May 14, 2004

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 2002N-278 - Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA) Reopening Comment Period

Dear Sir or Madam:

The following comments are submitted by the San Diego Customs Brokers Asscoiation on 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).

San Diego Customs Brokers Association is comprised of the customs brokers of San Diego. . Everyday, our members submit thousands of Prior Notices to FDA. Therefore they are well-positioned to provide input on the Interim Final Rule and how it is being implemented.

As a major advocate of a staged enforcement period, we are very disappointed that so many problems continue to plague the PN system after five full months of implementation. We look forward to working with FDA to address these problems prior to full enforcement. Furthermore, we urge FDA to postpone such enforcement to assure that the trade (importers and customs brokers) has a minimum of 90 days to make the adjustments needed once the problems have in fact been resolved.

Below are the outstanding issues we feel must be addressed prior to full enforcement, currently slated for August 12.

A. **Data Validation System Required**.

By FDA's own statistics, after five months of implementation, half of all data transmissions are incomplete or inaccurate. A major reason for this poor compliance rate is the fact that the automated filing system does not have the capability to advise the filer of the specific data inadequacies of the submission. Thus, there is no mechanism to educate filers as to the changes that must be made in order to be in full compliance prior to the August enforcement deadline. Without this education, the value of a phased-in

enforcement period designed to bring importers into full compliance with the law, is lost.

Some filers have been advised by FDA staff that they will know on August 12 of any specific inadequacies in our transmissions -- once the cargo is rejected. This is unacceptable. FDA's own Compliance Policy Guide, published in December 2003, states that "educational efforts will be made in response to **specific** violations" (emphasis supplied) during the enforcement grace period. Such efforts have not occurred. Currently the only input filers are receiving is a notice from the Director of the Prior Notice Center that there is a problem with the PN, and that they should work with their ABI representative to figure out what it is and how to fix it before August 12. The notice does not include any guidance on the specific inadequacies of the PN filing.

Our industry is eager to assist in increasing compliance rates, but we need FDA's help to do so. FDA must either find a way to provide such feedback well in advance of August 12, or it must postpone full enforcement to assure that the trade has sufficient time to make programming changes necessary to assure compliance.

B. **Lack of Communication with the Trade**.

As noted above, Customs brokers file over 80% of the Prior Notice submissions to FDA/CBP. Thus, the brokerage community can be a tremendous resource to FDA in a) identifying problems with the filing system b) helping to identify solutions to those problems and c) educating the trade (both importers and brokers) as to the changes required for full compliance with the law. Despite numerous initial outreach seminars, there has been little effort over the past five months to discuss and address specific operational problems with the trade. We understand that FDA has been meeting monthly by phone with the National Customs Brokers & Forwarders Association of America (NCBFAA), and we applaud them for this effort. Yet there are other industry groups which could help to bring the diversity needed to assure that all sectors of the trade are represented. We urge FDA to establish a more formal advisory committee with representatives of various industry groups. Such industry advisory groups have been used by other government agencies to address similar problems with new regulatory programs.

C. **Lack of Education and Outreach.**

The low rate of compliance indicates that importers and brokers do not have a clear understanding of exactly what is required for Prior Notification. We have read the regulations, and still have questions. In fact, many of your own FDA staff are unable to answer our questions. Clearly, further clarification is needed. FDA must find a way to reach out to the regulated

public to provide the education needed to assure greater compliance. This could be accomplished through additional guidance documents, educational seminars, web-based training, etc.

Again, FDA's own Compliance Policy Guide states that such outreach would continue throughout the eight months between implementation and full enforcement:

> *Policy:*
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> *The requirements for submitting prior notice to FDA are effective beginning December 12, 2003. However, as described below, during the first eight months following this effective date, FDA and CBP plan to focus their resources on education to achieve compliance with the prior notice requirements. While educational efforts will be made in response to specific violations, FDA and CBP also intend to continue their broad, pro-active educational initiatives during the initial eight-month period, including the following:*
>
> *1. FDA and CBP will distribute information flyers at the ports.*
>
> *2. FDA and CBP plan to:*
>
> *a. Gather data to track compliance with the prior notice requirements and to determine how best to use their resources to educate industry and the public in order to achieve full compliance.*
>
> *b. Provide industry and the public with summary information about the level of compliance with the prior notice requirements, including data on the types of errors in submitted prior notices.*
>
> *c. Provide the summary information on FDA's website at www.fda.gov.*
>
> d. *Utilize the data and summary information to assist the industry and the public in improving the submission of prior notice.*

FDA should follow its own policy guidance and ensure that such outreach occurs well in advance of any enforcement deadline.

**D. Ability to Correct Simple Clerical Errors**

Once the CBP entry/entry summary has been certified, there is currently no mechanism by which to make corrections without canceling the entry and submitting a new entry. In the air and truck environment, where cargo is processed on weekends and at off-hour operations, CBP is unavailable to process these entry cancellations. In such circumstances cargo could be forced into refused status due to CBP's inability to act in a timely manner. We urge FDA and Customs to find a way to address this problem, either by allowing clerical revisions even after the entry has been certified, permitting entry deletions under certain circumstances, or assuring CBP availability on a 24/7 schedule.

