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

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

Williams Clarke Company, Inc., acting as a Customs Brokers (transmitter) for numerous importers (submitters), in several food-related industries, has a first hand operational knowledge of the present FDA Prior Notice system. We are filing more than 75 prior notices per day into the Food and Drug Administration (FDA)/Customs and Border Protection (CBP) Automated Broker Interface (ABI) system and have developed some serious concerns as we move into the final phases of enforcement. Neither FDA nor CBP have made any viable effort to enhance the systems or communicate with the trade on operational questions. FDA has advised us 80% of the transmissions are being made via the ABI systems and 20% are through the FDA web portal. We have also been told 10% of importations have no prior notice transmission, 40% of the transmissions are correct, and that **50%** of the transmissions are inaccurate or incomplete. Based on our first-hand experience in working with the new regulations and systems, we feel the following areas must be addressed if we are to avoid serious cargo delays, economic impact to our food supply, unnecessary and costly penalties, and most importantly, not meeting the intent of the BTA to protect our food supply.

The follow areas of concern need to be addressed for a smooth transition into final full enforcement now scheduled for August 12, 2004:

- IMPROVED PRIOR NOTICE COMMUNICATIONS MUST BE ESTABLISHED BETWEEN THE AGENCIES AND TRADE
- NO VALIDATION SYSTEM IN PLACE FOR CHECKING ACCURACY OF DATA TRANSMITTED AND RECEIVED
- NO MEANS OF CORRECTING SIMPLE CLERICAL ERRORS AND FORCING MERCHANDISE INTO REFUSAL STATUS DUE TO INABILITY OF THE AGENCIES TO ACT IN A TIMELY MANOR

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Customs Brokers  
Freight Forwarders  
Established 1921  
OFI #0870F

- IMPROVED HELP ALTERNATIVES FOR OPERATIONAL QUESTIONS.
- EXEMPTION FOR NORMAL SMALL COMMERCIAL LABORATORY SHIPMENTS WHICH WILL NOT ENTER COMMERCE NOR REACH THE PUBLIC.
- INCONSISTENCY IN TIME FRAME REQUIREMENTS FOR FDA AND CBP
- ACCESS TO AND THE PROCESSING OF DATA THOROUGH THE FDA PRIOR NOTICE SYSTEM INTERFACE WEB PORTAL IS UNACCEPATABLE.
- INABILITY TO CHANGE OR CORRECT THE CBP MANUFACTURE IDENTIFICATION (MID) DATABASE
- ESTABLISH SECURED STORAGE FACILITIES AND PUBLISHED PROCEDURES FOR REFUSED IMPORTATIONS
- RESPONSE TO FDA C-TPAT AND FAST QUESTIONS

#### Improved Communications Between The Agencies And Trade

After passage of the BTA and during the initial phases of the Registration and Prior Notice rules FDA did make a sincere effort to communication the basic concepts of the new law and regulations to the trade. After the initial outreach FDA did not work with CBP in informing the trade the exact requirements and procedures necessary in a real world environment. Wisely FDA decided to implement enforcement over a period of time but without additional outreach to answer specific operational procedures and questions. A vast amount of confusion and misconception has developed within the trade community. I would suggest FDA and CBP consider the following suggestions:

1. Develop a web-based tutorial (with the assistance of trade) to explain each data element in detail.
2. Conduct outreach seminars at the major importing centers. Specific seminars for land, air, and ocean would be required as the requirements and procedures are different for each mode of transportation. At it's March 2004 Conference the National Customs Brokers and Forwarders Association of America, Inc. challenged both agencies to form a working committee to address specific operational questions. While this very important committee has been formed but it is very late in the enforcement process and cannot address all of the trade concerns in the limited time period before full enforcement. This committee must continue but it is imperative FDA and CBP increase its interaction with all trade elements to avoid disastrous consequences upon full enforcement.

3. From day to day operations it is being learned that all data elements in the ABI PN process are not mandatory and some are not required dependant on other data elements. Trade is expending large amounts of time and resources in trying to get information that may not be necessary. Such as vessel carrier flag when in fact we have now learned that this data element is not necessary when the carrier code is indicated. I would suggest a complete list of ABI mandatory and optional data elements be immediately published via the CBP Administrative Message system.

#### No Validation System In Place For Checking Accuracy Of Data Transmitted and Received

By FDA's own statistics 50% of the data transmissions are incomplete or inaccurate. FDA and CBP have not devised a system to notify the trade of systemic or specific data inadequacies on a shipment and line bases. Without this level of information industry cannot make the necessary adjustments in programming and databases before full implementation in August 2004. A realistic data validation is necessary to give FDA the adequate information for proper security selectively while not impeding the orderly flow of international trade. This high error rate, when trade is making a sincere effort to comply, is an indication that the systems and procedures of the interim rules are seriously lacking. Suggestions:

1. For a short trial period the full PN edits, with warning messages, should be turned on without rejection of CBP entry processing. Even if this were done for a week it would give trade an opportunity to test system integrity and pinpoint data concerns. This would give transmitters the opportunity to work with submitters to correct anomalies and increase the level of compliance without disruption of an already stressed intermodal system. The confirmation number received back after data transmission is no indication that prior notice requirement have been meet and have given trade a false sense of security they are compliant.
2. The August 12, 2004 full enforcement date should be extended until reasonable error rate can be achieved. FDA and CBP must work closer with trade through a viable data validation system to increase information reliability or the agencies will not be meeting the mandate of the BTA security goals and will be adversely effecting trade and the American public.

