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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, Rm. 1061
Rockville, MD, 20852

RE: Food and Drug Administration's (FDA) Prior Notice of Imported Food pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act), Reopening of Comment Period, Federal Register notice dated April 14, 2004, Docket 2002N-0278

Dear Sirs/Madams:

These comments to the Federal Register (FR) notice referenced above are submitted on behalf of Federal Express Corporation (FedEx), as supplementary information to our original comments submitted December 22, 2003. FedEx agrees with the FDA's stated goal of improving the safety and security of the U.S. food supply chain; however, we believe that certain changes in the Interim Final Rules are required to make the program more consistent with existing trade practices, and therefore allow the FDA and industry members to achieve this security goal with greater efficiency and reasonableness.

FDA has asked for comments on possible special considerations for Customs-Trade Partnership Against Terrorism (CTPAT) or Free and Secure Trade (FAST) approved companies, and also for other flexible alternatives. FedEx commends FDA for consideration of these elements, as we believe these are both important areas and properly considered in evaluation of best handling for the affected commodities and shipments.

Prior Notice Data Elements

Primarily, FedEx contends that the Prior Notice (PN) data elements are far greater in number than necessary. The Act identifies only 6 data elements; however, the Interim Final Rule calls for as many as 28 unique elements, far more than necessary to evaluate a food commodity as a potential security risk. This is additionally underscored by the fact that many of these same data elements are reported on both the Customs and Border Protection Agency (CBP) clearance entry, and the related FDA OASIS declaration. Thus, the duplication of data becomes expensive for industry trade members to collect and report.

FedEx's first recommendation is to reduce the number of PN data elements to a more reasonable level to avoid unnecessary duplication and still accomplish our mutual goal of safety and security of the U.S. food supply chain. The named elements in The Act should suffice for implementation of PN; additional elements could be added in the future if they are truly necessary for security screening. FDA may also consider acceptance of the CBP Advance Cargo Information (ACI) as PN; see next section for more discussion on this proposal.

Prior Notice Process Not Aligned With Trade Practices

In addition to the duplication of data elements from CBP entry, the disparate timing of the PN is also difficult to administer, and in some cases, is at conflict with CBP ACI rules for pre-filing an entry. For example, CBP entry for air shipments may be filed only when the aircraft has departed origin, i.e., "wheels up", while FDA requires PN not later than four hours prior to arrival. Many flights into the U.S. are far less than 4 hours in duration, thus, the FDA PN must be filed separately and prior to filing of the CBP entry. The disconnected procedures are difficult and expensive to administer and allow more room for error without providing additional security.

FedEx recommends that PN be aligned with the CBP ACI rules, for both timing and data elements. Fedex supports the FDA's joint plan with CBP to evaluate PN processing with shorter time. FedEx believes this is eminently possible, and more so with possible reduction in PN data elements as discussed above. FDA may want to consider a two-step process for PN, under which the CBP ACI data is accepted as the first step, filed at port of arrival as part of the ACI data, followed by complete PN in its current form, filed as a second step at the port of entry, i.e., concurrent with the clearance entry. This would eliminate the new and cumbersome process of notations on in bond documents at port of arrival, and automate the process for better, more efficient implementation by all parties.

Non-U.S. Destination Shipments

All shipments for non-U.S. destinations, which merely transit the U.S., should be fully exempted from the requirement for PN since providing this information for such shipments may result in increased security risks. Currently, the Interim Final Rule exempts non-U.S. destination shipments exported from the same port of arrival from PN requirements, yet it requires PN for any shipments transiting between two ports within the U.S. This requirement to submit PN for shipments transiting between two ports within the U.S. that are never out of the custody of the carrier is difficult to administer and may force carriers to diminish the integrity of the total supply chain. Prior to the Rule, customers shipping food items to non-U.S. destinations did not know their shipment would transit the U.S. In order to comply with the PN requirements under the Interim Final Rule, carriers now are forced to secure PN data from those customers, thereby revealing to them that certain shipments transit the U.S., and identifying to the customers which U.S. ports are utilized. Both CBP and TSA have counseled carriers not to publicize schedules or ports of entry for security reasons, yet we are forced to do so on many occasions in order to comply with the FDA requirement for PN.

Therefore, FedEx recommends that FDA eliminate the double standard for non-U.S. destination shipments and that all non-U.S. destination shipments be exempted from the requirement for PN.

CTPAT Carriers

It is important to note that FedEx is a CBP certified CTPAT carrier, as are many express carriers, and that we operate according to CBP regulations detailed at 19 CFR 128 (CBP hub security requirements). That means that we have extensive security measures in place to satisfy CBP about the safety and security of our transportation network. This should be a major consideration for FDA in considering revisions to the PN Interim Final Rules, which would include PN at port of entry rather than port of arrival, and exempting non-U.S. shipments from PN.

No De minimis Provision

The Interim Final Rules state that value is not a criterion for PN requirement, that is, any affected commodity entering the U.S. requires PN regardless of value. Thus, PN is required for every food or water sample for laboratory analysis, each of which in fact has no commercial value and is not for human or animal consumption. Similarly, low value shipments of prepared foods sent from and to individuals for their personal use are of little risk to the U.S. food supply, especially relative to the huge individual size and number of commercial shipments entering the country. FedEx recommends that FDA adopt a low value exemption (shipments under $200) for PN, whether for personal or commercial use, which would be consistent with CBP's de minimis exemption.

