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FedEx Express

VIA FEDEX OVERNIGHT LETTER AND ELECTRONIC FILING

May 13, 2004

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

RE: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes; Availability; Docket 2002N-0278

Dear Sirs/Madams:

FedEx commends the Food and Drug Administration (FDA) for its continued efforts to implement the extensive provisions of the Bioterrorism Preparedness Act of 2002 (The Act), especially the Prior Notice (PN) requirements as currently set forth in the Interim Final Rules. FedEx also supports the basic concept of the proposal in this Federal Register notice, namely a higher level of integration with existing Customs and Border Protection Agency (CBP) trade practices, for minimized impact on the food importing industry while still meeting the requirements of The Act.

Timing of the Data Submission

FedEx believes that the time requirements for submission of the PN data should be concurrent with the time requirements for submission of the CBP Advance Cargo Information (ACI). One of the primary reasons for coordinating PN timeframes with ACI timeframes is to minimize cost and expense to the trade community, which will nevertheless be expensive because of the global scope of the requirements. Additionally, coordinating the time requirements will help avoid confusion and opportunities for error created by separate data transmissions under different time schedules. PN for a U.S. destination shipment is already commonly filed by the U.S. Customs broker filing the clearance entry, and is therefore best handled as an integrated function of the entry preparation process. However, the current timeframes very often require submission of PN hours before the Customs entry can legally be filed. For example, PN for air shipments is due not later than four hours prior to arrival at the first port, but the Customs entry cannot be legally filed before aircraft departure from origin, i.e., "wheels up". That means double handling by the broker, since essentially the same data is required for PN

as for the Customs entry. This is applicable to flights under four hours in length, primarily from Canadian, Mexican and Latin American origins that constitute a significant population. Alignment of PN timing with the CBP ACI timing would significantly reduce the burden on the trade community, on FDA and on CBP, without creating additional security risks.

PN Data Requirements

FedEx believes that the number of data elements required for PN is simply far greater than necessary. In addition, we propose a two-step process for filing PN, whereby FDA would accept the same data submitted for CBP ACI to satisfy the PN requirements at the first port of arrival. Then, after accepting ACI data at the port of arrival, complete PN data would be filed at the port of entry as step two of the process. Utilizing ACI data for PN at the port of arrival would allow speedier processing, which is a significant issue considering FDA's concern about timely processing of PN under a shorter time schedule. This more complete data would be filed concurrent with the Customs clearance entry, and therefore provide FDA with the level of data desired, while removing the issue of time constraints under a reduced schedule measured against the port of arrival.

Schedule for the Joint Plan

The plan announced by FDA and CBP is scheduled to commence in August 2004, to be completed in February 2005, followed by publication of a Final Rule in March 2005. FedEx believes the schedule for publishing a Final Rule is too protracted and needs to be significantly accelerated. There is great industry concern about many of the inconsistencies in the current PN Interim Final Rule (IFR), and these need to be clarified much sooner than March 2005, which is almost a full year after publication of this Federal Register notice and one and one-half years after publication of the PN IFR. This is simply far too long for these inconsistencies and concerns to remain unaddressed.

The IFR is far reaching and requires significant changes by carriers, brokers, importers, suppliers and many other parties involved in the U.S. food import supply chain. These changes include system modifications, training, hiring and extensive procedural changes. It is eminently possible that some provisions of the IFR could be substantially changed, resulting in even more changes to systems and procedures. Even worse, some PN requirements could be eliminated, with the ironic result of having to restore systems and procedures as they were prior to the PN IFR at great expense to all parties involved. Finally, there exists the very real possibility that some members of the supply chain may be penalized during the interim period for rules that will eventually be eliminated.

Therefore, we propose that FDA accelerate the schedule for implementing the joint plan, and make this evaluation with CBP as quickly as possible. In the interim period, we also urge FDA to consider an official extension of the educational period for implementation of the Interim Final Rules, and suspend the provisions for fines or penalties until such time as the Final Rules are determined.

FedEx appreciates the opportunity to submit comments on these very important issues.

Sincerely,

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