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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0276

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 "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness Act of 2002."

IWLA is an international association of companies, which provide public and contract warehousing and related logistics services. Public and contract warehousing represent 18% of the \$100 billion warehouse industry. Contract warehousing is the fastest growing segment of the logistics industry and is expected to grow at a rate of 12 to 15 percent over the next two years. Public warehousing is also expected to grow by a rate of 6 to 8 percent during that time.

The distinction between a public warehouse and a contract warehouse facility is that the public warehouse provides short-term storage on a month-to-month basis and the contract warehouse provides long term storage, based on minimum pallet positions or minimum square footage. Many public and contract warehouses also provide bonded space that meets the requirements for bonded warehouse facilities under U.S. and Canadian Customs laws.

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. Such services, however, do not involve direct contact with the food. Contamination is not likely as the actual package is never unsealed. A warehouse, for example, might handle cereal products that arrive on pallets or in cartons. The pallet might be broken down or the shipping carton unsealed. But there would never be occasion to open the cereal box or the internal packaging. The warehouse might, however, select three different boxes of cereal to combine into a special retail package. Or, as another example, a

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warehouse might relabel a soup can but would never open and refill a soup can. The customer however, requires the warehouse to track code dates/production codes out of the original cases into the new package format. That is done routinely for "track and trace" purposes. Typically, major food customers require regular "recall" drills to demonstrate that within a few hours a warehouse can report where any particular lot of product has been shipped.

Registration

The registration requirement first raises many procedural questions which we urge be addressed in the final rule and associated guidance materials:

- Whether a single registration can be filed by a parent company on behalf of all subsidiary/member companies.

- Whether a particular status (i.e., owner, lessee, operator/admin. or agent, etc. of the facility) triggers a responsibility to file a registration form on behalf of the subject facility, whether it is a mutual responsibility, or whether it can be allocated through contract.

Optional Items Included in the Registration

FDA proposes to include several optional fields on the actual registration form, including the type of storage or manufacturing facility. If a facility is "solely a warehouse" it has the option of completing a simplified description of the type of warehousing provided: "ambient storage;" "refrigerated storage;" and/or "frozen storage" [Section 10 of the draft form]. Such a facility is not required to submit the detailed breakdown of the general food categories stored in the facility, as required in section 11 of the draft form.

This simplified option avoids the need to determine and track food categories for virtually thousands of different food items that enter or leave the warehouse. Not only would this be a complex exercise for warehouses, who utilize a much different tracking system, but it also would clutter the FDA with additional detailed data that yields no measurable enhancement in food safety. Practically speaking, a food grade warehouse may handle thousands of different food items with constantly changing product mix, making it extremely difficult, if not impossible, to continually update the registration. Therefore, the simplified option for warehouses is a sensible and welcome feature of the FDA draft form.

There is a need, however, to define what is meant by "solely a warehouse." Most, if not all, public and contract food warehouses also provide ancillary services that include labeling, relabeling, packing, and repacking. But the warehouse typically provides these services without in any way changing, contacting or doing anything at all to the actual food product. The warehouse never "goes inside" the primary

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packing, thus avoiding any potential for contamination. In our industry, these services are incidental to the core function of storing and handling and are performed strictly under the direction and control of the customer.

We recommend that the term "solely a warehouse/holding facility" be defined in the final rule to include "a facility that provides storage of food products and neither engages in manufacturing nor processing of the food products, except for incidental services that do not involve unsealing the primary food container." Examples of these incidental services include: applying a retailer's label to a can of soup, combining bags of potato chips into special retail packs, or adding/removing promotional materials (rebates, coupons, etc.).

The reference to incidental services will distinguish these services from the establishment types in Section 9 of the proposed registration form – "repacker/packer" and "labeler/relabeler." Without such a clarification of the definition of "solely a warehouse/holding facility," the simplified option for warehouse facilities would be of little benefit to either the industry or the FDA.

Further, we recommend that the use of the term "repacker/packer," whenever used in the rule be defined as a facility engaged in packing of the actual product itself into the primary container either for direct human consumption or for further processing, rather than any other kind of packaging change (labeling, display building, etc.).

We also urge the FDA to clarify what is meant by the term "animal food holder" in Section 9 and how this differs from a warehouse/holding facility.

Foreign Facilities

The FDA proposes to require registration by foreign facilities that conduct a significant activity with respect to the food, starting with the last manufacturer/processor involved, and ending with the last facility before the food is shipped to the United States. The following examples of which facilities would be subject to, or exempt from, the registration requirement are provided in the preamble to the proposed rule at 68 FR 5380.

