U.S. Global Trade Services
3650 Hacks Cross Road
Building E, 3rd Floor
Memphis, TN 38125-7433

Telephone 901.434.4262
Fax 901.434.4099

FedEx Express

July 31, 2006

Submitted via: http://www.fda.gov/dockets/comments

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

RE: Docket No. 2006N-0202, 71 FR 30940, May 31, 2006,
Notice for comments on Requirements for Prior Notice for Imported Food

Dear Sirs/Madams:

These comments are submitted by Fedex Express ("FedEx") in response to the FDA Federal Register notice requesting additional comments on the requirement for Prior Notice of food imported into the United States. FedEx handles regular shipments containing food items subject to the Prior Notice requirements, and we have worked closely with the Food and Drug Administration (FDA) since the inception of the Prior Notice (PN) rules. FedEx supports the intent of improved security and safety for America, and we appreciate the opportunity to submit additional comments to the FDA.

FedEx continues to believe that implementation of the PN regulations will require extended time due to the need to reach and educate the huge number of global vendors affected by these rules, and to secure required changes in the documentation procedures and business practices by all members of the global food industry. FedEx commends the FDA for their judicious use of enforcement discretion while PN is implemented; we believe it is totally appropriate for implementation of a regulatory change that is so broad in scope. Clearly, the number of shippers aware of the requirement for PN continues to increase, and many shippers have begun to incorporate it into their shipping procedures.

However, we also believe there are several sections of the collective PN regulations that can be improved, without compromise to the safety and security of the United States, as follows:

I. FDA Prior Notice System Interface (PNSI):
   a. PNSI is available only in English. PNSI should be made available in other languages to enable easier global access and improved compliance by shippers, many of who are not fully conversant in English.

b. PNSI requires internet access. Internet penetration is 65-70% in the leading countries, and only 10-20% in developing countries. A regular alternative must be developed for shippers in countries and regions where internet access is limited or unavailable.
c. PNSI is not practical for high volume shippers. PNSI requires lengthy sessions to submit the large volume of required data, rendering it cumbersome or impractical for high volume users. FDA should develop an alternative for high volume shippers, i.e. a method to allow "batched" or consolidated submission for multiple shipments, rather than per-shipment as presently required. A practical alternative for high volume shippers will increase the likelihood of timely PN, as the shipper can submit PN earlier via PNSI than a U.S. broker can by utilizing the CBP Automated Broker Interface (ABI) process.

II. PN should be integrated with the Customs and Border Protection (CBP) Advance Cargo Information (ACI) Program:
PN as currently defined requires far more information than is required by the Bioterrorism Act of 2002, and far more information than is necessary to protect the nation's food supply. PN in its current form is a cumbersome "agency-specific" declaration, and creates an unnecessary additional industry burden of time and expense to the shipping process. The May 31 Federal Notice contains an FDA admission that "...much of the information collected for PN is identical the information collected for FDA's importer's entry notice...". In addition, the data elements required by the Bioterrorism Act are included in the ACI data submitted to CBP. FDA could easily work with CBP and the importing community to align the PN program with the CBP ACI program so that PN data required by the Bioterrorism Act could be culled from ACI and delivered to FDA as necessary for separate PN analysis and risk assessment.

This point raises an important question: is it necessary for the PN data to be analyzed and evaluated separately by FDA, or can the pre-arrival security analysis be integrated into the CBP analysis of the ACI data? Understanding that FDA works closely with CBP in the analysis and evaluation of pre-arrival data for determination of risk, it seems reasonable that evaluation could be incorporated into the CBP ACI automated process, thereby eliminating the need for separate data submission to FDA, and eliminating the need for continued support of a separate FDA automated system. This would reduce costs for administration of the PN program, and potentially speed the process for review and analysis of all affected shipments. FedEx urges FDA to review and evaluate this recommendation closely.

