International Warehouse Logistics Association

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July 8, 2003

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0275 (Administrative Detention)

To Whom It May Concern:

The International Warehouse Logistics Association (IWLA) welcomes this opportunity to submit comments with regard to the regulation proposed by the U.S. Food and Drug Administration (FDA) entitled "Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness Act of 2002."

IWLA is an international association of companies that provide public and contract warehousing and related logistics services. Public and contract warehousing represent 18% of America's $100 billion warehouse industry.

A significant number of IWLA members in the United State and Canada provide food grade warehousing and related third-party logistics services to manufacturers, wholesalers, distributors and retailers of food products. Food grade warehouses operated by IWLA members meet or exceed all U.S. and Canadian federal, state and territorial requirements for the storage of raw materials, ingredients and finished food products.

Most, if not all, food grade public and contract warehouses provide additional services to their customers. These value-added services include labeling, picking and packing, packaging, bar coding, etc. It should be emphasized that such services do not involve direct contact with the food. Contamination is not likely as the actual package is never unsealed. Rather, the warehouse will receive the food product for a finite period of time after which it will ship the product per the instruction of its customer.

Administrative Detention

Although the International Warehouse Logistics Association and its membership is committed to securing the nation's food supply chain, it maintains that the proposed

2002N-0275 C44

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regulation does not adequately recognize the roles and relationships that different entities within the supply chain have with the detained food at issue. For example, the owner of the product has a unique interest in the food product that is different from that of a public warehouse or carrier. It is crucial that FDA acknowledge the different relationships so that it might better identify the obligations and responsibilities of each respective entity as it pertains to the administrative detention of food product. In so doing, the Association requests that FDA address the following procedural questions in the final rule.

1. Who is responsible for paying for storage, handling, security, transportation and other charges during the detention period? (initially and/or at secure facility)

Although one would consider it appropriate for the Administration to detain product that may present "a threat of serious adverse health consequences or death", the proposed regulation makes no reference as to who is responsible for paying costs associated with the detention such as storage, handling, etc. Furthermore, the proposed regulation does not adequately address the legal and financial responsibility for food that ultimately must be disposed as a result of the threat it presents. Logically, one would assume that an entity with a vested interest in the product, e.g., the owner, would bear such responsibility. FDA should address this significant issue in light of the potential costs. At a minimum, failure on the part of the food product owner to pay storage, handling and related costs should be considered a violation of the Federal Food, Drug, and Cosmetic Act.

2. What constitutes credible evidence and/or information serving as the basis for product detention?

The Act states that "[a]n officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has *credible evidence or information* indicating that such article presents a threat of serious adverse health consequences or death to humans or animals." What constitutes credible evidence and/or information serving as the basis for product detention? Although the proposed regulation identifies the evidentiary standard in a broad sense, it would be helpful for FDA to develop guidance, identifying specific factors and/or scenarios that would automatically subject the food to detention. Is the FDA suggesting that carriers, warehouses and others in the supply chain process adhere to specific security standards? If so, such standards should be clearly identified.

3. Who is responsible for paying for the costs incurred in marking and/or labeling the detained food?

Although the importance of identifying product subject to detention is not disputed, the Administration must recognize that costs will be incurred in performing the marking and/or labeling as well as any necessary removal of labels. Although the proposed regulation outlines a cost assessment, it would be appropriate for FDA to

address financial responsibility for performing this function. As highlighted in question #1 above, it would be appropriate that an entity with a vested interest in the product be held fiscally responsible. As suggested above, failure on the part of the food product owner to pay storage, handling and related costs should be considered a violation of the Federal Food, Drug, and Cosmetic Act.

Cost of the Proposed Regulation on the Regulated Community

As highlighted in the questions above, it is clear that FDA has not adequately considered the cost of the proposed regulation on the regulated community.

1. Although the administrative detention process is modeled after FDA's medical device administrative detention regulation, the Agency must recognize that detention of food presents unique concerns and requirements in light of the perishable nature of many food products. Medical device and food contexts may differ with respect to a number of potentially relevant issues, such as the type and amount of products on the market, the types of problems associated with those products, and the type and level of information that FDA requires and receives. Can FDA realistically accommodate administrative detention appeals in a timely manner? When identifying the detention and appellate timeframes, the Agency must consider the logistical requirements (placing shipping orders, transportation and other distribution requirements) in evaluating the potential shelf life and value of the food product. In accordance with the proposed rule, FDA is required to issue a decision on an appeal confirming or revoking detention within 5 calendar days after the date the appeal is filed. Is 5 days sufficient? From a logistical standpoint, can perishable product still be consumed?

2. The proposed rule states that FDA "assumes that these warehouses [third party public warehouse] would provide proper storage conditions to maintain the safety and wholesomeness of the food" and that using warehouses should provide some additional security because the owner of the food relinquishes custody of the food to the warehouse. It would be beneficial for FDA to identify any specific security requirements for storing detained product. Furthermore, nothing in the proposed regulation should be interpreted as elevating the warehouse's duty of care beyond that identified in the Uniform Commercial Code as to do so will jeopardize the warehouse's insurance coverage.

The Association appreciates the opportunity to comment on this proposed regulation.

Sincerely,

Joel Hoiland

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