulations that are unnecessary for the proper performance of FDA's functions and that they duplicate the collection of information already gathered by the Tax and Trade Bureau (TTB), formerly the Bureau of Alcohol, Tobacco and Firearms (BATF). FDA has failed to consider options that would minimize the burden of collection on respondents.

In August of 2002, NABI was part of an alcohol beverage coalition that formed to respond to FDA's request for comment by stakeholders as FDA developed proposed regulations implementing the provisions of the "Bioterrorism Act of 2002." The coalition submitted comments to FDA on August 30, 2002. (See attached Exhibit No. 1) In that comment, the coalition argued that FDA should not propose regulations that would duplicate regulations already in place and

02N-0276

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PRESIDENT

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BERNADEEN P. EMAMALI
CORPORATE SECRETARY

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administered by other agencies. We believed then, and continue to believe now, that the TTB collects all of the information that would be necessary for FDA to carry out its responsibilities under the Bioterrorism Act of 2002.

We urge OMB to insist that FDA not propose or adopt any regulations that would be duplicative of regulations already in place and administered by other Federal agencies. In that regard, Sections 302 (c) and 314 clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of Federal agency activities. The Congressional Record is evidence of such intent.

The Senate proposal authorized the Secretary to require the maintenance and retention of other records relating to food safety in consultation with other Federal departments and agencies that regulate food safety. (148 Cong Rec H 2685.) Since the Secretary had authority under Section 701(a) of the FFDCFA to issue regulations for the efficient enforcement of the Act in combination with other provisions, the Senate proposal was not adopted. (148 Cong Rec H 2685.)

The House also advocated close coordination with other Federal agencies, such as U.S. Customs Service, in implementing the notice requirement with a goal of minimizing and eliminating unnecessary, multiple, and redundant notifications (147 Cong Rec E 2388) and encouraging simplicity and cooperation with respect to the registration requirement, reducing paperwork and the reporting burden on facilities (147 Cong Rec E 2388.) Therefore, Congress recognized that the Act called upon functions of other Federal agency activities and intended to coordinate, rather than duplicate, such functions.

Understanding the need to immediately obtain information relating to foods imported or offered for import into the United States in reaction to a crisis, NABI urges the FDA to implement a coordinated strategy with other Federal agencies that have established regulatory measures governing beverage alcohol. This clear allocation of Federal agency activities, such as TTB and Customs vis-à-vis their respective regulatory schemes governing beverage alcohol, will best utilize the procedures and processes already in place to 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.

The Secretary is required to establish registration requirements for specified food facilities by regulation necessary for effective enforcement. Congress encouraged efficient operation of the registration requirements and grants the Secretary the ability to exempt certain facilities from the requirement of

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registration (148 Cong Rec H 2685.) NABI urges the FDA to accept the current permit system for beverage alcohol producers, importers, and wholesalers/distributors, thereby exempting such facilities from registration requirements. The current permit system is far more restrictive and grants the government greater control than this Act.

Requiring a producer, importer, or distributor of beverage alcohol to register with FDA under Section 305 would be a duplication of existing licensing and/or permit requirements. Not only are producers, importers, or wholesalers/distributors required to obtain Federal permits, such facilities are also licensed and regulated by each State. Any applicant for a permit or registration with TTB must go through an extensive background and financial investigations review. Foreign producers can only import beverage alcohol through an entity that holds a Federal Basic Importer's Permit.

Further, the electronic filing directive set forth in Section 305(d) was borne out of the initiative to help reduce the paperwork and reporting burden, calling for a one-time registration. (148 Cong Rec H 2685.) The goal of the one-time registration is accomplished by the regulatory scheme imposed by the TTB. Additional registration requirements imposed on the beverage alcohol industry would be duplicative, inefficient and costly, not only to the regulators but also to the regulated community.

If, in the final analysis, it is determined that foreign facilities that manufacture, process, pack, or hold food for consumption in the United States must register, then FDA should propose a registration system that would allow U.S. agents to register the foreign facility.

