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December 22, 2003

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

**Prior Notice Regulations under the BioTerrorism Act
 Dockets Nos. 02N-0276 and 02N-0278**

Dear Sir or Madam:

The Miami-Dade Aviation Department, operator of Miami International Airport (MIA), is pleased to submit these comments in response to the FDA's Interim Final Rules implementing the BioTerrorism Preparedness Act of 2002 (the "BTA Rules" and/or the "Act", as appropriate).

General Information About MIA

MIA is among the busiest airports in the world. There are over one hundred airlines serving MIA to approximately 150 destinations around the globe and MIA continues to be the number one airport in the U.S. for international freight, and number three in the world for total freight. MIA's annual impact on local tourism, cruise, international banking, trade & commerce is \$18.6 Billion and MIA, and related aviation industries, contribute 237,421 direct/indirect jobs to South Florida (one out of five).

Ongoing expansion of the cargo facility area on the west and north sides of MIA's airfield has provided over 2.4 million square feet of new, Class A cargo handling facilities and future development will raise total facilities to nearly 2.8 million square feet. The majority of MIA's international import cargo comprises perishable products including flowers, fruits, vegetables, seafood, plus some assembled clothing. Accordingly, as a landlord of this cargo facility and, also, as a port to which food articles arrive, MIA has unique concerns regarding the BTA Regulations that it respectfully brings to your attention.

02N-0278

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Comments and Discussion

I. Facility Registration

MIA is the owner of multipurpose cargo facilities in which it leases a variety of differently sized warehouses to different businesses, which distribute a range of products into the United States. These businesses may operate multiple facilities at different locations throughout the World, whether as leased space or otherwise. Moreover, these businesses may or may not be food related.

Nevertheless, because the FDA regulation provides that facility registration is the responsibility of the owner, operator or agent in charge of a facility and does not limit such an obligation to the businesses actually operating within that facility --- despite Congressional intent to the contrary --- MIA is compelled to assume responsibility for registration of its cargo facilities if only to avoid exposure to penalties under the BTA Regulations. This is true even though MIA does not itself conduct any business within its facilities, except that of a landlord. Accordingly, such assumption of responsibility, while necessary and understandable under the existing BTA Regulations and the FDA's erroneous interpretation of the Act, is misplaced, unfortunate and bound to compromise the Act's objective of ensuring the safety of America's food supply.

The BTA Regulations should be amended to indicate that facility registration is the responsibility of the entities conducting business within such a facility. This is what Congress provided and intended under the Act and what is necessary to ensure effective enforcement of the Regulations.

A. Congress Clearly Intended Facility Registration To Be The Responsibility of Businesses Operating Within the Regulated Facility

The FDA, in its preamble to the BTA Regulations, states that the Act mandates registrations with the Agency of facilities, not businesses. Specifically, the FDA states that:

The Bioterrorism Act (21 U.S.C. 350d(a)(1)) requires that each domestic and foreign facility be registered. "Facility" is defined as "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food" (21 U.S.C.

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350d(b)(1)). Thus, the plain language of the Bioterrorism Act requires registration to be by individual facility, not by firm."

But this is, respectfully, only half of the correct interpretation of the Act.

The Act does, indeed, require registration of every facility that manufactures, stores, holds, packs or processes food for consumption in the U.S. in order to permit inspections and bioterrorism-related notification. However, the Act requires that "registrants" be held responsible for registration of those facilities at which they "conduct business." To highlight this intent, Section 415(a)(2) of the Act is reproduced below:

"(2) **REGISTRATION.**--An entity (referred to in this section as the 'registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information.

By the clear terms of the legislative language, Congress clearly intended that the responsible "registrant" is that entity "conducting business" in those facilities it registers...whether or not the registrant "owns" such a facility. For this purpose, Congress determined that the registrant could be the "owner, operator or agent in charge" of such facility, clearly depending upon which of those parties conducts business within the facility to be registered. The issue for Congress was not merely that a structure be registered with the Secretary but that the businesses within that building --- that facility --- be held responsible for registering that facility with the Agency.

To reiterate, Congress constructed the Act so that facility registrants were absolutely and without a doubt those entities that "conduct business" within the registered facility. This is clear because Section 415 of the Act requires facility registrants to advise and describe to the FDA those facilities in which they "conduct business."