**E. Secured Storage Facilities and Procedures Needed**

As refused merchandise must be held at the port of arrival, moved to a secure facility or exported, we are concerned that a) no procedure for handling refused merchandise has been published and b) there are insufficient storage facilities at many of our nation's ports. We are particularly concerned about cargo refused at the U.S.-Mexico border, where there simply are no cold storage facilities. Without adequate storage facilities, our ports could be rapidly overwhelmed once full enforcement begins.

**F. Late receipt of PN Confirmation Number**

This is particularly a problem along the U.S.–Mexico border where brokers consistently complain that it can take an hour or more to receive the PN confirmation needed to move the cargo. Since the 2-hour wait to enter the U.S. begins once the PN confirmation is received, border brokers are consequently having to wait three or more hours after submission of the PN before crossing the border. This is a programming issue that can and must be addressed prior to August 14.

**G. ABI Revisions Needed for Cargo Already in the U.S.**

The current ABI system cannot accept Prior Notice once cargo arrives in the U.S. Instead, filers must use the PNSI system. This should be resolved to allow filers to use the ABI system even after cargo has arrived in the U.S.

**H. Update MID Database**.

The CBP Manufacturer Identification Database (MID) is over 18 years old and woefully out of date. Currently there is no mechanism by which to update the MID. Until the MID is updated, imported shipments may be subject to rejection or refusal for no legitimate reason. We urge FDA to work with CBP to allow the MID system to be updated, and to assure that cargo is not rejected due to a mismatch with the MID.

## I. Lack of Knowledgeable Resources at FDA

The FDA Prior Notice help desk has proven to be incapable of answering specific operational questions in a timely manner. This office must be staffed with people who can provide the assistance sought by the regulated community. Further, once questions are addressed, FDA must have an effective mechanism for disseminating this information to the rest of the trade. Such a system would eliminate the need for one importer to contact FDA on an issue that has already been resolved in response to another importer's request.

It has been suggested that FDA post PN Center e-mail boxes for different technical and operations areas. This would be a good way for FDA to easily determine where the major problems in the system exist.

## J. Exemptions Needed

The objective of the Bioterrorism Act was to protect the nation's food supply. We do not feel there is adequate threat to the nation's food supply posed by certain classes of goods entering the country, including:

1. Small commercial laboratory samples used for testing and evaluation purposes, not for sale or other distribution under the following circumstances:
    i. Food being imported by a quality control laboratory who imports food samples in limited quantity in order to test them for trade law compliance, and related reasons and not to released for sale or other distribution;
    ii. Food purchased in a foreign country in limited quantity at the request of a U.S. entity, that is Registered with FDA, solely for testing, tasting or other analysis within that facility and would not be released for sale or other distribution.
2. Household goods (personal effects and property) shipped to the U.S.
3. Unadulterated U.S. exports that have been returned to the U.S.

We recommend that such items be exempt from PN requirements.

## K. Harmonize CBP and FDA Reporting Timeframes

The disparity between FDA Prior Notice and CBP Entry requirements imposes additional and unnecessary effort and expense on the regulated public. Numerous problems arise for filers using the ABI system when trying to file PN for cargo for which they cannot yet make entry. This is particularly problematic in the air environment and for quota class merchandise. We urge FDA and CBP to address these timing disparities.

## L. FDA PNSI System Capability Must be Improved

The FDA's Prior Notice Internet System Interface (PNSI) was intended as an alternative to the primary CBP automated entry interface. It also serves as a back-up system when Customs' system is inoperable. With its current limited capacity, the PNSI system has been proven inadequate to serve as back up for all Prior Notice entries. The PNSI system capacity must be dramatically increased before the August enforcement deadline in order to assure that legitimate trade is not impacted due to a failure of the system.

## M. Filer Needs Immediate Notice of Rejections and Refusals

According to the Prior Notice Interim Final Rule, the carrier is the point of contact if an article of food is refused. Since the carrier has neither the incentive nor the ability to resolve the refusal, FDA should also notify the filer when rejections or refusals occur. This will assure that valuable time is not lost between notification of the carrier and notification of the filer, which could be much later. By contacting both the filer and the carrier, FDA can help to reduce delays and congestion associated with refused food.

## N. Enforcement Deadline Should be Postponed

We understand that FDA is working hard to get its own system glitches corrected prior to the August 12 enforcement deadline. Obviously such programming changes take time. Yet FDA must also understand that there are programming requirements on our end that must also be made. Thus, we need additional time – a minimum of 90-days -- after FDA has finalized its internal revisions to make the necessary adjustments on our end. Again, we urge FDA to consider postponing enforcement beyond August 12 to allow for such adjustments to be made.

In closing, we wish to emphasize that the objective of the Bioterrorism Act of 2002 was not to promulgate regulations and increase reporting by the trade. The objective was to assure the safety of our nation's food supply by implementing an effective mechanism for screening food imports. Legitimate food importers have the information you need to do this screening, and are willing to provide this information so that FDA can fulfill its responsibilities under the Act. We are certain that FDA would prefer to use its scarce resources chasing down criminals and real threats to our

nation's food supply, not pursuing baseless enforcement actions against legitimate food importers. Thus, we hope that FDA will continue to work with the trade to assure proper reporting of food import data.

Thank you for your consideration of the above comments. If you have questions or require additional information, please contact Leonor Ferrer at 619-661-6755
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Respectfully -submitted,

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