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

Reference: Comments on Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

DOCKET NUMBER 2002N-0278

The following comments are submitted by the Houston Customs Brokers and Freight Forwarders Association (HCBFFA) regarding the Interim Final Rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), 69 Fed. Reg. 19763 (April 14, 2004) (Prior Notice Interim Final Rule).

Members of the HCBFFA are responsible for submitting a large percentage of Prior Notice information to FDA, and we are therefore well qualified to provide comment and input on the Interim Final Rule and its implementation.

We have grave concerns about the many problems that exist with the Prior Notice system, and we feel strongly that these issues must be addressed prior to the commencement of full enforcement of the PN regulations. We believe that enforcement should be postponed until such time as these problems have been addressed, and the trade has had a sufficient period of time to implement changes needed once the problems have been resolved.

Following are the issues that we believe must be addressed prior to the currently scheduled full enforcement date of August 12, 2004.

- 1. Data Validation Issues:** According to FDA statistics, half of all PN data transmissions contain incomplete and/or inaccurate information. We believe that a significant reason for such a high rate of noncompliance on data submissions is the lack of the automated system's capability to advise filers of data inadequacies. This means that there is no system in place to educate PN filers about changes that need to be made in order to be fully compliant prior to the enforcement deadline. There is no value to

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having a phased-in enforcement period if there is no education for filers as to what they are doing wrong. We have been advised that we will know after full enforcement begins what the specific problems are with our data transmissions, when rejects are received. This is not acceptable. While we are willing and eager as an industry to assist in improving the rate of compliance, we must have FDA's assistance to do this. A way must be found to provide meaningful education and guidance prior to the August 12 deadline, or the enforcement deadline must be postponed to allow trade and industry the necessary time to make programming changes to assure compliance.

- 2. Lack of Education and Outreach:** The low compliance rate on PN submissions indicates that there is not a clear understanding among importers and brokers as to exactly what is required to file a proper Prior Notice. FDA staff are often unable to answer questions or assist in any significant way. Clearly, further education and training is needed, and we believe that FDA must find ways to provide this to the trade prior to the commencement of enforced compliance.
- 3. Requirement for Storage of Refused Merchandise:** We do not believe that the requirement to store refused merchandise at local port facilities makes sense, nor do we believe it provides any measure of security or safety to the food supply. Refused shipments have up to now been allowed to be held at importer's premises, and we believe that this practice should be allowed to continue. The ports and land borders do not have sufficient storage capacity to handle the possibly overwhelming demand for space that this section of the regulations will create, and we believe that this requirement should be completely revised and/or removed from the final rule.
- 4. Lack of Knowledgeable Personnel at FDA Help Desk:** The personnel staffing the FDA Prior Notice Help Desk are often not capable of answering operational questions in a timely manner. The help desk must be staffed with people who are able to provide the assistance that is clearly needed when someone calls them. FDA also needs to have an efficient system for dissemination problem resolution information to the trade once an issue has been addressed, as this will eliminate the need for multiple importers or brokers to contact FDA on already resolved problem issues.
- 5. FDA Prior Notice System Capacity:** The Prior Notice Internet System Interface (PNSI) has limited capacity. This capacity must be significantly increased before the enforcement deadline in order for the PNSI to function as intended, and to ensure that the flow of trade is not negatively impacted by system failures. There have been instances recently when the ABI system has failed, and the PNSI was unable to handle the volume

of traffic generated. This is not acceptable and must be addressed prior to August 12. We would also request that PN data be allowed to be filed via the ABI system even after the PN time limitations, as there seems to be no valid reason for not allowing this capability.

- 6. Ability to Correct Clerical Errors:** There is not currently any way to make corrections to Prior Notice data once the entry/entry summary data has been transmitted in the ABI system, short of canceling the entry and submitting a new one. There are many situations where cargo is processed during the weekends and in off-hour operations, when Customs is unavailable to process entry cancellations. In these situations it's possible that cargo could be forced into a refused status due to Customs' unavailability. We strongly urge FDA and Customs to jointly find a way to correct this problem, by allowing PN revisions in ABI after entry data has been certified.
- 7. FDA/CBP Timeframe Inconsistencies:** Serious differences in timing exist between FDA Prior Notice and CBP entry requirements. We urge FDA and CBP to equalize these differences to allow for the smooth flow of trade.

In light of all the problems listed above and others that have been presented to FDA via this comment process, we strongly believe that full enforcement of the Prior Notice final regulations should be postponed. We realize that FDA is working to get its system problems worked out before August 12, and that these changes take time. We feel that FDA must recognize that the trade community will also need additional time after these problems are resolved to make the changes necessary to our own systems. We urge FDA to consider postponing enforcement to allow for these adjustments.

In closing, we want to stress that the purpose of the Bioterrorism Act is to ensure the safety of the U.S. food supply. Our industry is committed to helping FDA accomplish this. We hope that these comments, as well as the comments of importers and other trade associations, will assist FDA in streamlining this system into one that is workable for all parties, and that does not excessively burden the trade and industry with regulations and reporting that do not address the very real issue of food safety.

Sincerely,



Kathryn Terry, FDA Committee Chairperson
Houston Customs Brokers and Freight Forwarders Association