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TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
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FR: Tom Lovelace
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RE: [Docket Number 02N-0277] Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Fresh Express respectfully submits the following comment regarding the proposed regulations for the establishment and maintenance of records as provided under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Act").

We take the issue of potential terrorist acts against the food supply and food security very seriously. We have instituted measures in security awareness and practices for all our processing locations.

The current proposed recordkeeping requirements will substantially impact food costs by requiring substantial and significant modifications in current practices, while it may potentially only marginally enhance food security. Although records are currently kept pursuant to other federal and/or state regulations, as well as business reasons, the added requirements create a significant added burden.

If you have any questions or would like to discuss submitted Fresh Express comment further, please feel free to contact me at (817) 849-3421.

Very truly yours,

Tom Lovelace
Chief Executive Officer

02N-0277

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Relevant Background

Fresh Express is the share leader of the value-added ready-to-eat fresh salad category and operates in both the retail and foodservice segments. In all, Fresh Express offers retail and foodservice customers over 500 separate food items manufactured in six strategically located facilities in the United States. Fresh Express pioneered the packaged salad category at retail and continues to lead the industry in technological, product and food safety programs and innovations. As our core mission, Fresh Express strives to provide consumers and customers with the highest quality, freshest and safest products possible in the marketplace.

We offer the following comments for consideration in establishing the regulations for the establishment and maintenance of recordkeeping requirements:

1. Statutory Requirements

The purpose of the authority for records are clearly specified in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Act"). FDA is provided under the Act, upon reasonable belief of credible evidence, the authority to: 1) determine whether a suspect food product poses a threat of serious adverse health consequences; and 2) to trace the distribution and recovery of any foods that meet that standard. Only recordkeeping or access requirements that accomplish those objectives are authorized by the Act.

The Act provides that the FDA "may" provide recordkeeping regulations. The Act does not mandate that the FDA must establish regulations for recordkeeping. The Act also provides that the recordkeeping requirement applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of an article maintained by or on behalf of such person in "any format (including paper and electronic formats) and at any location". FDA has recognized that it does not have the authority to establish the form or manner of the records. The FDA thereby proposes to establish requirements for information needed to trace the transfer of food but not the form or type of recordkeeping.

Recommendation:

We agree with the FDA position that the proposed regulations should describe specific information that must be kept to accomplish the purpose of the Act, but not specify the form or type of systems in which those records must be maintained. The regulations should give businesses the flexibility to use existing recordkeeping systems and also to store records in the manner they find most efficient and effective.

Further, the FDA should harmonize with other federal departments and agencies with responsibilities for regulating food, such as PACA, in establishing rules and regulations for recordkeeping procedures in order to lessen the burden to the food industry for recordkeeping practices.

2. Standard of Investigation Requirements

The proposed regulations establish a "reasonable belief" standard similar to the administrative detention provision. Specifically, if the Secretary has "reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly

designated by the Secretary... permit access to and copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals." The term "reasonable belief" is vague, discretionary and open to interpretation.

Recommendation:

- a. Specific guidelines should be developed to clearly define what is considered "reasonable belief" and to assure that a clear and present threat or danger exists. In particular, the FDA should have clear evidence such as laboratory analysis to confirm the presence of an adulterant and/or affidavits sworn to under penalty of perjury. "Reasonable belief of credible evidence or information" should be similar to a "probable cause" standard and be based on more than mere speculation or an anonymous telephone tip.
- b. Similarly, specific guidelines should be developed to clarify that the access to records authorized under the Act should not be required to be made available during the course of normal, routine inspections.

3. Notification for Request to Review Records

The Act provides that FDA will have authority to access upon written notice to such person, at reasonable times, and within reasonable limits, and in a reasonable manner to have access to records to identify potentially violative product. However, the proposed regulation does not clarify how or to whom the request shall be delivered.

Recommendation:

- a. Procedural safeguards should be put in place to protect manufacturers and their customers from the undue burden of providing access and copying of records. It is recommended that the proposed regulations establish assurance that reasonable written notice be required to be provided by the inspector, accompanied by personal service upon the "responsible individual" at the specific individual, location. The written notice should also contain an explanation detailing how the "reasonable belief" standard is met.
- b. Further, the term "responsible individual" should be clarified to ensure that sufficient procedural safeguards are in place when the FDA desires to exercise its authority to review the records pursuant to the Act. The responsible person should be identified as a specific person of authority, such as the owner or plant manager located at the specified site.
- c. Specific guidelines established to identify what records are to be made available under the regulations as authorized under the Act. The Act provides that records be kept to identify the immediate previous source and immediate subsequent recipient of the food.
- d. Specific guidelines established for an opportunity to object to the records review for a period prior to access of the records.