3. When possible a warning message should be established to indicate a duplicate PN is being filed. Many times submitters and transmitters are unaware that the manufacturer, shipper, or carrier filed the PN. Without this warning unnecessary data is being transmitted burdening the PN system resources and adding costs to trade.

#### No Means of Correcting Simple Clerical Errors And Forcing Merchandise Into Refused Status Due To The Inability Of The Agencies To Act In Timely Manner

At the present time once the CBP entry/entry summary has been certified no means of correcting the ABI PN data is available short of complete cancellation of the CBP entry and refiling a completely new entry and PN with a new entry identifier. In the air and truck environment, where cargo is processed on weekends and at off-hour operations; unless CBP will process entry cancellation on a 24/7/365 basis cargo could be forced into refused status by the agencies own inability to act timely. Under the present AMS system duplicate entry posting would send incorrect manifest information to the carrier and stop delivery of the cargo. Suggestions:

1. Permit entry deletions rather than cancellation for legitimate reasons, which can now be executed within the present entry processing procedures.
2. Require CBP to keep a database of all entry number deletions and require filer/transmitter to furnish change information upon request.
3. As an alternative to permitting entry deletions, require CBP to furnish 24/7/365 capability for entry cancellation.

#### Improved Help Alternatives For Operational Questions

Until recently the only help assistance on BTA issues was through the Prior Notice Help Desk. The help desk was out sourced and operated by contracted non-FDA personnel. This source of information was helpful in addressing the general law and regulatory issues but proved to be totally ineffective in answering real world operational questions needing immediate attention. Phone communications are difficult, if not impossible and e-mail have not been answered in a timely useful manner. Recently it has been learned a phone number has been established for direct communication with the Prior Notice Center for operational and technical issues. It is not known how difficult communications will be using this new phone number. Suggestions:

1. In addition to posting operational change, communication, and data requirement information on the FDA website a CBP Administrative Message should also be issued to filers.
2. Separate PN Center e-mail boxes to be established by specific technical and operational areas such as: data elements; transmission problems; response

problems; etc. Response time would be within a 24 hour time frame and would be used for less critical questions leaving the phone line open of immediate problems. This would allow the agency to efficiently address many of questions in a timely manor and have a better understanding of problem areas.

#### Exemptions For Normal Small Commercial Laboratory Shipments Which Will Not Enter Commerce Nor Reach The Public

The Prior Notice Interim Final Rules offers exemption status for homemade foods and personal use food products accompanying individuals arriving in the United States. FDA deems these exempted products pose little risk to public health. Multinational firms send large number of repetitive test samples to maintain quality control. The prior notice requirement for small laboratory and test samples pose excessive burden and costs for products that would be of little security risk provided very specific security requirements are controlled. Suggestions:

1. Laboratory samples for testing and evaluation be exempted from prior notice requirements provided:
  - Manufacture, shipper, ultimate U.S. consignee are pre-registered with FDA
  - Limited quantity and value are maintained
  - Special Affirmation of Compliance code is used for entry purposes
  - Packages are clearly marked: Samples for testing purposes only- not for resale or consumption
2. Present CBP security measures such as the 24-hour rule and C-TPAT could also be used to provide the desired security for these low risk food products.

#### Inconsistency In Time Frame Requirements FDA And CBP

A serious timing disparity exists between FDA Prior Notice and CBP Entry requirements. FDA permits data transmission five days before arrival but CBP restricts entry processing for air shipments to no more than wheels up. Land transportation requirements for PN and Entry are not equal causing excessive processing and shipment delays. Suggested:

1. Survey be conducted by FDA including CBP and trade input to determine area of disparity
2. Effort should be made between FDA and CBP to harmonize timing issues.

Access To And The Processing Of Data Trough the FDA Prior Notice System Interface  
Web Portal Is Unacceptable

FDA has established two separate systems for transmitting the required prior notice data to the agency for review. FDA originally estimated over 80% of the required data would be transmitted through the CBP Automated Broker Interface (ABI). The ABI system has been proven to be the most efficient means for meeting the prior notice time requirements. The trade community has devoted a large amount of resources in system programming and procedures with limited amount of FDA feedback on individual systems compliance status. The trades systems appear to be operating correctly but as of date FDA and CBP have not confirmed this assumption. The WP-Independent Prior Notice system, while being a valuable tool, still leaves serious omissions and processing problems.

