

American Association of Exporters and Importers

1200 G Street, NW, Suite 800, Washington, DC 20005

July 12, 2004

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

Re: Docket No. 2002N-0278 – Availability of Joint CBP-FDA Plan

Dear Sir/Madam:

For more than 80 years the American Association of Exporters and Importers (AAEI) has been a national voice of American business in support of fair and open trade among nations. AAEI's expertise in international trade and customs matters is widely recognized in Washington and other national capitals. AAEI is the only national association dedicated exclusively to representing the interests of both U.S. exporters and importers before U.S. government agencies, Congress, international organizations, and foreign governments. Accordingly, it is with pleasure that AAEI provides the U.S. Food and Drug Administration (FDA) with its comments in connection with the Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes (the Plan), published on April 14, 2004 [Federal Register: Volume 69, Number 72, Pages 19765-19766].

Description of AAEI

AAEI's members include manufacturers, distributors, and retailers of a broad spectrum of products including chemicals, electronics, machinery, footwear, automobiles and automotive parts, food, household consumer goods, toys, specialty items, textiles and apparel, and footwear. AAEI membership also comprises organizations serving the international trade community such as carriers, customs brokers, freight forwarders, banks, attorneys, and insurance firms. AAEI's large and diverse membership base provides it with a high level of credibility among policy makers. As a prominent representative of the U.S. international trade community, and of both importers and exporters, AAEI is able with particular effectiveness to make the point that trade restrictions and protectionism ultimately injure the world's largest consumer market and the world's largest exporter: the United States.

Overview

AAEI is highly encouraged by, and very much supports, the actions of the FDA and CBP in promulgating a plan to increase integration and examine whether the FDA

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can amend the timeframe requirements in its Prior Notice interim final rule (68 FR 58974, October 10, 2003) to match the advanced notice timeframe requirements for arrivals by road, rail or air that are currently required by CBP's advance electronic information rule. We understand that the goal of the Plan is to assess whether the integration can occur and still allow the FDA to meet its statutory mandate under section 801(m)(2)(A) of the FD&C Act, which states that the time period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification. AA EI is confident that, with proper planning and development, additional integration of the security processes and the differing timeframes can be coordinated through the actions outlined in the published plan.

Increased Integration

AA EI supports the idea of increased integration between the FDA and CBP as regards their risk targeting techniques and actions to implement the operational requirements that importers must meet for advanced shipment notifications under the Prior Notice section of the bioterrorism regulation and the advanced notice requirements of the Trade Act of 2002. This appears to be a logical move forward as the statutory mandates are similar under both acts and similar technologies are being used to meet the legislative requirements. AA EI understands that the current plan includes the following as a summary of some of the planned steps towards that integration and we note AA EI's views with respect to each.

- 1) Co-locating All FDA Prior Notice Staff with CBP's National Targeting Center. We believe this is a positive step in that the two agencies' personnel who are accountable for the risk analysis of both the import security and the bioterrorism security risks will have continuing access to each other and can easily interact and share information that is appropriate and allowed under current regulation. We would also hope that the two agencies' management teams would continue to dialogue in regard to increased efficiencies in and integration of the risk analysis process.
- 2) Further Refinement to FDA's Targeting Rule Sets in CBP's Automated Targeting System (ATS). AA EI strongly supports the continued refinement of the FDA targeting rule sets in order continually to improve the methods by which specific shipments are flagged for security concerns. It is to the benefit of all parties involved that both the FDA and CBP target those shipments and importers for which there is little or no information and/or that pose the most risk to the U.S., while at the same time facilitating those shipments and importers that are well known and have provided the agencies with the means by which they can be assured that the shipments are generally compliant. In addition, for reasons outlined in our comments regarding the Prior Notice process (69 FR 19763, April

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14, 2004), AAEI believes that food products subject to the FDA's Prior Notice requirements must be eligible for the full expedited processing and information transmission benefits allowed with the C-TPAT and FAST programs, and any similar programs established in the future. As such, we strongly encourage the FDA and CBP to incorporate the current information contained within these programs and allow for the removal of the maximum number of flags within the risk analysis system for those companies that evidence their compliance by participation in these additional security programs.

- 3) Additional Training of FDA Staff in Targeting Techniques. AAEI strongly supports agency initiatives for additional training that will increase the efficiency and effectiveness of the border crossing systems. We note, however, that additional training should be targeted towards those individuals and issues that will provide measurable additional value to the prompt and efficient release of compliant cargo, and that continued dialogue with impacted members of the trade community could very much assist in refining those efforts.
- 4) Targeting Support From CBP and Other Federal Law Enforcement Analysts at the NTC. AAEI supports this initiative.
- 5) Enhanced Communications and Cooperation with CBP to Facilitate Information Exchange and Ensure Fast Access to Foods that are Subject to Prior Notice Holds. This will be critical to the AAEI membership that is impacted by these new regulations. Any hold-up of food or food-related shipments that are actually compliant or found to be compliant after being held will add costs and inefficiencies to the current international supply chain. Fast and efficient processing of all shipments will help to minimize additional incurred costs.

