IFDA
international foodservice distributors association

CONNECTING THE FOODSERVICE INDUSTRY

December 23, 2003

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

Re: Registration of Food Facilities; Docket No. 02N-0276;
Prior Notice of Imported Food; Docket No. 02N-0278

The International Foodservice Distributors Association (IFDA) appreciates this opportunity to submit comments to the Food and Drug Administration (FDA) on the agency's interim final rule requiring registration of food facilities. 68 Fed. Reg. 58,894 (Oct. 10, 2003).

IFDA is a trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 135 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 appreciates the effort FDA has made to take into account the needs of the food industry in developing the interim final rule. We believe a few further modifications and clarifications would help minimize the burden of the registration requirement on the food industry without compromising the goals of registration.

1. **The definition of an exempt "retail food establishment" should be modified to provide that an establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers during any of the preceding three years, or an average of the preceding three years.**

2002N-0278 C252

201 Park Washington Court • Falls Church, VA 22046-4519 • P: 703/532-9400 • F: 703/538-4673 • Web: www.ifdaonline.org

The interim final rule defines a "retail food establishment" as an establishment that sells food directly to consumers as its primary function. An establishment's primary function is selling food directly to consumers if the annual monetary value of its sales of food products directly to consumers exceeds the annual monetary value of its sales of food products to all other buyers. 21 C.F.R. § 1.227(b)(11).

For some retail food stores, such as "cash and carry" stores, the balance between sales of food directly to consumers and sales of food to commercial customers in any given year may be very close. To avoid a situation in which a retail establishment may yo-yo back and forth across the threshold, being required to register one year and exempt the next, IFDA requests that FDA modify the definition of "retail food establishment." We request that, for purposes of determining whether the annual monetary value of sales of food directly to consumers exceeds the annual monetary value of sales of food to all other buyers, the establishment may use any of the preceding three years or an average of the preceding three years.

2. **FDA should confirm that warehouses that hold only meat food products, poultry products, and/or egg products are exempt from registration.**

The interim final rule provides that facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) are exempt from registration. 21 C.F.R. § 1.226(g). FDA states that facilities that manufacture/process, pack, or hold only meat food products, poultry products, and/or egg products qualify for this exemption. 68 Fed. Reg. at 58,903. However, facilities jointly regulated by FDA and USDA are not exempt.

This raises a question that FDA has not definitively resolved. Warehouses that hold only meat food products, poultry products, and/or egg products are under the concurrent jurisdiction of FDA and USDA. However, FDA's statements in the preamble to the interim final rule suggest that FDA intends to exempt such warehouses from registration. IFDA requests that FDA confirm that warehouses that hold only meat food products, poultry products, and/or egg products are exempt from registration.

3. **FDA should respond to inquiries as to whether a specific facility is registered with FDA.**

It is essential that foodservice distributors be able to confirm that their suppliers' non-exempt facilities are registered with FDA. IFDA understands that the Bioterrorism Act prohibits FDA from making publicly available any information that discloses the identity or location of a registered facility. 21 U.S.C. § 350d(a)(4). However, we believe it should be possible for FDA to respond to a yes or no inquiry as to whether a specific facility is registered.

4. **FDA and CBP should issue a joint guidance document explaining their procedures for holding food at the port of entry.**

If an article of food offered for import is refused admission under § 801(m)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) for inadequate prior notice or is held under § 801(l) because it comes from an unregistered foreign facility, such food may be held at the port of entry until adequate prior notice is submitted or the unregistered facility registers with FDA. Such food will become general order merchandise under Bureau of Customs and Border Protection (CBP) regulations. FDA has stated that "general order merchandise must generally be held in a general order warehouse," but that "Customs regulations also empower the port director, if merchandise requires specialized storage facilities that are unavailable in a bonded facility, to direct the storage of the merchandise by the carrier or by any other appropriate means." 68 Fed. Reg. 58974, 59019 (Oct. 10, 2003). Moreover, "FDA agrees that appropriate storage and holding conditions must be considered for perishable and frozen foods refused for inadequate prior notice." *Id.*

IFDA requests that FDA and CBP jointly issue a guidance document explaining in greater detail how they intend to hold and store articles of food refused admission into the United States. While IFDA appreciates FDA's statement that perishable foods held at a port of entry should be held under appropriate storage conditions, we would appreciate a more formal statement of policy.

IFDA thanks FDA for this opportunity to comment.

Sincerely,

David French RAH

David French
Senior Vice President, Government Relations