BARNES, RICHARDSON & COLBURN

ATTORNEYS & COUNSELLORS AT LAW

475 PARK AVENUE SOUTH
NEW YORK, N.Y. 10016

TELEPHONE: (212) 725-0200
FACSIMILE: (212) 889-4135
E-MAIL: barnes@brc-ny.com
http://www.barnesrichardson.com

1225 EYE STREET, N.W.
SUITE 1150
WASHINGTON, D.C. 20005
TEL. (202) 457-0300
FACSIMILE (202) 331-8746

303 EAST WACKER DRIVE
SUITE 1100
CHICAGO, ILLINOIS 60601
TEL. (312) 565-2000
FACSIMILE (312) 565-1782

JAMES S. O'KELLY
ROBERT E. BURKE
DONALD J. UNGER*
MATTHEW T. McGRATH*
SANDRA LISS FRIEDMAN
BRIAN F. WALSH*
KAZUMUNE V. KANO*
F.D. VAN ARNAM, JR.
LAWRENCE M. FRIEDMAN*
ALAN GOGGINS
ROBERT A. SHAPIRO

CAROLYN D. AMADON*
ILYA A. BAKKE*
STEPHEN W. BROPHY*
JAMES B. DORAN*
DAVID G. FORGUE*
HARVEY KARLOVAC*
BEATA KOLOSA*
DIANE A. MacDONALD*
JENNIFER L. MORGAN*
CORTNEY O'TOOLE MORGAN
WILLIAM J. MURPHY*
JOSEPH M. SPRARAGEN
KEVIN J. SULLIVAN
JANE E. WELSH*

SPECIAL COUNSEL
ANSIS M. HELMANIS*

OF COUNSEL
RUFUS E. JARMAN, JR.
GUNTER von CONRAD*

INTERNATIONAL TRADE ANALYST
AMY H. WARLICK

*NOT ADMITTED IN NEW YORK

April 3, 2002

Via Federal Express

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

Re: Notice of Proposed Rulemaking: Prior Notice of Imported Food

Dear Sirs:

On February 3, 2003, the Food and Drug Administration published notice of proposed rulemaking in the Federal Register at 68 Federal Register 5378 *et seq.*, relating to the implementation of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188 ("Bioterrorism Act"), requiring the submission of a prior notice of imported food to the FDA for the purpose of "enabling such article to be inspected at ports of entry into the United States." The Notice afforded interested parties until April 4, 2003 to submit comments. Our law firm represents numerous food importers on whose behalf we are submitting these comments:

1. **The Data Elements Included in the FDA Proposal Go Far Beyond the Requirements of the Statute**

Congress, in enacting section 307 of the Bioterrorism Act was careful not to seek to erect unnecessary barriers to trade, and accordingly sought to limit the amount of information to be provided in the prior notice to only those data elements necessary to enable the imported food to be inspected by the FDA before it moved into the commerce of the United States. Hence, Congress specifically enumerated the following data elements to be provided:

> The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry of the article.

These data elements were adopted by the Conference Committee after considering different approaches suggested by the House and the Senate. The House Conference Committee Report 107-481 at page 491-492 notes that the House version of the bill listed the seven data elements ultimately adopted by the Congress. In contrast, the Committee noted that the Senate version of the bill required "the identity of the food, the food's country of origin, the quantity imported, and *other information that the Secretary may require by regulation.*" [Emphasis added]. The Conference Committee rejected the Senate version which would have allowed the Secretary to decide what information was to be provided in the prior notice in favor of the House version, which specifically enumerated the information to be submitted on the prior notice.

The FDA proposal, however, contains many data elements which go beyond what was intended by the Congress, and is clearly contrary to the deliberate decision made to limit the amount of information to be requested in the prior notice. The FDA proposal would have importers include such information as the type of packaging for the article, brand name as well as trade name of the article, lot numbers, identifying codes ordinarily submitted to the FDA and Customs after entry, detailed information such as name, address, telephone and facsimile numbers, and email addresses for each of the parties to be identified, as well as for the carriers. Much of this information is not available to the importer prior to arrival of the shipment, if ever. More importantly, however, it was never intended by Congress to burden the importer with the task of providing any more information in the prior notice than what was clearly spelled out in the statute.

