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United States Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852  
Docket No. 02N-0278

**Prior Notice of Arrival of Food Articles – Published Regulations**

Dear Mr. Shapiro:

This letter responds to the proposed regulation published in the *Federal Register* of February 3, 2003 that would require the filing of a Prior Notice of every arriving food article, whether or not intended for U.S. consumption.

At the outset, we applaud the FDA's efforts to draft regulations addressing the tremendous role Congress assigned to the Agency as part of the Bioterrorism Preparedness Act of 2002. The need for proactive border enforcement is critical to protecting U.S. consumers from unsafe food articles and we fully support the FDA's mission, commitment and objectives in that regard. However, we are concerned that the regulations, as published, would increase the costs and burdens of importing food articles into this country so exponentially that the entire industry is threatened. Because we are certain that this is not the result the Agency intended, we respectfully submit to you the following thoughts and comments in connection therewith.

**BACKGROUND INFORMATION**

Flegenheimer International, Inc. is a small Customs Broker company in Los Angeles. We prepare and submit entry documentation for a variety of food importers and, in particular, on behalf of domestic importers of perishable fish items from throughout the World. As we are sure you are aware, under current regulations, U.S. Customs, FDA and USDA require documentation to be filed in connection with seafood

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importations. In this regard, we utilize the existing ABI Customs System that allows electronic submission of all of the information required by each agency to be filed simultaneously. Without such coordinated timely, accurate and complete submission of this documentation, the perishable items would be unacceptably delayed at the Port of Arrival and, frankly, we would be out of business.

### ADDITIONAL COMMENTS

The proposed Prior Notice regulations do not provide for any user interface with any other agency's databases or reporting modules. In addition to the burden this will place on Customs brokers charged with ensuring proper and timely submission of import documents, the additional work created as a result of requiring submissions to different agencies of oftentimes duplicative information will necessarily result in additional importing fees that will naturally be handed down to the importers themselves and ultimately the consuming public.

Currently, the OASIS system requires the submission of information that, if presented to the FDA --- even through the existing systems --- prior to arrival (instead of the current procedure whereby FDA only has the opportunity to review this information at or post-entry) would clearly satisfy the stated congressional requirement for the Prior Notice submission. Moreover, since Customs is now requiring advanced manifest information for ocean bound cargo and will soon be requiring that advance transmission for all modes of transport in connection with all importations, it is confounding that the FDA believed a coordinated agency requirement for a single pre-arrival submission was impossible to implement. It must be said that, by appearances, the FDA intentionally contradicted its Congressional mandate to improve agency communication by electing, without reason or evident purpose, to broaden the required data elements in the Prior Notice to purposely make it impossible to utilize existing information systems. As a result, not only will importing food articles become more time-consuming, onerous and oftentimes impossible, but the additional time for the duplicative filings and the substantial verification of information that will be required of the Prior Notice submitters will raise the cost of importing goods to an unacceptable level and will, without a doubt, lead to products becoming unmerchantable as they sit at the ports while the Brokers work 24/7 trying to obtain the extraordinary amount of supply chain detail the FDA erroneously believes is necessary to protect the Nation from an unsafe food supply.

Importantly, the information required to be provided on the Prior Notice not only inexplicably expands that information statutorily mandated in the BioTerrorism Preparedness Act of 2002, but unnecessarily increases the information gathering and verification procedures that will be expected of the Customs Broker. The Proposed Regulations make the submitter of the Prior Notice responsible for the accuracy of the information provided therein. Consequently, many brokers will be unwilling to accept this additional liability since their roles are merely to transmit information to Customs (and/or the FDA) that they are provided with from their clients. However, importers, very likely, will also not be so willing or even able to timely submit the Prior Notice

documentation since much of the information required on the submission relates to the actual entry identification that only the Brokers will be able to provide.