Prior Notice at Port of Arrival (POA) vs. Port of Entry

The Interim Final Rules' requirement for PN at POA is very problematic for every carrier with flights arriving at one U.S. port and moving import shipments under CBP bond to a subsequent location for CBP clearance. This is a normal daily mode for FedEx, and for many express consignment operators (ECO) processing import shipments in facilities operating under provisions of the CBP regulations as set forth in 19 CFR 128. This section of the CBP regulations requires an ECO to build a facility to CBP specifications, including very extensive provisions for automated systems, facilities for on-site CBP personnel, and general security for the facility and all shipments. The ECO is required to provide electronic manifest data in advance to both CBP and other agencies, to exercise "closely integrated administrative control", to provide Customs surety bonds, and a host of other security measures that are appropriately not publicized. Background checks are performed on all employees. FedEx is also a CBP certified CTPAT carrier. All of these elements add up to a highly efficient enforcement chokepoint for CBP, FDA and any Federal regulatory agency regulating imports into the U.S.

Unfortunately, the requirement for PN at POA rather than port of entry dictates that express carriers actively prevent food shipments from moving to our secure Part 128 facilities if PN is missing or deficient at the POA. This seems contrary to the intent of improving the safety and security of the U.S. food supply. Therefore, FedEx recommends that express carriers operating hubs and express consignment clearance facilities (ECCF) pursuant to 19 CFR 128, be allowed to move affected food shipments from the POA to their Part 128 facilities at the port of entry in the event that PN may be deficient or missing upon arriving at the POA.

Prior Notice System Interface (PNSI)

The PNSI as currently available has several problems. First, as mentioned above, the data elements are simply too extensive, far beyond the 6 elements identified in the Act. We understand that CBP and FDA will need an identifier number for each record, which should be no more than a carrier's bill of lading number, a CBP entry number, and perhaps a filer's own reference number. These reference numbers and the small number of true PN elements should total no more than a dozen or so elements. This change would make PN less complicated to provide and more readily available from shippers, which would therefore benefit FDA through earlier PN availability. In addition, the PNSI as currently programmed has drop down "sub-menus" for several data elements, depending on the commodity, which results in even more data elements being required than are specifically stated in the Interim Final Rules. Further, the PNSI is available to the rest of the world only in English. Documents for many shipments into the U.S., food or otherwise, are commonly not in English, and while we understand that English or a translation is required, a very high volume of food shipments sent by express carriers are from and to individuals who may not know English. These individuals may not have any

experience with preparing shipping documents for personal use food articles due to absence of requirements prior to implementation of the BTA provision. We are concerned that one effect of the rules as currently written would be a loss of this business to express carriers, with the volume moving to postal services without proper declaration of contents or proper PN as required, resulting in decreased security to the U.S. food supply chain.

The PNSI has also proven to be too slow and too unreliable, often taking an hour or more to complete PN for one shipment. This is simply not fast enough for commercial use and the delay renders the system effectively useless; customers therefore shift the responsibility to service providers such as U.S. Customs Brokers or Express Consignment Operators, who can utilize the ACS/ABI path from a U.S. location. Another barrier to shippers' use of the PNSI is the requirement for multiple data elements that are not normally available to a shipper, e.g., CBP identifier number (whether IT, T&E, or entry numbers), Harmonized Tariff Classification Number, FDA product code, port of arrival and time of arrival.

All of these reasons render the PNSI effectively useless for shippers to provide PN. If shippers could use this system, FDA would have PN several hours earlier than under the present arrangement, perhaps even days earlier, and administration of these shipments by other trade industry members would be far more efficient, e.g., carrier identification and control of food shipments, CBP identification in ACS/AMS/ABI, and carrier or broker preparation of in bond documentation. We recommend that the PNSI system be extensively overhauled to address these issues and make the system faster, more reliable and more functionally accessible to shippers.

In summary, our recommendations center on the following points:

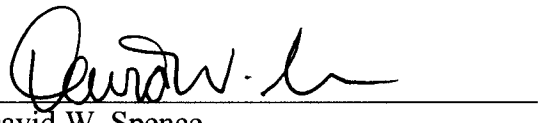
1. **CTPAT Carriers**. CTPAT carriers should be allowed special considerations due to a higher level of security. Special considerations should include filing of PN at port of entry vs. port of arrival and exemption of all non-US destination shipments.
2. **CBP Regulated Hubs**. Express carriers operating hubs under CBP regulations should be allowed special considerations. The unique status of these facilities means that imported food shipments should be allowed to move through those facilities for maximized security and allowed to flow freely to those facilities whenever possible. The current rules for PN at port of arrival often result in keeping shipments from moving to those facilities, and therefore, in a less secure environment.
3. **De Minimis Provision**. Express carriers handle many food shipments of very low value, including gifts, personal use items and samples for analysis rather than consumption. We recommend these low value shipments under $200 be exempted from PN.

4. **PN at Port of Entry vs. Port of Arrival**. Express carriers should be permitted to submit complete PN at port of entry rather than at the first port of arrival for the reasons stated above.
5. **Non-U.S. Destinations**. Non-U.S. destination shipments should be fully exempt from PN requirements for the reasons stated above.

FedEx would like to thank the FDA for the opportunity to submit these additional comments, and we look forward to positive revisions in the Interim Final Rules to make this program more efficient in order to better improve the safety and security of the U.S. food supply.

Sincerely,

FEDERAL EXPRESS CORPORATION



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