Accordingly, while the FDA is accurate that the Act requires registration of individual facilities, it is incorrect that registration must be accomplished by such individual facilities and not by the individual firms operating within that structure. Congress made it very clear that registration of facilities is to be accomplished by businesses that may be the owner of the facility, the operator of the facility and/or the agent in charge of the facility. It is reasonable to assume that in all cases, at the very least, businesses *operating* within a facility, whether leasing space or otherwise, would

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qualify as "operators" of such a facility. Accordingly, these operators --- who may also be the owners or agents in charge of a particular facility --- are those parties responsible, and solely responsible, for ensuring that those facilities in which they conduct such business are duly registered with the FDA.

B. Omission of a Definition of a "Registrant" in the BTA Regulations Creates Confusion and Ineffective Enforcement

Despite this clear congressional intent to hold food businesses responsible for registering those facilities in which they conduct business, FDA has implemented BTA Regulations that include no section about or definition of "registrants." This assumed unintentional oversight necessarily results in marketplace confusion.

The FDA has, as stated above, determined that the owners, operators and agents in charge of their facilities are responsible for registering those facilities with the Agency and, by doing so without consideration of whether or not those parties are actually conducting food business within those facilities, the FDA has not only run afoul of Congressional intent but has frustrated the very purposes of facility registration espoused by the Agency itself.

The FDA indicates that the Act requires that the "... FDA compile and maintain an up-to-date list of registered facilities; this list will serve two purposes. One purpose of the registration database is to provide FDA with information that will permit FDA to respond promptly to a bioterrorist event or other food safety emergency. A second purpose is to provide the agency with a list of facilities for inspection." How will the FDA know which of the businesses leasing space in MIA's cargo center is importing food products if merely the warehouse itself, as a single non-specific address owned by the airport itself, is the "facility" that is registered? How will the FDA determine which of these businesses may be a link to a bioterrorist event if it does not even require that those businesses be registered individually with the Agency for purposes of emergency response or inspection? Requiring registration of "facilities" involved in storing food products intended to be consumed in the U.S. may be important for purposes of ensuring American food safety; but requiring that this be done by either the "owner, operator or agent in charge" leaves responsibility for this important act to parties with completely different interests in the facility, and often with no knowledge about the food held there. It defies logic to hold three parties, which may be completely distinct, equally responsible for compliance with the same regulation in connection with the same facility.

The FDA states "if a facility has multiple owners, operator or agents in charge all are collectively responsible for registering the facility and any one of these individuals may register the facility. Although these persons may decide themselves how, as a practical matter, their facility will be registered, the existence of multiple owners,

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operator agent in charge does not affect the legal obligation each has under the rule to register the relevant facilities." Therefore the FDA appears to be more concerned with ensuring that someone -- or multiple parties -- is held liable in the event of non-compliance than they appear to be concerned with ensuring receipt of information necessary to protect the domestic food supply.

In contrast, the Act is not, on its face, primarily concerned with assessing liability; it is intended solely to protect the American food supply by ensuring that the FDA knows the identity of registrants involved in the governed industries and the facilities at which they do business. By not clearly linking facility registration with the need to know the identity of the businesses operating within those facilities, the FDA has created a gap in enforcement, implementation and intent that is of no benefit to the American consumer or to the Agency itself.

Under the existing BTA Regulations, owners of buildings, such as MIA, have no alternative but to register with the FDA those facilities to which they hold title -- even if they themselves are merely uninvolved landlords --- solely because, otherwise, they may be subject to civil and criminal penalties. This fear of prosecution does not in any way facilitate protection of the American food supply.

It is also our strong belief that the existing regulation has already generated a confusing and less-than-useful database. We are aware of many instances in which the FDA has accepted multiple registrations for the same facility. There is no way that the FDA can identify which is the entity with real knowledge about the food products warehoused there, nor is there anyway that the FDA can determine whether a landlord without knowledge of the food registered, but the tenant responsible for the food did not. The regulations should require registration by the party handling the food, as does the statute.

Concluding Comments Regarding Facility Registration

MIA respectfully submits that the FDA should amend its current BTA Regulations to make clear, as intended by Congress, that while all defined "facilities" must be registered with the Agency, such registration must be accomplished by registrants "conducting business" at those locations. To hold otherwise, and to insist only upon a collective liability without further clarification, will result not only in a clear misinterpretation of the Act but is also likely to result in the FDA lacking the specific information about those businesses within the marketplace actually conducting food related business so that the stated objectives of the registration requirement itself is defeated.

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II. **Prior Notice Time of Submission**

Prior Notice for air cargo shipments from airports north of the Equator should be permitted upon departure from a foreign port, i.e. "wheels up". If the FDA insists upon submission of the Prior Notice 4 hours prior to arrival, shippers from the Caribbean, Mexico, Canada, Central America and Northern South America will necessarily and nearly always be unable to comply. This is an unacceptable consequence of federal rulemaking. Moreover, we are unaware of any reason why the FDA would adopt a different time frame than recently adopted by CBP in its advanced manifest rules.