There is no one entity who will have the ability to verify all of the information required on the Prior Notice nor should only one such person bear such a responsibility. If the Customs Broker provides the FDA with information to sufficiently identify the imported article, entry information, place of manufacture, identification of manufacturer, shipper and importer, country of origin and anticipated arrival information, then, not only is this sufficient to ensure immediate recall of tainted goods and to facilitate arrival inspections, but it is also information that the FDA will be able itself to verify as to accuracy. If the manufacturer is responsible for registering, then submission of proper registration information should be the responsibility of the manufacturer and not the Customs Broker or the importer who may have no ability to obtain that information directly or expeditiously. Similarly, the submitter of the Prior Notice should be able to rely upon the information systems being created by the FDA to confirm that the indicated supply chain participants have complied with their respective responsibilities -- -to pass that burden onto a hired Customs Broker who may be charged only with timely filing of paperwork with federal agencies is not only inappropriate but it may, in fact, hinder the efforts against terrorism. Please note that it would, however, be an unacceptable response to eliminate the ability of the Customs Brokers to submit the Prior Notice since this type of import-related documentation submission is the very nature of the brokerage business in its most basic form.

As a result of Customs Brokers being unable to verify sufficiency or accuracy of information required under the Proposed Regulations in connection with the Prior Notice, even a simple amendment to the original Prior Notice may not be sufficient to correct the natural deficiencies. Accordingly, the original Prior Notice will have to be cancelled and a new one filed...while these perishable articles linger at the Port. In addition, we often do not learn the time of anticipated arrival of a shipment until it actually arrives --- transporters are often delayed through no fault of planning or intention and, accordingly, lack of a timely update similarly would be the result not of intentional non-compliance but unfortunate circumstance. Nevertheless, once again, the perishable goods will be left at port while a new Prior Notice is submitted, accepted and reviewed as to accuracy. Again, this duplicative work will necessarily increase the costs and burden placed upon legitimate tax-paying U.S. importers and such an extreme disruption in normal trade cannot be an acceptable consequence of these regulations.

Finally, although the underlying legislation motivating the rulemaking, i.e., the BioTerrorism Preparedness Act of 2002, requires that the FDA increase communication and information sharing between agencies, the proposed rule specifically requires no such communication or sharing of information. The information that is required to be submitted pursuant to the BioTerrorism Preparedness Act of 2002 is already being reported to U.S. Customs on a per shipment basis and there is no rationale for requiring the increased, detailed information per line item as the published rules propose. The resulting costs for new software systems, programming operators and business operations that will be required to track the multitude of information required by the Prior Notice for

each and every line item included in a single shipment is unduly burdensome and cost prohibitive.

### CONCLUSION

This country is largely supported by small businesses such as mine. We provide a valuable service to the importing community because we are able to ensure the safe and timely entry of perishable food items. The proposed Prior Notice regulations, however, will raise the cost of importing products into this country and will necessarily delay entry of these products so that American consumers will have no option but to forego fresh seafood entirely in favor of, perhaps, only frozen goods. This is not only unfortunate, but unnecessary.

We urge the FDA to continue its commitment to keep America's borders safe and honor its obligations under the BioTerrorism Preparedness Act of 2002 by working with the other Agencies responsible for imports into this country. Especially at this time in our country's history, when our country's importers have already evidenced their commitment to safety and integrity of imported goods by reinventing their business operations in order to comply with increased disclosure requirements established by U.S. Customs, it would be illogical for the FDA to intentionally sacrifice these same tax-paying U.S. small businesses --- providing products desired and called for throughout the domestic marketplace --- by implementing regulations that will impossible to comply with. Unfortunately, however, because of the increased costs and burdens associated with the proposed Prior Notice regulations, as published on February 3, 2003, the legitimate importing community of perishable food items in particular will suffer tremendously and may, in fact, be eliminated entirely.

Accordingly, we urge the FDA to reconsider its regulations and to particularly consider how its obligations under the BioTerrorism Preparedness Act of 2002 may be fully met by coordinating directly and sharing information with U.S. Customs and other federal agencies.

If you should have any further questions or wish to discuss this matter in greater detail, please feel free to contact the undersigned directly at any time.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William A. Flegenheimer', with a long horizontal flourish extending to the right.

William A. Flegenheimer