The second system available to transmit prior notice data is the FDA web base Prior Notice System Interface (PNSI). Individuals or transmitters who do not have the capability to transmit through ABI can utilize this system in an interactive environment. This system was well deigned for its intended use but does not lend itself for transmission of vast amounts of data. The time requirement for input through interactive systems is taking far too long in a real world environment. This system has been designated as the primary backup system should the ABI systems become unusable. During a recent failure of the ABI/OASIS system the PNSI was used for all PN transmission. It became impossible to log into the PNSI web portal. Transmitters were dropped from the portal during PN input and processing time became unacceptably long. Adding the requirement that all PN data be transmitted via the PNSI portal after the PN time limitations or refusal will increase the load on this limited system. Suggestions:

1. FDA should develop a parallel PNSI system using the same data elements but allowing transmission via a batch system of PN's. A batch system would save a vast amount of input time and allow the agency faster processing capability. This system would still be slower that the ABI systems and would mainly be used as a backup during times of CBP/FDA system failures.
2. Increase the input capability of the PNSI web portal.
3. Review and revise the actual data elements needed. Remove data elements that can be obtained from the current CBP security data base such as the 24-hour advance shipment and manifest data.

### Inability To Change Or Correct The CBP Manufacture Identification (MID) Database

Part of the ABI/PN automation data transmission compares the FDA Registration number to the information contained in the CBP Manufacture Identification (MID) database. This database is over 18 years old and has been corrupted with incorrect information. CBP has not provided a means to correct the MID information that could cause a rejection or possible refusal of the imported shipment. CBP has yet to address this system deficiency. Suggestions:

1. Permit incorrect and duplicate MID information be corrected though secure CBP system.
2. Compare MID data to the Registration database. Notify the transmitter of a MID mismatch while keeping actual Registration information secure. This would give the submitter and transmitter of a prior notice noncompliance alert and also alert the agency of possible additional intensive review requirement even before PN has been completed.
3. Consider not requiring MID or complete address information when shipper and manufacture registration numbers are used.

### Establish Secured Storage Facilities And Publish Procedures For Untimely Prior Notice And Refused Importations

The interim final rules specifies merchandise with inadequate or not PN is subject to refusal. Refused merchandise must be held at the arriving port of arrival, moved to a secure facility, or exported. With only three months remaining until full enforcement is implemented no secure facility or refused merchandised has been established as required by the interim final rules. The interim final rules also allows for merchandise to held under "constructive G.O." or send it to the nearest G.O. warehouse. Many major ocean ports, airline terminals and border crossing points are unable to handle "constructive G.O." merchandise and the current G.O. warehouse system may be inadequate to handle any major infrastructure stress. Suggestions:

1. FDA and CBP develop a joint operational plan with input from the importing and shipping industries.
2. Refused merchandise procedures, adjust for individual points of arrival, needs to be published prior to the August 12, 2004 final enforcement date. Direction on executing CBP 6043 Permit to transfer or CBP 7512 "Restricted in-bond" is needed to avoid major congestion.

3. Establish a clear definition of "Perishable shipments". Destroying or selling frozen, refrigerated, and fresh merchandise held at a secure facility after 3-days, for inadequate PN, is unreasonable and an excessive financial burden on international trade.

#### Response To FDA C-TPAT and FAST Questions

1. Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?

It would be to the best interest of the FDA if all avenues of supply chain security were utilized. Both C-TPAT and FAST participants are reviewing the complete supply chain from its source to its ultimate destination and would be able to furnish to FDA more accurate and reliable data. This higher level of voluntary security would assist the agency in achieving its risk management goals using fewer resources. By using these programs with its certified participants FDA may be able to reduce the time limits and the amount of data elements.

2. If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?

Yes, any harmonization of FDA and CBP security programs would only assist the orderly flow of trade at the border crossing points. Having one set of timeframes would reduce the number of separate agency requirements, misunderstanding of the various rules, and increase the level of compliance.

3. Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

No, the C-TPAT is a well thought out program. With its current security profile requirements and present follow up verification system the program is already well suited to handle human and animal food shipments. The present program does not need to be modified to meet the FDA's requirements.

#### Response To FDA Flexible Alternative Questions

Actual importers and submitters are in a better position to answer questions 1 through 6. As a transmitter I see there is a need to streamline the security processes used by FDA and CBP. If the interim final rules are refined I see no necessity to offer more flexible alternatives. If alternatives are offered they should be completely integrated into

the CBP existing programs. Duplicating security programs and splitting limited resources are not in the best interest of our security goals and the protection of public health.

7. Should FDA offer a prior notice submission-training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

I feel the lack of a training program is one of the major shortcomings of the interim final rules. A large amount of apprehension, misunderstanding, and paranoia exists within the trade community. I feel this is priority one and would resolve many of the other problems being encountered with the present rules.

I would like to thank the Food and Drug Administration for all of the efforts in drafting a workable set of regulations for protecting the public health. The conditions of our times dictate these very important security measures be placed into effect without delay while using a very limited amount of resources. Working with CBP and the trade in developing some further refinements these rules can be made workable to meet both the mandated security measures and the commercial realities. These comments are presented in the spirit of collaboration and are not meant to be critical. My firm and I pledge our continued support and will continue assisting the agency in any way possible.

Sincerely,

A handwritten signature in cursive script that reads "Roger M. Clarke". The signature is written in black ink and is positioned above the typed name and title.

Roger M. Clarke  
President