Several members of Congress specifically addressed the concern that the prior notice requirements not become an undue burden for the importer. In remarks published in the Congressional Record of May 22, 2002 at 148 Cong Rec H 2844,, Congressman Tauzin of Louisiana stated that in developing regulations to implement section 307 of the Bioterrorism Act,

> . . . the Secretary of Health and Human Services should coordinate and consult with the Secretary of the Treasury regarding the notifications already required by the U.S. Customs Service with the goal of eliminating, reducing or consolidating duplicative or unnecessary notice

> requirements and minimizing potential trade impacts of the prior notice requirements of this section.

In a similar vein Congressman Shimkus of Texas is quoted in the Congressional Record at 148 Cong Rec H2844 as stating that

> The Secretary [of Health and Human Services] should exercise discretion in promulgating and implementing these rules to assure that prior notice requirements never become a barrier to the smooth flow of commerce.

As noted by various commentators in submissions already presented to the FDA, much of the data being requested is duplicative, of questionable necessity, and will certainly create a barrier to the smooth flow of commerce. Accordingly, we submit that the FDA should revise its proposed rule to limit the data to be provided in the prior notice to only those data elements enumerated in the statute, as cited above.

2. **The FDA Proposal Does Not Take Into Account Different Modes of Transportation As Required by Congress**

The House Conference Committee Report, at page 492 also notes that in promulgating regulations establishing the specified period of time for submitting the prior notice the Secretary should take into account "the effect on commerce, the locations of various ports of entries, the various modes of transportation, the types of food imported into the United States, and other such consideration."

It is clear from this statement that Congress never intended that all imported foods be subject to identical reporting requirements, at least so far as the time interval in which the prior notice has to be submitted. For example, the FDA has already received many comments from the fresh fish and produce industry pointing out the impossibility of providing detailed information about the food to be delivered the following day, when such information does not become available until much closer to the arrival of the goods.

With respect to notification of arrival time, the proposed rule seems to be geared to ocean shipments and does not take into account the specific issues that may be faced with other modes of transportation such as air or truck. In the case of an air shipment, for example, it is highly improbable that an importer will know, by noon of the day prior to arrival, that its goods will be arriving on a specific flight. In many instances, the importer could not obtain such information no matter what procedures it adopted because it is up to the airline to decide which plane will be loaded with which cargo. Even if an importer is notified, it has no control over weather conditions or other circumstances that could delay the arrival of the plane, which could cause the product to arrive later than the time anticipated in the prior notice.

Similarly, most importers do not know when or where a truck will cross the border. For example, the importer may be informed that the truck will pick up goods from a manufacturer on a specific day for delivery at a specified later date, but that does not inform the importer when or where, the trucker will cross the border. In addition, as with the case of air freight, there are numerous circumstances that can affect the arrival time of the truck at the border, such as weather, mechanical breakdown, unavailability of a trucker, etc.

In order to recognize the difference in information that is available to importers depending on what mode of transportation is used, as well as when that information becomes known, the FDA should establish different windows of time for reporting the arrival of a food product coming by ocean as opposed to air or truck. We further suggest that these times be developed in conjunction with the appropriate trade groups representing the different carriers.

3. **The FDA Should Allow the Carriers to Submit Amended Prior Notice of Arrival Time**

Since all the issues described in paragraph 2 are issues that, in the ordinary course, are managed by the carrier, we suggest that the FDA consider amending its proposed rule to require the carrier to notify the FDA when a particular vessel, whether it is a ship, plane or truck, has an amended arrival time. Allowing the carrier, rather than requiring each consignee of an article on a specific vessel, to individually notify the FDA of an amended arrival time would drastically reduce the number of amended notices that the FDA would have to review, but would still inform the FDA of the information that it needs to locate a specific shipment.

We appreciate the opportunity to submit these comments.

Respectfully submitted,

Barnes, Richardson & Colburn

By: Sandra Liss Friedman
Sandra Liss Friedman

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