David W. Spence
Managing Director
Regulatory Affairs
Legal

3620 Hacks Cross Road
Building B, 3rd Floor
Memphis, TN 38125

US Mail PO Box 727
Memphis, TN 38194-7103

Telephone 901 434 8578
Fax 901 434 9289
Email dwspence@fedex.com

FedEx Express

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

RE: Federal Register ("FR") notice published Oct. 10, 2003, Registration of Food Facilities, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. Law 107-188, 116 Stat. 594, Docket No. 02N-0276 (the "Bioterrorism Act" or the "Act")

Dear Sirs/Madams:

These comments are submitted on behalf of Federal Express Corporation ("FedEx") in response to the Food and Drug Administration's ("FDA") Interim Final Rules for registration of food facilities as published in the FR notice referenced above.

FedEx supports the intent of the Bioterrorism Act, and the concept of facility registration for actual food processing and storage facilities; however, we believe that the Interim Final Rules ("IFRs") as published misconstrue Congressional intent and are inappropriately broad, which will impose overly burdensome requirements on the express carrier industry and in some areas will not serve the FDA's stated purpose.

The notice summary states that registration "..." is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be affected by the outbreak." We submit that the FDA's requirement for registration of transportation providers' stationary facilities, i.e., terminals, stations, hubs, etc., does not serve any of these purposes, and in fact is beyond the intent of Congress in preparation and passage of this legislation.

The comments and responses in the FR notice make it clear that "transport vehicles" are exempt from registration, while "stationary facilities that serve to assist transporters are required to register *because they hold food*" (emphasis added). "Facilities" are defined in IFR §1.227(b)(2) as "any establishment, structure, or structures at one general physical location". "Holding" is

defined in IFR §1.227(b)(5) as "storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks."

Transport vs. Storage

The simple issue is that express carriers do not "hold" any shipments. FedEx is in the business of *moving* shipments, and as for all express carriers, as quickly as possible to meet a time definite delivery commitment, commonly overnight from shipper to consignee. No portion of this express transportation movement constitutes holding, whether by actual function or by FDA's regulatory definition. Note that the examples cited by FDA in defining "holding" in the IFR have a common theme, that being intended storage or restraint from movement. We submit that the service targeted by Congress is one involving non-movement pending some future action, whether transportation to another location or manufacturing/processing in a true food processing facility. This is the simple and critical distinction between "holding" and a temporary pause in movement of a shipment being transported from a shipper to a consignee under terms of a carrier bill of lading or contract of carriage. A pause in movement does not constitute "holding". No shipment under transport is always at movement, and it is a rare shipment that is delivered to the consignee in or on the same transport vehicle utilized at the initial movement from the shipper. Movement of individual shipping pieces on and off transport vehicles, in and out of carrier facilities, is a normal part of a carrier's business, and does not constitute "holding". In the event that a transport provider may offer services beyond that of transportation, e.g., storage or warehousing, or when food shipments may be stored by that carrier, those facilities would clearly require registration. The distinction is in the desired service, whether transportation or storage.

Fedex has a variety of facilities with an assortment of automation. Some facilities are so highly automated that a shipment is never at rest from the moment it enters the facility until it departs the facility. By a literal interpretation of the definition in the IFR, those facilities would not be required to register since no holding occurs. Even in lesser-automated facilities, individual consignments and packages are stationary only in connection with the normal course of providing transportation service to the customer. Such occasional non-movement does not constitute holding as defined in the IFR, and express carrier facilities should clearly be exempted from facility registration.

- The comments and responses in the FR notice also make reference to H.R.Conference Report No.481, 107th Congress; however, we believe that FDA has in fact interpreted the contents of this report incorrectly. Section 305, page 134 of this report states that ... "the managers intend that, for purposes of this section, 'facility' does not include trucks *or other motor carriers, by reason of their receipt, carriage, holding, or delivery of food in the usual course of business as carriers."* (emphasis added). There are several aspects in this statement that lead only to the conclusion that registration of carrier facilities utilized in their normal course of business was not intended by Congress. Fedex submits that Congress intended to address the business of motor transportation and not the operation of individual trucks, planes, and rail vehicles.