4. Availability of Records

- a. The proposed regulations provide that records be made available within 4 – 8 hours of a request. The FDA itself has stated that this is a very shortened time

compared to what the FDA has experienced during its investigations. The shortened access time requirement is not practical and will impose a burden and additional costs, which will ultimately be passed on to and borne by the consumer.

Recommendation: Urge that the availability of records be changed to be at least within 24 hours after written request is delivered to the owner or person in charge of the facility being audited (Section 1.361).

- b. The proposed regulations require that the records be maintained at the site where the activities described in the records occurred or at a reasonable accessible location (section 1.360(e)). FDA states that it recognizes that there may be more records than available storage space at the location where the activities occurred and proposes that records may be stored offsite, provided that the records be made available within the time period prescribed in the regulations.

Recommendation: We agree with the FDA that the records may be maintained either at the location site of the activity or at an off-site location, so long as the records are made available within the prescribed timeframe.

5. "Perishable Food" Definition.

Harmonize the Bioterrorism regulations with the other current regulatory provisions such as PACA for Perishable Foods, where available. In particular, clarify and expand the definition of "Perishable Food" to coincide with the existing regulations provided under PACA.

Recommendation: The definition for "Perishable Food" should include all fresh fruits and vegetables of every kind and character where the original character has not been changed. The effects of the following operations **shall not** be considered as changing a commodity into a food of a different kind or character: water, steam, or oil blanching; chopping; color adding; curing; cutting; dicing; drying for the removal of surface moisture; fumigating; gassing, heating for insect control; ripening and coloring; removal of seed, pits, stems, calyx, husk, pods, rind, skin, peel, etc.; polishing; precooling; refrigerating; shredding; slicing; trimming; washing with or without chemicals; waxing; adding of sugar or other sweetening agents; adding ascorbic acid or other agents used to retard oxidation; mixing of several kinds of sliced, chopped, or diced fruits or vegetables for packaging in any type of containers; or comparable methods of preparation. (For example, fresh iceberg lettuce, romaine and carrots would be included, as well as fresh-cut and packaged salads; fresh green beans would be included; frozen or canned green beans would not; fresh oranges would be included; frozen concentrated orange juice would not.)

6. Clarify the Term "Responsible Person"

The FDA proposes that each shipment of product identify the "responsible individual" for the nontransporter and the transporter, for both the immediate prior source and immediate subsequent recipient. We have serious concerns with the practical effect of this proposed requirement. It is impractical and extremely burdensome to identify the "responsible individual" on every commercial transaction. In particular, it is vague and confusing as to who would be the "responsible individual" for the transporter, whether the owner/manager of the company or the driver of the truck. We further question the need for both the manufacturer who ships the

food and the third-party warehouse or wholesaler who receives it to retain such detailed information about the transporter of the food.

Recommendation: We urge that the requirement to identify the "responsible individual" be eliminated as a recordkeeping requirement on each commercial transaction. The FDA should utilize the information obtained through the facility registration requirements to best identify the "responsible individual" for each company and each of its locations. To require the shippers and receivers to maintain these records is not only burdensome and redundant, but also runs the risk of having outdated or conflicting information.

7. Tracking Outer Packaging

Although this requirement was stated in the Act, the FDA has taken a position that there is minimal likelihood of contamination of the outer packaging, which is not high enough to warrant regulation. The burden of recordkeeping and tracking outweighs the minimal benefits to be expected.

Recommendation: We agree with the FDA position that the level of risk for potential contamination of outer packaging is minimal and not high enough to warrant inclusion of outer packaging in the final regulations. We therefore urge that this requirement be excluded from the regulations.

8. Segregation of Each Product

Proposed section 1.337(a) may be construed to require maintenance of lot-by-lot distribution and receipt records, which would require development of expensive new recordkeeping systems throughout the food industry without improving public health protections. This regulation would be impractical and significantly burdensome.

Recommendation: We urge that the FDA eliminate the requirement for segregation of each product, or at the minimum develop guidelines that require capturing the information that is reasonably available to connect the finished product with its source.

Thank you for the opportunity to comment on the proposed regulations.

Respectfully submitted,



Tom Lovelace
Chairman and CEO