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

December 22, 2003

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, Prior Notice of Imported Food, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. Law 107-188, 116 Stat. 594 (the "Bioterrorism Act" or the "Act"), Docket No. 02N-0278

Dear Sirs/Madams:

These comments are submitted by Federal Express Corporation ("FedEx") in response to the Federal Register notice referenced above, in which FDA has published Interim Final Rules ("IFRs") for Prior Notice ("PN") of food articles imported into the United States. FedEx supports the concept and intent of the Bioterrorism Act; however, we believe the FDA has severely misinterpreted the intent of the Act in several areas, and that the requirements of the Act could and should be administered more consistently with existing trade practices established in accordance with the U.S. Bureau of Customs and Border Protection ("CBP").

Scope of the Act

Fedex's first concern is about the scope of the IFRs, which are stated to apply to food articles for consumption, distribution, or storage in the U.S., but also covering "food for transshipment through the United States to another country...." Requiring PN for shipments not intended for any U.S. destination, even temporarily, appears to be beyond the statutory provisions of the Act. Title III, Sec. 307 of the Act covers PN, and states that PN is required for "...an article of food that is being imported or offered for import into the United States...." A shipment that merely transits the United States as an incidental part of the movement from a non-U.S. origin to a non-U.S. destination is not "imported or offered for import" into the U.S. Import is defined as "to bring in from a foreign country or another source", that is, for use in the destination country. There is a distinction between importing and transiting. A business entity that purchases from outside of that entity's country for use in the entity's home country is an "importer", i.e., one who imports. An imported shipment is one that has been brought into a country from external sources for use in the importing country. Clearly, a shipment transiting one country on its way to the destination country is not an imported shipment for the transiting country, but rather for the destination country. This simple issue is causing significant operational complications for

FedEx, and for many carriers whose shipments transit the U.S. while being transported between non-U.S. origins and destinations.

We submit that the IFR at §1.277 that requires PN for non-U.S. destination shipments is without statutory foundation, in that the Act clearly states that only shipments imported or offered for import to the U.S. are affected. Therefore, we recommend exempting shipments that merely transit the U.S. from the shipments that require PN.

Prior Notice at Port of Arrival vs. Port of Entry

The Act also allows FDA to consider many factors in promulgation of the regulatory provisions, including "effect on commerce", "locations of various ports of entry in the United States", and "various modes of transportation" (Title III, Sec. 307). By requiring PN at port of arrival, rather than aligning the PN process with long-standing, existing CBP clearance processes and infrastructures at the port of entry, FDA has not adequately considered either the effect on commerce or efficient use of various ports of entry in the United States.

FedEx, as do many carriers, utilizes legal and compliant CBP procedures to move shipments under Customs bond ("in bond") from port of arrival (POA) to port of entry (POE). This allows efficient use of expensive aircraft, capital structures, airport land, handling equipment and labor. The FDA rules that require PN at POA will result in severe disruption to our flight schedules, by requiring identification and verification of PN filing for all food shipments at POA, with the possible consequence of aircraft offload for any affected food shipment for which PN was not filed. This burden of PN verification at POA is inconsistent with a very complex system of in bond movement by all modes of transportation, utilizing a broad network of U.S. ports of entry. Simply put, the FDA PN requirement is inconsistent with the existing clearance processes of CBP and all other U.S. regulatory agencies. All carriers will be faced with significant increased costs to accommodate this practice if it is adopted as the final rule. We recommend that FDA allow PN at POE so that it may be efficiently incorporated into the clearance process, i.e., electronic entry data filed by a CBP broker or the importer themselves. PN can be filed in only one of two methods, either the FDA's internet based Prior Notice System Interface or CBP's ABI program. FDA's own estimate is that 80-90% of PN data will be filed by the ABI filer, so it is therefore logical that PN should be filed at the same port where clearance entry is filed. Requiring PN at a different port serves to unnecessarily complicate the process and force all parties involved to undergo operational convolutions in an attempt to accommodate FDA's specific procedures while not providing any additional security to the U.S. food supply. The cost to the trade to do this is significant, and perhaps incalculable. CBP and all ABI filers must modify their systems at great expense, new training will be required, new timing is required as PN may be required before the Customs entry may be legally submitted, and new levels of long distance coordination are now required, all due to PN being linked to POA vs. POE. This whole process could be made much simpler if it were merely linked to the ABI clearance entry filing at POE.

Prior Notice System Interface

The extensive data required to complete PN also makes the process difficult. Unfortunately, the shipper is not likely to have many of the required elements and will therefore not be able to utilize the FDA's Prior Notice System Interface (PNSI). The requirement for this data is the primary cause for 80-90% of PN data being filed by ABI. No party other than the U.S. entry filer, whether the broker or the importer themselves, will have all the data required to complete the PN. The only parties likely to be able to use the PNSI will be International Mail shippers, as the data elements required for mail are fewer than for all other modes of transportation. However, herein lies a recommendation that will in fact make the PN process more palatable for the industry, and provide far more advance notice to FDA for affected food shipments.

We recommend that FDA use the data required for International Mail shipments as a benchmark, and adopt the same level of data for all other modes of transportation. By eliminating such data as the Customs identifier (assumed to be the clearance entry), the Customs entry type, the port of entry, and other data such as tariff classification number and FDA product code, this would allow shippers to use the PNSI and therefore provide FDA with hours additional advance notice. The PN record could easily be started by the shipper with additional data added by the entry filer if required, such as the entry number and entry date, if FDA determines this data is required as part of the PN. The shipment tracking number, whether ocean or air bill of lading, or truck pro number, would allow interface and linkage to Customs entry data. FDA could also issue a PN confirmation to the shipper, as currently provided for mail shippers, to allow the U.S. entry filer to access the PN record and add additional data that might be required to complete the record. This is how the PNSI should work, and we strongly recommend that FDA consider this proposal very carefully, as we truly believe it will provide significant additional time for processing of PN data and would allow far easier implementation by the entire food importing industry.

PN Data Elements

The Act names only seven specific items that must be provided as part of Prior Notice. Adding identification numbers for other parties such as the U.S. clearance entry number, the carrier's bill of lading number, the customer's own reference number, etc., the total is still only 10-12 data elements. However, the FDA has chosen to ask for 26 or more data elements for each food article in a shipment, almost four times that required by the Act. We believe that the PN process could be made far simpler with little or no increase in risk, by reducing the data required for Prior Notice. Additional detail that might be required or desired by FDA could easily be extracted from the ABI entry data, or simply on demand from the importer, as required.

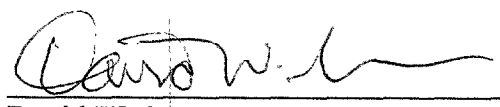
Conclusion

FedEx supports the intent of the Act and FDA's efforts to improve the safety and security of the U.S. food supply chain. However, we believe that shipments to and from non-US parties are

beyond the scope of the Act and should therefore be exempted from Prior Notice. Also, the data elements required for and method of providing Prior Notice should be simplified to allow for greater efficiency and ease of implementation, all of which is allowed by the statutory provisions of the Act.

Sincerely,

FEDERAL EXPRESS CORPORATION



David W. Spence
Managing Director
Regulatory & Industry Affairs