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VIA FEDEX PRIORITY OVERNIGHT

July 12, 2004

U.S. Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD, 20852

RE: Docket No. 2002N-0278, Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness Act of 2002 (the Act). Additional comments accepted through July 13, 2004.

Dear Sirs/Madams:

Federal Express Corporation ("FedEx") has submitted comments on this issue previously, and would like to take the opportunity of an extended submission period to submit additional comments. FedEx is primarily concerned with three areas of the Prior Notice provisions, including the extremely narrow restrictions contained in the June 24, 2004, revisions to the Prior Notice Compliance Policy Guide (CPG) concerning "non-commercial shipments" of food items.

The focus of the June 24 CPG revisions was on personal consignments of food commodities. The revision to the CPG shows that such consignments remain subject to Prior Notice when sent from a business, even though Prior Notice would not be required for those same articles when shipped from an individual to an individual for personal, non-commercial purposes. This is an overly restrictive definition of a "non-commercial" shipment, which provides little, if any, benefit to the FDA in maintaining security of the American food supply or to the shipping industry handling these shipments. These shipments, by definition, are non-commercial, due to the simple fact they are purchased for personal use and not for resale. They should therefore all be exempt from Prior Notice requirements, regardless of whether or not shipped from an individual or from a business entity. The simple fact of direct shipping from a business should not constitute a commercial transaction for purposes of Prior Notice, just as an individual purchasing food for personal use at a grocery store and shipping it to another individual does not constitute commercial transaction. There does not appear to be any additional security of

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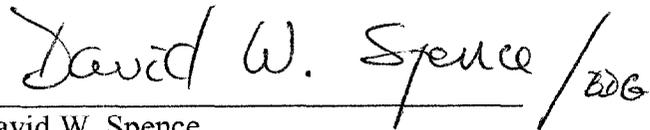
the U.S. food supply by defining a commercial transaction based on whether the shipper is a business or an individual rather than on the content of the shipment. Therefore, FedEx urges the FDA to review this interpretation and the definition of non-commercial shipments, and to define any consignment to an individual for personal, non-commercial use, as exempt from Prior Notice, regardless of whether the shipper is a business entity or an individual.

Additionally, small samples for testing and evaluation should be exempted from Prior Notice, as they are not in fact for consumption by human or animals. These shipments could be clearly labeled, on the documents and the product itself, for additional controls by the importer, consignee, and any party involved in the handling after import into the U.S., but they should be exempted from the requirements for Prior Notice. FedEx and all express carriers carry a high volume of low value shipments, both for personal use and consumption by individuals, and for laboratory testing and evaluation. Express carriers may in fact be the most affected segment of the global food supply chain due to the combination of a high number of low value shipments and the express industry core service of speedy, time definite service. The very short amount of time between tendering the shipment for movement and delivery to the consignee affords little time to submit Prior Notice. Therefore, we urge the FDA to include a provision in the Final Rule for food commodities entering the U.S. solely for the purpose of testing and evaluation.

Finally, FedEx urges the FDA to also exclude non-U.S. destination shipments entirely from the requirement for Prior Notice. The current double standard is difficult and confusing for all parties to administer, and serves only to interrupt and potentially delay completely legitimate shipments to non-U.S. destinations merely because they happen to transit multiple U.S. ports en route to the shipment destination. Given the fact that the shipment is in the custody of the express carrier at all times and given the security requirements for express carriers, this Prior Notice requirement for non-U.S. destination shipments that transit multiple U.S. ports does not provide additional security of the U.S. food supply, which was the intent of the Act. This Prior Notice requirement seems inequitable, especially considering the fact that many shipments will transit the U.S. without problem and without being subject to Prior Notice when exported from the same port of arrival, but on other days, will fall subject to Prior Notice merely due to carrier routing, equipment changes, weather, or other totally benign and unrelated reasons that have no impact whatsoever on the security or integrity of the food commodity.

FedEx agrees with the spirit and intent of The Act; however, we urge the FDA to infuse the regulations for Prior Notice with a greater degree of reasonableness. We look forward to the Final Rule and the positive changes that can be made to implement The Act with minimized negative impact to the global food supply chain.

Sincerely,

Handwritten signature of David W. Spence, with a horizontal line underneath the name and the initials "DWS" to the right.

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