(1) A foreign facility would be required to register if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.

(2) A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be required to register, unless the further manufacturing/processing entails adding labeling or other de minimis activity. If the further manufacturing/processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility immediately prior to it would be required to register.

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(3) The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be required to register, even if the food subsequently is held or stored at a different facility outside of the United States. FDA is proposing to require these manufacturers/processors to register because the Bioterrorism Act exempts a foreign facility from registering only if another facility subsequently processes or packages the food.

(4) Facilities located outside the United States that take possession, custody or control of finished foods for holding, packing, and/or storage prior to export to the United States, would be required to register.

These examples raise several questions for foreign public and contract warehouses that can be resolved by the following recommendations.

1. A warehouse/holding facility located outside the United States that takes possession, custody or control of food (as defined in section 201(f) of the act) for holding, packing, and/or storage **immediately** prior to export to the United States, would be required to register. By adding the word "immediately" it is clear that the registration requirement only applies to those warehouse/holding facilities that hold or store the food product at the last point in the supply chain before shipment to the United States.
2. A warehouse/holding facility located outside the United States, but within North America, is solely a warehouse/holding facility for registration purposes if the facility provides storage of food products and neither engages in the manufacturing nor processing of the food products, except for incidental services that do not involve unsealing of the primary food container."

These changes would ensure consistency between U.S. warehouses and foreign warehouses.

The proposal requires a foreign facility to designate a U.S. agent and permits the agent to register for the foreign facility. We agree with FDA's recommendation in the proposal that the U.S. agent and foreign facility enter into a written agreement specifying the U.S. agent's responsibilities. Additional guidance from the FDA as to what these responsibilities should entail would be helpful.

Imports

The proposal in § 1.241 requires if an article of food is imported or offered for import and a foreign facility that manufactured/processed, packed, or held that food has not registered in accordance with this subpart, the food must be held at the port of

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entry unless FDA directs its removal to a secure facility. If FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a bonded warehouse, container freight station, centralized examination station, or another appropriate secure facility approved by FDA.

It is reasonable to detain food products entering the United States from a foreign facility that is not properly registered at a port of entry or secured facility until the foreign facility has submitted its registration to FDA. However, the proposed rule does not adequately address responsibility for payment of storage, transportation and other charges incurred as a result of such product detention. The rule should specify responsibility for payment of such charges. Since FDA will make the determination as to what product is to be detained, FDA should assume responsibility for paying such charges and seek reimbursement from the entity that failed to register with FDA. Any entity providing a service function, e.g., storage, transportation, etc., should not have to absorb such costs. In the case of the warehouse, it would have no tangible, possessory interest in the goods, and no means of securing reimbursement if the product becomes "abandoned."

Because of the potentially large amount of food products that will arrive at a port from unregistered food facilities, we recommend that the rule require removal to a secure facility within 24 hours of arrival at the port. Keeping the product at the port for any longer period of time presents security problems, as well as the potential for inadvertent contamination.

We agree with FDA's decision in the proposal to include bonded warehouses, container freight stations and centralized examination stations as secure facilities. In addition, we recommend that the list of secure facilities include registered food grade warehouses where product can be stored under an FDA Hold. In the warehouse industry, product is placed on "Hold" electronically in the inventory system and it is placed on "Hold" physically in the warehouse by way of placards. To avoid any confusion, however, the final rule should clarify that such facilities must demonstrate compliance with applicable FDA and USDA food sanitation standards. We also recommend that either in this rule or in a subsequent rule, FDA outline the process by which a bonded warehouse, container freight station, or centralized examination station can become eligible to be a secure facility for purposes of this rule.

Additional Comments

FDA needs to ensure strict confidentiality in the registration process. FDA must guarantee that the registration list and all derivative information shall be protected from public disclosure; the confidentiality should be particularly safeguarded with respect to personal (i.e., home and cell telephone) information.

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FDA should coordinate this registration requirement with states that have already promulgated their own registration requirements, so as to minimize duplicative filings (perhaps make the Federal registration preemptive). FDA should also coordinate the registration requirement with Customs Trade Partnership Against Terrorism.

On behalf of the members of the International Warehouse Logistics Association, thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Joel Hoiland". The signature is written in a cursive, flowing style.

JOEL HOILAND
President and CEO