III. Clarification of definition in the Interim Final Rule:
Country from which the article is shipped (1.276(b)(3)): The definition in the interim rule states this means "...the country in which the article of food is loaded onto the conveyance that brings it to the United States...". This definition fails to consider the normal and regular intermodal handling of

shipments by multiple modes of transportation, under which a shipment that actually originates in one country is commonly moved by one mode, e.g. truck, to another country, where it is loaded to another mode of transport, e.g. air, for movement to the United States. Thus, a more accurate term would be "exporting country" as currently used and defined by Customs and Border Protection. CBP defines "exporting country" as "that country from which the merchandise was shipped to the United States having last been a part of the commerce of the country and without contingency of diversion." FedEx recommends that FDA adopt the term and definition of "exporting country" to replace the current term "country from which the article is shipped".

IV. Exemptions:

FedEx recommends that the final rule for Prior Notice include exemptions for the following situations:

a. Low value shipments, commercial or non-commercial: FedEx recommends that shipments valued not over USD200 be exempted from the requirements for Prior Notice.
b. Non-commercial (personal use) shipments: FedEx recommends that FDA fully exempt all non-commercial food shipments from Prior Notice. Non-commercial shipments would include manufactured and/or purchased food items for the personal use and consumption by an individual purchaser or consignee.
c. Shipments transiting the U.S. to a non-U.S. destination: all such shipments should be fully exempted from PN, whether or not the shipment is exported directly from the port of arrival. The double standard now utilized for transiting shipments creates confusion on the part of foreign shippers and causes confusion for carrier operations in the U.S. Further, and perhaps more importantly, this requirement creates additional security risk through forced revealing of a carrier's routing through the U.S., which the Transportation Safety Administration (TSA) has advised is undesirable from a security perspective. That is, TSA recommends that air carriers do not disclose details of their flight routings to minimize risk of hazardous, undeclared items on those flights. Therefore, in order to ensure maximized security, a foreign shipper sending a food item to a non-U.S. destination should not be concerned with having to determine if the shipment will transfer multiple U.S. ports; the shipper should have no concern at all over U.S. transit. PN requirements for some transit shipments and not others is unpractical and burdensome for a foreign shipper who is likely unfamiliar and inexperienced with making declarations to U.S. regulatory agencies.
d. Food that is not for human or animal consumption: The FDA Compliance Policy Guide (November 2005) describes certain situations under which FDA and CBP would "typically consider not taking any regulatory action", one situation of which is food for testing and not for consumption. FedEx recommends that food items imported for testing and analysis and not intended for human or animal consumption should be fully exempted from Prior Notice. Some restrictions would be reasonable, e.g. a weight

and value limit, statement on the shipper documents, and labeling on the items.

V. Estimated Annual Reporting Burden:

The information provided in this Federal Register notice regarding the number and costs of PN submitted by FDA's Prior Notice System Interface (PNSI) and Customs and Border Protection's Automated Broker System (ABI) is interesting and revealing. The data shows that PNSI has more than 30 times the number of users than ABI (214,400 vs. 6500), and an average length of time for PN submission that is more than double that for ABI (23 minutes vs. 10 minutes). These numbers represent the difference between PNSI use by foreign shippers and ABI use by U.S. Customs Brokers and entry filers, and demonstrate the slower performance of PNSI.

If PNSI performance were improved to capture half of the 13 minutes difference between PNSI and ABI, the 214,400 PNSI users would reduce the time spent on PN submission by 192,781 hours (214,400 shippers x 8.3 per shipper annually x 6.5 minutes = 11,566,880 minutes, or 192,781 hours).

FDA admits that much of the PN data is "identical" to the importer's entry notice, and the "burden hour" tabulation for PN submitted by ABI should therefore be reduced to avoid double counting, as the data is simultaneously captured for PN and the import declaration. However, no details are stated regarding the adjustment in the burden hour analysis. We are therefore unable to determine the accuracy of this theoretical adjustment.

FedEx would like to reiterate our support to the FDA for the implementation of the various aspects of the Bioterrorism Act, and we applaud the FDA efforts to implement the regulations with prudence and discretion so that this industry is not unduly disrupted. We appreciate the opportunity to submit these additional comments.

Sincerely,

Robby Beau, Managing Director
Global Trade Services
FedEx Express
3650 Hacks Cross Road
Building E, Third Floor
Memphis, TN, 38125