FDA considered eight (8) options in the NPRM. None of the options, however, contain an analysis of FDA accepting another agency's permit system as a registration under the Bioterrorism Act. The cost of this option would be significantly less – for both government and industry - than the option that is being proposed by FDA. Under current law administered by TTB, the Secretary of the Treasury must find that the applicant for a permit to produce, warehouse, import, or wholesale an alcohol beverage has not, within five years of the application date, been convicted of a felony under Federal or State law; nor has the applicant, within three years prior to the application date, been convicted of a misdemeanor under any Federal or State law relating to liquor, including the taxation thereof.

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The law also requires the Secretary of the Treasury to determine that the applicant, by reason of his/her business experience, financial standing, or trade connection, is likely to commence business (operations) within a reasonable period of time and will maintain such operations in conformity with Federal law. The Secretary of the Treasury must also determine that the proposed operations will not violate the laws of the State(s) in which they are to be conducted. While brewers are not required to obtain a permit, they must register with the TTB. It is obvious that the permit/registration system administered by TTB is far more comprehensive than anything currently proposed by FDA. Any FDA registration of domestic/U.S. importer alcohol beverage facilities would be redundant and a waste of government resources in addition to being a burden on the regulated industry. Clearly, the TTB permit system could easily be integrated into the FDA registration system.

We will now address the questions asked by FDA as a result of the provisions of the Paperwork Reduction Act of 1995.

- 1) Is the proposed collection of information necessary for the proper performance of FDA functions, including whether the information would have practical utility

As outlined in the above paragraphs, NABI Members feel that the proposed regulations are redundant and an unnecessary burden on the regulated industry. FDA did not consider an option that would have incorporated the registration systems of other Federal agencies.

FDA is proposing to require more information from the registrant beyond that mandated by the Bioterrorism Act. The volume of the information alone brings its utility into question. FDA has not justified its need for the information, especially in light of the fact that it, in our view, is a redundant collection.

- 2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

We believe that FDA has grossly underestimated the number of respondents/registrants. It is impossible to tell from reading the NPRM just how FDA arrived at the number of 205,405 respondents (see Table 48.) Does that number include the thousands upon thousands of small vineyards that also produce a small quantity of wine, hoping that they will get a chance to sell it in

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the United States? The number shown in Table 48 appears to be unreasonably low. The total burden hours shown by FDA is also probably very inaccurate because the number of respondents that FDA shows in Table 48 is wrong.

3) How can the quality, utility and clarity of the material be enhanced

It can be enhanced by reducing the duplication caused by FDA's attempt to establish a "stand alone" registration system. FDA should rely on other agencies' permit/registration systems that have served the government's needs well for many years.

4) How can the burden of collecting information on respondents be reduced

As it relates to the alcohol beverage industry, most of the information required under the Bioterrorism Act is already on file with the TTB. In fact, BATF submitted a detailed memo to FDA describing its permit/registration scheme. A copy of the BATF memo is attached (See attached Exhibit No. 2) for your ready reference. It would appear, from reading the NPRM, that FDA completely ignored the alcohol beverage industry letter on this issue and the BATF memo.

NABI has many small members. These small companies will undoubtedly have to retain lawyers, consultants, or customs brokers to help them comply with the proposed regulations. The costs for that professional assistance will certainly exceed the \$58 to \$83 estimate of FDA. The proposed rule will cause many small companies, both in the United States and in other parts of the world, to deal with complex government regulations. They will undoubtedly need a considerable amount of professional help.

CONCLUSION

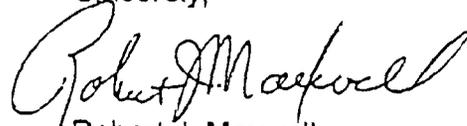
In summary, we ask that OMB insist that FDA coordinate with other Federal agencies to insure that duplication is avoided and that permit and registration systems of other agencies be incorporated into the Bioterrorism Act registration system. We see no reason, legal or otherwise, why FDA can't deem the permit/registration systems of TTB to be registration also for the purposes of the Bioterrorism Act of 2002.

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We thank you for this opportunity to comment on these proposed regulations. We ask that OMB use the powers vested in it by law to ensure that FDA regulations do not unnecessarily burden the private sector or negatively affect the economy. We stand ready to work with you at any time and to assist FDA in the drafting of regulations that meet the requirements of the law without placing an unnecessary burden on the regulated industry.

If we can be of further assistance, please do not hesitate to call on us.

