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FDA Desk Officer
Office of Information and Regulatory Affairs
Dockets Management Branch
5630 Fishers Lane, Room 1061
HFA-305
Rockville, MD 20852
Docket no. N02N-0278

Subject: Docket no. N02N-0278, Comments on the "Bioterrorism Proposal" published in the Federal Register dated 2/3/2003

Gentlemen,

The proposed federal register ruling in regards to the "prior notice of arrival submission form" requires this letter. The way this form is in the FR proposal, it will make the fresh food imports impossible to import into this country. It will increase the cost of importing at 50% and will cause a tremendous amount of congestion at our borders and the airports through out the United States. The borders and the airports are over crowded now. We do not need additional waiting time for the trucks with fresh fish and fresh produce on board. The airlines would have to find cooler space for all the fresh shipments that would be held up because of this ruling, and the airlines do not have enough cooler space to handle the cargo that is being imported now if the cargo had to stay at the airlines. Requiring the "prior notice of submission" on each and every shipment would additionally over burden the systems of handling the regular flow of products coming into the U.S. We are all for homeland security in fact U.S. Customs and portions of USDA will be under the new homeland security department joined together within a month from now.

In addition, this will lessen the quality of both fresh seafood and produce arriving at our borders and arriving by air. Because the "prior notice of arrival" has to be perfect with only one amendment allowed. This is very restrictive and limiting to any submitter that maybe willing to take on the task of preparing this and submitting it properly. The flow of cargo changes constantly and unless we are allowed to keep updating the "prior notice of arrival" without worrying about the form being rejected, everybody has to wait until the cargo is counted in at the airlines, before they can submit this "prior notice form" to be accurate. Can you imagine what kind of chaos and confusion it will cause with FDA

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personnel? This will create a major burden for both FDA and the commercial side of importing. Which of course will cost FDA as well as increasing the cost to the small businesses. The small businesses will not be able to compete with the big businesses and they will possibly go out of business. One solution is to change this "prior notice form" to make it more user friendly. Remember that FDA is still getting their required information on a shipment-by-shipment basis via oasis and ABI. This does satisfy six of the seven points of the new law set forth by congress.

Therefore, perhaps FDA can look at a "Blanket Reporting Notice of Arrival" and eliminate the details of each shipment on this form because again FDA is already getting this information on a shipment-by-shipment basis via Oasis.

Because of the strict requirements of this "prior notice of arrival" it could wipe out the fresh products being imported into the U.S., it would be impossible to file a perfect form the first time. One of the restrictions is the time of arrival, which sometimes cannot be obtained until the airplane lands. Therefore, the "prior notice of arrival" cannot be submitted until the cargo gets here. FDA is getting this information anyway via Oasis, so why do they need this information on this new form. In addition, the carton count is required on this new form. The carton count could change in mid flight without the submitter knowing about it until the plane lands. Again, FDA is getting this information via Oasis on a shipment-by-shipment basis. What may happen as this "prior notice arrival form" will be filled out speculation guessing the actual amounts, time frames, and flight information, etc., which is required on this form.

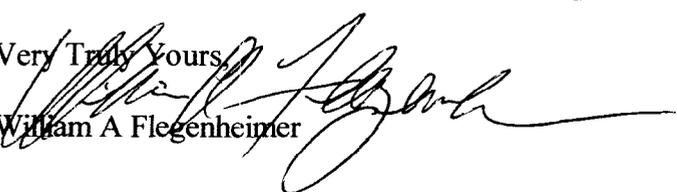
This would mean FDA would not accurately have the information and then their statistical information would not be correct for congress. These scenarios are both very bad for both FDA and the commercial side of the industry. The potential results are not what congress intended under homeland security.

I respectfully request that FDA works together with the trade organization to come up with something that everybody can live with. One of the items might be to remove the entry number off this form, plus the requirement for the flight arrival information and truck crossing information, plus the carton count. This would go along way towards helping the importers and carriers complete this form more accurately and correctly.

I believe in homeland security and I want to work together with FDA to find a more appropriate solution that works for both FDA and the industry together. Please let us put in some good hard homework on the "FDA Notice of Submission and Arrival" to make the details of this form something that everybody can live with and be proud of for the sake of homeland security.

Also this proposal has such far reaching changes and new regulations that in effect will change the way whole industries work, you at FDA have only given the trade only sixty days to respond. I respectfully request an extension in time to submit our responses.

Very Truly Yours,


William A Flegenheimer