Assessing Reduced Timeframes

AAEI supports the overall plan as outlined in the Federal Register notice. In summary, we understand that FDA and CBP will work towards the following:

- 1) Assess Current Practices Used to Receive, Review and Respond to Prior Notice Submissions During the First Three Months of Full Enforcement. AAEI supports the action overall. We would caution, however, that any assessment taken up during this time frame must take into account the problems inherent in the current systems as experienced by the agencies during start up, as well as the fact that not all submissions will be properly prepared or followed up on. In all probability, this could potentially translate into current practices or staffing appearing to be inadequate when, in fact, they may not be. AAEI members have provided feedback in regards to systems issues, such as the inability to submit certain data or entry types through the ABI system.

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- 2) Identify Changes to Work Practices and Staffing Necessary to Receive, Review and Respond within Reduced Time Frames that Match Current CBP-Published Time Frames under the Trade Act of 2002. AAEI fully supports this process and encourages FDA to provide for any changes that may be needed to allow the timing reductions so critical to economic prosperity. Again, we would caution that the early set-up and systems glitches be taken into account when making this analysis. Once the program has been up and running for a time, and the systems glitches worked out from past experience, the trade expects that this would translate into a faster processing time than what may currently be achievable.
- 3) Implement Necessary Changes and Make Appropriate Adjustments to Ensure Reduced Time Frames. AAEI would encourage both agencies to ensure that they allow for the proper communications with the trade industry prior to planning for or implementing any changes as a result of the above assessments. That way, all the interests and requirements of all the parties involved in the process can be assessed and the best, most efficient changes can be implemented. As has often been the case in dealing with CBP and other agencies, the trade is frequently able to offer recommendations that serve to benefit both the private sector and government.
- 4) Issue a Prior Notice Final Rule in March 2005 that will Respond to all Comments Received on the Prior Notice IFR, This Plan and the Additional Open Comment Periods.

The Plan also states that the agencies are emphasizing that “the evaluation of whether to reduce the timeframes for Prior Notice review will depend on the level of compliance industry achieves during the assessment.” While AAEI agrees with this statement in part (in that agency processing and staffing time requirements would be directly related to the ability of the trade to provide their Prior Notice submissions as accurately and efficiently as possible) we do not believe it is appropriate for the agencies to place the burden of compliance entirely on the trade. The trade’s ability to provide the information required also depends on the systems working properly, the efficiencies of the government personnel involved, the educational outreach levels and the feedback individual importers receive in relation to their current processes. These are areas that are controlled and managed by the agencies and so must also be considered when assessing the probability of reducing timeframes.

Most companies impacted by these regulations have already spent a considerable amount of time and resources in proactive internal planning to meet the requirements. However, a critical part of the planning process involves the ability to self-assess and then fix the gaps, if any, that each may have in its current process. The current phased-in

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approach to full enforcement of the Prior Notice requirements, allowing for the necessary time and training to occur for both importers and government officials under a new and relatively untested system, appeared to be a workable solution for allowing this self-assessment.

Under the guidelines, the FDA stated its intent to provide a transition period, during which it would emphasize education about the Prior Notice requirements to help industry achieve compliance with the regulations. Of special importance was the intent to gather data to track compliance with the Prior Notice requirements and to use that data and summary information to assist the industry and individual companies in improving the submission of Prior Notice. FDA had indicated that the appropriate data related to specific errors in submission for importers would be tracked within the new system and that during the first two enforcement phases the information, in the form of a written communication back to the importer or its broker, would be provided to allow importers time to fix any systems or process issues they may have in regards to their current submission process. This, in turn, would obviously impact the FDA's assessment regarding workable timing standards.

While AAEI's members appreciate the summary information that has been published on the FDA's website and are able to use this information as a general guide as to how the process is working overall to-date, it does not assist them in identifying individual company process gaps that would allow a proactive approach to fixing those gaps and ensuring as efficient a submission process as possible.

AAEI understands that the inability to provide this critical information is a result of a required FDA/CBP systems upgrade that has not yet been completed. As such, AAEI strongly urges that the agencies take this into account when making decisions regarding the trade's future ability to provide a high level of compliance during the assessment process.

Conclusions

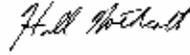
Implementation of the BTA Prior Notice regulations has been a major effort undertaken by FDA and CBP together, but also in partnership with the trade community; a partnership that should be built on by fully incorporating communications with the trade as early in the process as possible. AAEI appreciates the opportunity to provide the FDA with these additional comments on the Plan. We sincerely hope that the concerns expressed in this correspondence are helpful to the FDA and CBP as this process moves forward.

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Should you have any questions or concerns regarding this submission, please do not hesitate to contact us. We would welcome the opportunity to provide any additional information you may need.

Respectfully submitted,



Hallock Northcott
President