IFDA
international foodservice distributors association

Government Relations / Educational Services

July 8, 2003

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

Re: Docket No. 02N-0275 -- Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam:

The International Foodservice Distributors Association (IFDA) appreciates this opportunity to submit comments to the Food and Drug Administration (FDA) regarding the agency's proposed rule on Administrative Detention of Food for Human or Animal Consumption under section 303 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (codified at 21 U.S.C. § 334(h)). 68 Fed. Reg. 25,242 (May 9, 2003).

IFDA is a trade organization representing foodservice distributors throughout the United States, Canada, and internationally. IFDA's 145 members include broadline and specialty foodservice distributors that supply food and related products to restaurants and institutions in the "food away from home" business. IFDA members operate more than 550 facilities, and sell more than $64 billion in food and related products to the fastest growing sector in the food industry. Formerly a division of Food Distributors International, IFDA was established as an independent trade association on January 1, 2003.

IFDA strongly supports the purposes of the Bioterrorism Act and of this proposed rule. Indeed, IFDA's comments upon the administrative detention proposed rule are limited to relatively minor clarifications that would, overall, increase the smooth implementation of FDA's new administrative detention powers. IFDA asks that FDA consider incorporating the following changes to the final rule:

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1. The Final Rule Should Require Additional Information In The Detention Order (Proposed § 1.393).

IFDA believes it would be useful for the administrative detention order FDA issues to include additional information. The order would, under the proposed regulation, include a statement that, with certain exceptions, an informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under 21 C.F.R. Part 16. Given the very short time deadlines by which a claimant must initiate an appeal of an administrative detention order, IFDA believes it would be valuable for the order itself to describe these appeal procedures and applicable deadlines.

The administrative detention order could include the following from proposed 21 C.F.R. § 1.402:

- The claimant has a right to appeal the order.
- The appeal must be submitted in writing to the appropriate (and identified) FDA District Director.
- The number of days the claimant has to file the appeal and request a hearing, and the date by which such appeal and request must be made.

2. The Final Rule Should Clarify That The Parts Of A Shipment Not Detained May Proceed.

The administrative detention proposed rule is very clear regarding the procedures applicable to food FDA has detained. The proposed rule, however, does not clarify what occurs if a particular product is detained when it is part of a larger shipment. For instance, a single shipping container, truck, or rail car could contain numerous products, including different brands and types of products from a single manufacturer or supplier, or many different products from different manufacturers and suppliers. If FDA administratively detained one part of a shipment, IFDA believes that the suspect product should be removed from the conveyance and secured, and the remainder of the shipment (and the conveyance carrying it) should be allowed to proceed. The final rule should explicitly state that FDA will not interfere with the distribution of that part of a shipment that is not subject to a detention order.

Indeed, IFDA believes that in any instance in which FDA has administratively detained product on a conveyance, the detention order should include provisions for the product's immediate removal to secure storage. Biosecurity could be seriously undermined if suspect product remains on a conveyance. Removal of a product from a conveyance to secure storage should be one of the bases

on which a claimant may seek a limited conditional release under proposed 21 C.F.R. § 1.381(c). The final regulation should include a provision so stating.

It is vitally important that FDA not inadvertently tie up the free flow of safe goods in the United States by imposing restrictive administrative detentions that immobilize the conveyances that transport food products. Manufacturers, warehousers, shippers, and distributors cannot afford to have their trucks, rail cars, and vessels embargoed because they contain or contained a suspect product. IFDA believes FDA's final regulation should clarify that the agency will administratively detain only the suspect product, and not the conveyance on which it is traveling.

IFDA assumes, of course, that products and the conveyances carrying them should proceed only so long as the suspect product has not contaminated the conveyance and any other non-detained product in the shipment.

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IFDA thanks FDA for this opportunity to comment on the proposed rule.

Sincerely,

David French

David French
Senior Vice President, Government Relations