



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

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November 17, 2004

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

RE: Docket 2003D-0554 – Prior Notice

Dear Sir/Madam:

This comment is being submitted on behalf of the members of the National Association of Beverage Importers, Inc. (“NABI”). NABI is a national trade association that represents importers of beer, wine, and distilled spirits.

NABI members recently learned of the Food and Drug Administration’s (“FDA”) decision to eliminate the requirement that importers show the registration number of the foreign supplier when submitting a “prior notice.” NABI members believe that eliminating this requirement is a grave mistake and in fact, significantly reduces the effectiveness of the Bioterrorism Act of 2002 (“the Act”). Allowing importers to substitute the producer’s name and address for the registration number destroys the traceability of the product shipment in question and weakens the FDA’s ability to enforce the registration requirements of the Bioterrorism Act on foreign producers. Most alcohol beverage producers list their names and address on the bottle label. This information is therefore available to everyone, including those who would seek to do us harm. Without a registration number, how can the FDA be sure where a shipment of food has been or who had access to such shipment if the producer is not required to say that it came directly from him/her.

We understand the FDA has made this change because some importers are not able to obtain the producer’s registration number. That rationale makes no sense to us. In order to protect the American public from bioterrorism, the United States Congress decided that producers of food, both foreign and domestic, must register their facilities with FDA before shipping certain food products into the United States. The law further required FDA to assign a unique registration number to each registered facility. In the FDA Interim Final Rules, FDA made the determination that the registration number was an integral part of “prior notice” and a necessary enforcement tool. In addition, FDA has determined that showing the FDA registration number in a “prior notice” submission was an essential tool that FDA needed to enforce effectively the registration provisions pertaining to foreign producers.

2003D-0554

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ROBERT J. MAXWELL
President

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Corporate Secretary & Assistant Treasurer

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We agree with the need for a registration number and with the original FDA thinking that if made a part of a prior notice filing, it would be an effective and efficient enforcement tool. FDA has not in our opinion made the case to reverse its original thinking and rationale.

The safeguards contained in the registration and prior notice provisions of the Bioterrorism Act speak for themselves. If an importer cannot supply the registration number, then most likely the product is not coming directly through a secure supply chain, is probably not C-TPAT compliant, and the integrity of the system established by FDA and CBP has been violated. This concern far outweighs any paperwork problem that an importer may have. NABI members have no problem/objection with being required to show the registration number of our foreign suppliers when filing a prior notice. We believe the inability of certain importers to obtain the registration number from the producer speaks to the strength and effectiveness of the regulations. It is exactly what Congress and the FDA regulations intended and is designed to present exactly the obstacle to which some people are objecting. Simply because some importers complain is not reason enough for changing the rule and weakening the traceability of a shipment of food destined for sale to U.S. consumers. In fact that is a clear signal that the program works!

Additionally, FDA should be aware that many NABI members are members of the U.S. Customs and Border Protection program C-TPAT (Customs and Trade Partnership Against Terrorism) and have invested a substantial amount of money making their supply chains secure and C-TPAT compliant. In doing so, they have taken steps to modify systems and documentation to ensure that the FDA registration number is included on shipping papers in an effort to facilitate completion of a prior notice. This program has created an enormous burden of paperwork and maintenance, a burden that NABI members have willingly accepted. Although the additional paperwork is cumbersome and expensive, it engenders a level of safety and security that our country demands, and NABI members are willing to provide. This spirit of cooperation should be embraced by all in the overriding interest of homeland security. NABI members, who are also the authorized importers for their foreign suppliers, have also expended capital to insure that they and their foreign suppliers are properly registered. We believe the registration number is necessary because it is the only assurance that the registered foreign supplier is the entity that actually produced the product.

If the registration number is not an essential component of the supply chain security system, then why did Congress and the FDA require the foreign supplier to register and obtain a registration number? Registration seems to be a useless exercise without the registration number. The law has not changed and the FDA has not changed its interpretation of the law with respect to registration requirements.

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Summary

The FDA should not eliminate the requirement for showing the registration number of the foreign supplier in a “prior notice.” The registration number is an integral component of the system designed to protect the integrity of the food supply chain. Eliminate the need, and you invite “any” third party shipper in the world, to buy product, alter it, and ship it to the U.S. without a problem. The FDA cannot say that making our food supply chain secure is our prime objective if the food product is imported by an unauthorized importer who cannot obtain the foreign supplier’s registration number. Security must be our number one concern and not secondary to the economic concerns of an unauthorized importer. Authorized importers, who are members of NABI, have demonstrated their concern for food safety and product integrity by quickly becoming members of C-TPAT and ensuring that their foreign suppliers are properly registered with FDA.

Sincerely,

A handwritten signature in black ink, reading "Robert J. Maxwell". The signature is written in a cursive style with a large, sweeping initial "R".

Robert J. Maxwell
President – NABI