Sincerely,



Robert J. Maxwell
President - NABI

Attachments (2)
8/30/2002, Joint Industry Comment
BATF memo to FDA

August 30, 2002

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

- RE: (1) Section 303 – Docket No. 02N-0275 (Detention)
(2) Section 305 – Docket No. 02N-0276 (Registration)
(3) Section 306 – Docket No. 02N-0277 (Recordkeeping)
(4) Section 307 – Docket No. 02N-0278 (Prior Notice)

Dear Sir/Madam:

The undersigned are a coalition of trade associations (see Attachment A) 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 provide initial comments concerning the Food and Drug Administration's (FDA) proactive efforts to liaise with the foods community in implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Act). We fully support this FDA initiative, which is designed to create a focused regulatory scheme that does not unnecessarily duplicate existing statutory and/or regulatory requirements currently in place. To that end, our comments focus upon how the directives of the above-referenced Sections of the Act already are met and satisfied by the existing extensive regulatory scheme governing beverage alcohol.

Since the 1930s, the Bureau of Alcohol, Tobacco and Firearms (BATF) and its predecessor agencies have regulated the beverage alcohol industry in terms of both import and domestic trade.¹ BATF has a comprehensive set of regulations that governs 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 BATF or be registered with BATF. The beverage alcohol industry also is governed by an extensive regulatory scheme administered by BATF, which, among other things, requires industry members to strictly account for all products. Simply put, the existing regulations enforced by BATF more than satisfy the provisions of this Act.

¹ See generally, Federal Alcohol Administration Act, 27 U.S.C. §§ 121-211, Internal Revenue Code 26 U.S.C. §§ 5001-5691, and Title 27, Code of Federal Regulations.

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In addition, industry members involved in the production, importation and distribution of beverage alcohol products are licensed by each State in which they do business. Each State also has regulations that require recordkeeping and mandate the filing of periodic reports of beverage alcohol products shipped into and/or sold in that State. Although excluded from the scope of the Act, beverage alcohol retailers also are licensed by the States in which they do business.

The U.S. Customs Service further regulates importers of beverage alcohol products. Importers must maintain records to establish upon request that goods imported have been classified correctly, taxes have been paid, and the importer of record has complied with all regulations specifically dealing with beverage alcohol. Further, as discussed more fully below, Customs has several initiatives in place, such as the Container Security Initiative, that requires extensive information about U.S. bound shipments at least 24 hours before the vessel sails to the United States.

We urge FDA to avoid proposing or adopting regulations that would be duplicative of regulations already in place and administered by other federal agencies. In that regard, Sections 302(c) and 314 clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of federal agency activities. This clear allocation of responsible action among federal agencies, such as BATF and the Customs Service vis-à-vis their respective regulatory schemes governing beverage alcohol, will best utilize the procedures and processes already in place to 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.

Duplicative regulations and unnecessary regulations are costly and create inefficiencies, as well as spawn potential confusion within the regulated community. Further, such measures 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.

Finally, we urge that the resources and appropriations allocated to implement the Act be available to the federal agencies, such as BATF, that are a critical component in effectuating its provisions. In addition, such agencies also should have available the necessary resources and funds to meet various procedural elements of the Act, such as the electronic filing directive set forth in Section 305(d).

The following are our comments regarding specific Sections of the Act.

Section 303 - Administrative Detention

No person can hold a federal permit to produce, import or distribute beverage alcohol if that person has been convicted of a felony within five years prior to the date of application or within three years of the date of application to have been convicted of a misdemeanor relating to beverage alcohol. Without a permit, importers, distillers, vintners, and distributors cannot

EXHIBIT No.1

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engage in the beverage alcohol business. Permits can be revoked or suspended for reasons specified in federal law. The current permit system for beverage alcohol producers, importers and wholesalers/distributors is far more restrictive and gives the government greater control than anything contemplated in instant Act.

Section 305 – Registration of Food Facilities

Requiring a producer, importer, or distributor of beverage alcohol to register with FDA would be a duplication of existing licensing and/or permit requirements. All importers, domestic producers and wholesalers/distributors of beverage alcohol must obtain a permit from the federal government. While brewers are not required to obtain a permit, they must register with BATF. Any applicant for a permit or registration with BATF must go through extensive background and financial investigations. Foreign producers can only import beverage alcohol through an entity that holds a Federal Basic Importer's Permit.