Individual Facility Registration Serves No Purpose

As stated in the summary of the IFR, FDA intends to be able to respond quickly in the event of an attack on the U.S. food supply, and to notify quickly the facilities affected by such an outbreak. In fact, registration of thousands and thousands of carrier stationary facilities does not facilitate or accomplish this goal. Carriers have no direct function in the manufacturing, processing, packing, or holding of food articles, and therefore will not be part of the supply chain data provided or available to the FDA. That is, in the event of a foodborne illness, the FDA will, at best, be able to determine what carrier picked up and moved an affected food article from a genuine food facility. The FDA will not be able to determine from this supply chain information what facility or facilities the carrier utilized in transporting the shipment. A carrier with tracking and tracing capability will be able to determine this detail with a tracking number, e.g., a truck pro number or air waybill number, which is essential to making that determination. A shipment history can be determined from the tracking number, and a shipment in transit can be located and stopped by utilizing the shipment number and the carrier's tracking number, but a shipment cannot be located by facility. Therefore, registration of individual facilities is meaningless and inefficient with respect to the goal of being able to respond quickly to an outbreak of some kind.

If the FDA is in fact seeking to obligate carriers to a statutory requirement of the Bioterrorism Act, this could be far more easily attained at a corporate level than by registering hundreds or thousands of facilities. If FDA is seeking carrier cooperation to locate, isolate and control a shipment or shipments suspected of being contaminated, the simplest and most effective way is a single, corporate registration that would fulfill this obligation, rather than expending valuable time and resources on submitting and maintaining facility registration for thousands of facilities.

Holding vs. Transportation

The Final Guidance on Registration of Food Facilities issued by FDA in December 2003 includes specific questions about registration of personal residences where commercial activity is taking place. FDA's conclusion is that personal residences that hold affected food articles for commercial purposes are exempt from registration merely due to being a personal residence. The IFRs state that "[t]he private residence of an individual is not a facility" for purposes of registration under these rules. We submit this conclusion is inequitable and inconsistent with FDA's conclusion that motor carriers' stationary facilities are required to register merely on the basis that shipments in transport may occasionally come to rest on a temporary basis. If FDA can exempt a personal residence from registration, even when holding of commercial food articles occurs at that location, then it is similarly logical that carrier facilities should also be exempt from registration, since at best, food shipments may occasionally come to rest on a temporary basis, and then only in connection with the carrier's normal course of business. To reiterate our recommendation, express carriers – and perhaps all motor carriers – should be exempted from the requirement to register stationary facilities utilized in the normal course of transportation business.

FDA Should Clarify What is Expected from Carriers

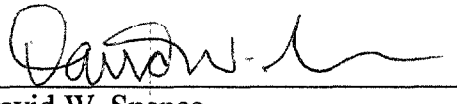
There is some question about what information might be provided to a carrier regarding a suspected shipment, i.e., to locate the suspect shipment in the carrier's operation. The most useful information to a carrier would be the pro or tracking number, or the Customs entry number for an imported shipment. Carrier facility information would not be available to the FDA until after the carrier researches a specific shipment and identifies what facilities were used, and where the shipment might be if still in the carrier's custody. Again, this serves to verify the statement that registration of a carrier's physical facilities does not serve the FDA's stated purpose of being able to respond quickly or notify affected facilities of an outbreak. FDA will not be able to notify any carrier "facility", as they simply will not be able to determine what facility to notify. Only the carrier can make that determination from research through the pro or tracking number.

Conclusion

As stated previously, FedEx supports the concept and intent of the Bioterrorism Act, and certainly supports improved safety and integrity of the U.S. food supply. However, we do not believe that "motor transport" physical facilities should be required to register as "holding" facilities for food, or that registration of such facilities serves the FDA's stated purpose.

Sincerely,

FEDERAL EXPRESS CORPORATION



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