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April 3, 2003

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: Registration of Facilities

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 a provision in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188 ("Bioterrorism Act"), requiring the registration of all foreign and domestic facilities which manufacture, process, pack, or hold food for human or animal consumption in the United States, with the FDA by December 12, 2003. We have been requested by several clients who import food products to obtain clarification of the following scenarios:

1. Goods are received by a freight forwarder overseas for shipment to the United States. Due to unforeseen circumstances, for example, the inability of the freight forwarder to have the freight loaded onto a carrier immediately because of lack of space, weight considerations, or other reasons, the freight is diverted to the freight forwarder's warehouse, where it is held until it can be delivered to the carrier. The food which is received by the freight forwarder is in a condition packed, ready for export. The freight forwarder will not handle the food in any manner, other than to hold it for delivery to the carrier. Further, the importer will most likely never be made aware that this temporary diversion to the freight forwarder's warehouse has occurred. This situation can occur with either air or sea freight.

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Under the proposed rule, a facility is defined to include one which 'holds' food. We note that the House Conference Committee Report, No 107-481 (May 21, 2002) , at page 134, states that a "facility does not include trucks or other motor carriers, by reason of their receipt, carriage, holding or delivery of food in the usual course of business as carriers." We submit that freight forwarders who are temporarily holding food pending delivery to the carrier fall within the exception expressed by Congress for motor carriers. Like the motor carriers, the freight forwarder is only taking possession of the food in order to facilitate delivery to the purchaser. This occurs in the usual course of business of the freight forwarder. Accordingly, we request confirmation from the FDA that, in the circumstances described above, the freight forwarder is not a 'facility' subject to the registration requirement of section 305 of the Bioterrorism Act.

2. An importer receives samples of food products in the United States from potential suppliers for internal evaluation and conducting taste tests. The quantities received are small, that is, insufficient for commercial distribution. All of the taste testing will be conducted in-house with employees who have volunteered for the taste test. Do these facilities have to register?

Under our reading of the Bioterrorism Act, it appears that these facilities would be exempt from registration because these food products do not present the kind of security risk that the provision is intended to address. In its prefatory comments to the proposed rule, the FDA correctly states the intent of Congress in enacting this provision as enabling the "FDA to act quickly in responding to a threatened or actual bioterrorism attack on the U.S food supply or to other food-related emergencies." Fed. Reg. at 5379. Since the food samples received under the circumstance described above, are not distributed outside of the company receiving the samples, they could not present a "threatened or actual bioterrorism attach on the U.S. food supply." Furthermore, the company would have the identity of every individual who participated in the food test in the event anyone had an unfavorable reaction to the food and would be in a position to address the problem immediately. Accordingly, we request confirmation from the FDA that

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facilities which ship food samples to the United States to be used only for internal food tasting by the recipient are not required to register with the FDA.

We appreciate the opportunity to submit comments on this proposal.

Sincerely,

Barnes, Richardson & Colburn

By: 
Sandra Liss Friedman

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