Section 306 – Maintenance and Inspection of Records for Foods

Under current federal laws and regulations, importers, producers and distributors/wholesalers of beverage alcohol must maintain "one up and one down" records. During normal business hours, these records must be kept and made available for review by a federal officer. The objectives of Section 306 are met or exceeded by current BATF recordkeeping requirements/regulations. Any additional recordkeeping requirement by FDA would be duplicative and unnecessary.

Section 307 – Prior Notice of Imported Food Shipment

The U.S. Customs Service already receives advance notice of the arrival of a ship and of the ship's manifest well in advance of the ship's arrival. Given the Customs Service's various security initiatives, there is no need for FDA to issue more regulations that would require something already required by the U.S. Customs Service. For example, Customs is in the process of finalizing its new requirements that would require ocean carriers and non-vessel-operating common carriers to present detailed cargo manifests 24 hours before a container is loaded onto a ship. Shippers – food importers – play a crucial role in satisfying these requirements.

The Custom's checklist requires fifteen (15) information elements that are far more detailed than the directives of the Act. These information elements are: (1) foreign port of departure; (2) carrier SCAC code; (3) voyage number; (4) date of scheduled arrival in first U.S. port; (5) numbers and quantities from carrier's master or house bill of lading; (6) first port of loading, or first port of receipt, of the cargo by the inbound carrier; (7) a precise description (or the Harmonized Tariff Schedule numbers if the HTS classification is provided by the shipper) and weight of the cargo, or, if the container is sealed, the shipper's declared description and weight of the cargo (generic descriptions, specifically freight-all-kinds, general cargo, and STC (said to contain) are not acceptable); (8) shipper's name and address, or an identification number, from all bills of lading; (9) consignee's name and address, or the owner's or owners' representative's name and address, or an identification number, from all bills of lading; (10) advise Customs when actual boarded quantities do not equal quantities indicated on the relevant bills of lading (carriers

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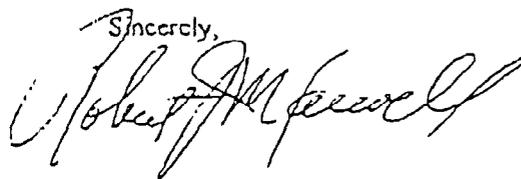
are not required to verify quantities in sealed containers); (11) vessel name, national flag and vessel number; (12) foreign country of origin where cargo is loaded onto vessel; (13) hazardous-material indicator; (14) container number (for containerized shipments); and (15) seal number affixed to container.

Customs' efforts to improve security impose requirements beyond the dictates set forth in the Act. U.S. companies must educate their suppliers not only about the new manifest rules referenced above, but also about the Customs-Trade Partnership Against Terrorism (C-TPAT) and other security measures. Although technically a voluntary program, C-TPAT is becoming an industry standard.

Conclusion

In summary, we recommend that FDA meet with other agencies that have regulations and jurisdictions to govern the importation, production and distribution of beverage alcohol in order to coordinate responsibilities. Such a liaison will avoid duplication of government resources, government manpower and government regulation. We submit that this suggested course of action will enable the federal government and the food industry to focus their resources more efficiently and effectively upon efforts that will enhance security and will avoid unnecessary and redundant burdens that otherwise could be imposed upon both enforcement and compliance efforts.

Thank you for the opportunity to present our views concerning FDA's actions to implement the Bioterrorism Act. We stand ready to work with you at any time to assist FDA in the development of implementing regulations that will result in the efficient and effective implementation of this Act. If we can be of any further assistance, please do not hesitate to call on us.

Sincerely,


Attachment A

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Lynne J. Omlie, Senior Vice President & General Counsel
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DEPARTMENT OF THE TREASURY
BUREAU OF ALCOHOL, TOBACCO AND FIREARMS

Washington, DC 20226

Rec'd 9,

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-0278

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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 those 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

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3/5/03

TO: Stuart Shapiro (202) 395 6974

FROM: Bob Maxwell
NABI

RE: FDA Docket No. 02N-0276

We tried to hand deliver the attached
to you but we could not get past
your security. I will put the originals
in the mail to you. The earlier fax that
I sent you was for 02N-0276

Bob Maxwell

Number of pages (including cover page)

If you do not receive a clear copy, or do not receive the entire document please call us at (240)453-9998.