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WRITER'S DIRECT DIAL NUMBER

July 13, 2004

FEDERAL EXPRESS

Food and Drug Administration

Room 1061

5630 Fishers Lane

Rockville, MD 20852.

Attention: Director, Dockets Management Branch (HFA-305)

Re: Interim Final Rule Comments & Questions
Bioterrorism Preparedness Response Act
Our Reference: 03-2961-1(3)I

Dear Sir/Madam:

On behalf of the New York/New Jersey Foreign Freight Forwarders and Brokers Association Inc. (NYFFBA), we submit the following comments concerning the Food and Drug Administration's interim regulations implementing sections 305 and 307 of the public Health Security and Bioterrorism Preparedness Response Act, HR 3448, P.L. 107-188 ("the Bioterrorism Act"). Interim final rules were published on October 10, 2003 at 68 Fed. Reg. 58974 et seq.

The NYFFBA is an association comprised of customs brokers and freight forwarders operating in the ports of New York and New Jersey. NYFFBA members will be directly affected by many of the proposed regulations. Because specific portions of the proposal may adversely impact its members, the NYFFBA requests FDA to consider the following comments and suggested modifications to the proposed regulations. Initially, we have one comment regarding the interim regulations, and we have a number of questions regarding the working day-to-day issues that the FDA and CBP should address in these final rules:

COMMENT REGARDING INTERIM REGULATIONS

The interim regulations state in § 1.283(d) page 59021 of the October 10, 2003 Federal Registered notice that:

After refusal, the submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article is subject to the requirements of this subpart under §§ 1.276(b)(5) and 1.277, or whether the prior notice submission is accurate. The interim final rule also sets out procedures and timeframes for this review process.

We believe that the final regulations should make it clear that the request for the review and / or the participation in the review can be conducted by any of the named parties set out above or a designated representative such as a Customs broker, freight forwarder, or attorney.

QUESTIONS CONCERNING IMPLEMENTATION

- (1) Where food items will be entered after the arrival of a vessel or an aircraft, will the information for FDA clearance be allowed to be transmitted via ABI and / or PNSI? If such a transmission is allowed, and the entry is untimely filed, what error message will be sent back to the transmitter? Will the transmitter receive a refused admission status or some other error message? It would be helpful if the transmitter could be provided with an electronic means to resolve the refused admission status. Would that be possible? What will the timeframes be for the release of refused status goods or will “refused goods” have to be exported or destroyed?
- (2) How does the transmitter request / designate a “secure facility” if the goods are put in refused admission status? The CF3461 currently designates a Customs exam site in box 29. Will refused goods be sent automatically to the designated Customs exam site or can arrangements be made to designate another facility? Will FDA publish a list of approved “secure facilities” by port so that transmitters can designate these facilities?
- (3) Will the FDA verify the FDA registration number timely (minutes, not hours) and give the transmitter the message so that the transmitter may request the correct

registration number, name, address, etc. prior to the transmission becoming untimely filed? As the transmitter will have to obtain this information from the vendor or shipper overseas, the transmitter should receive a 24 – 48 hour delay before a refused admission message is issued. This would provide the transmitter with an opportunity to correct the registration number problem before the merchandise is refused admission.

- (4) Will Customs put a manifest “hold” on food cargo until the PN confirmation is received? Cargo at the present time can be moved inland on an IT or T & E entry without FDA review. Goods with carriers door move bill of lading can be moved without the FDA may proceed. Will the FDA remind transmitters that products should remain intact until a may proceed message is received? Will ocean carriers be advised of the FDA status of the goods where the shipment involves door moves beyond 50 miles from the port of entry?

CONCLUSION

We applaud the FDA’s efforts to continue to coordinate the review and release of food products with the CBP. We would like to continue to work with these agencies to facilitate expediting the processing and release of food entries in the United States. If you have any questions please feel free to contact the undersigned.

Very truly yours,

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