A. **The Memorandum of Understanding Between CBP and the FDA Eliminates Concerns About Lack of Available Personnel for Review of Prior Notices**

On December 3, 2003, the Bureau of Customs and Border Protection (CBP) and the FDA executed a Memorandum of Understanding (MOU) whereby the FDA would commission CBP officers to help it implement the Prior Notice regulations. In its announcement of the MOU, the FDA indicated that "As part of the MOU, FDA can commission all the CBP officers the two agencies consider necessary to conduct examinations and investigations in accordance with the FDA's recently issued interim final rule requiring prior notice of food imported or offered for import to the United States." Accordingly, it would appear that there is no longer any reason for the FDA to be concerned that it must be provided with Prior Notice far enough in advance of arrival of the food product to ensure adequate resources for review.

Moreover, in its preamble to the BTA Regulations, the FDA predicts the MOU in its explanation of why the submission timeframes were shortened dramatically from the submission requirements first set out under the proposed regulations published earlier this year. "Two major agreements between CBP and FDA allow FDA to reduce significantly the time necessary to receive, review, and respond to prior notice information. First, FDA and CBP have agreed to commission or use CBP staff to perform examinations for FDA when FDA is not present at the port of arrival. Since CBP staff generally will be available where FDA is not, this means that FDA no longer needs lead- time to travel significant distances to conduct inspections. In addition, CBP agreed to modify ABI/ACS to receive, transmit, and communicate prior notice information electronically between CBP and FDA for most entries of imported foods by the statutory deadline in the Bioterrorism Act of December 12, 2003. CBP's assistance with prior notice means that FDA needs far less time to respond to prior notices."

Upon consideration of the foregoing, it is puzzling that the FDA would adopt time requirements for submission of Prior Notices that predictably will lead to significant levels of non-compliance, or will disrupt air traffic schedules. As the FDA clearly is

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aware, air shipments from many foreign jurisdictions arrive in less than four (4) hours. Especially since there is no longer any issue of adequate personnel for enforcement of the Prior Notice regulations, MIA respectfully suggests that the FDA immediately amend its BTA Regulations to reflect its commitment to facilitate compliance and not unnecessarily hold shipments at the port.

B. FDA's Commitment to Harmonizing Its Regulations with CBP's Should Not Be Delayed

The FDA has stated within the preamble to the BTA Regulations that the "FDA is committed to exploring ways to increase integration and reduce the prior notice timeframes further. Accordingly, FDA and CBP will continue working together to determine what is needed to achieve this goal." Simply stated, there is no reason to delay such collaboration. The likelihood of product sitting at the port due solely to Prior Notice regulations imposing impossible time submission requirements upon otherwise lawful importers and shippers is an unacceptable consequence of the BTA Regulations, especially to airport operators such as MIA.

CBP recently published its regulations for electronic transmission of air cargo manifests and CBP, recognizing and studying the business needs and realities of the air cargo industry, allowed such transmissions to be made at "wheels up." There is no rational explanation why FDA should not immediately amend the BTA Regulations to similarly accept Prior Notice transmission for incoming air shipments at the time of departure from the foreign port.

It is unfair to expect importers and air cargo shippers to operate in an environment in which currently final BTA Regulations require pre-arrival transmissions within a time frame that guarantees non-compliance in the hopes that the FDA will eventually "fix" this problem. The FDA must *now* provide assurances to these lawful international businesses that Prior Notice submissions may be made within a time frame more reflective of actual business practices and needs. There is no benefit provided to either the industry or to the FDA by withholding such an announcement until some unknown later date.

CONCLUSION

MIA is a substantial contributor not only to the economic growth of South Florida but to the entire nation. The uncertainty created by the FDA under the BTA Regulations as described herein is of great concern to our client. The BTA Regulations should be immediately amended -- and certainly before full implementation -- to clearly indicate that those businesses conducting business within a regulated facility are the "operators" required under the Act to register that facility with the FDA. In addition, the FDA should

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fulfill its own promise by harmonizing the BTA Regulations with those of the CBP to permit the submission of Prior Notices for air cargo shipments at wheels up.

We appreciate this opportunity to express our view on the BTA Regulations. Should there be any questions regarding the foregoing comments, or should you wish to discuss these matters in greater detail, please contact me at your convenience.

Sincerely,



Angela Gittens
Aviation Director
Miami Dade Aviation Department