

January 24, 2005

Submitted electronically to: <http://www.fda.gov/dockets/ecomments>

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

RE: Docket No. 2004G-0381, Draft Guidance for Records Access Authority,
Federal Register notice December 9, 2004

Dear Sirs and Madams:

These comments are submitted on behalf of Federal Express Corporation (FedEx Express) and FedEx Trade Networks Transport and Brokerage (FedEx Trade Networks), hereinafter collectively referred to as "FedEx".

FedEx supports the FDA in its activities to secure and protect the U.S. food supply chain from bioterrorism attack and other public health emergencies, and the draft Guidance Document that is the subject of this Federal Register notice is another good resource to identify and explain to the affected members of the food supply chain how FDA intends to administer these provisions. However, FedEx believes some elements of the Guidance Document are overly broad, and that the document would benefit by greater clarity on some areas, and by ensuring that the stated processes are readily visible to all affected parties.

Comment No.1:

Section II, Background, Legal Authority, of the Guidance Document, states that FDA's primary interest in these records is to establish "...the immediate previous and the immediate subsequent recipients of food." FedEx agrees that this should be the primary focus, and that records retained by affected parties and requested by FDA should be focused on this determination. However, the discussion goes on to state that the Secretary is authorized to "...access and copy all records related to an article of food..." (emphasis added), subject to certain conditions. We submit that this provision is very broad and thus must be carefully exercised. FedEx requests that FDA add clarity and specificity to this discussion to better identify the situations under which FDA might request "all records" pertaining to a food shipment, and provide some examples of what those records would be, and what records would not be required.

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Comment No.2:

Section III, Discussion, Question A, states that FDA can use this authority "...whether or not terrorism is known or suspected." Two conditions must be met, those being a reasonable belief that an article of food is contaminated and presents a serious threat to human or animals, and that records are necessary to assist FDA in making a "such a determination". This statement also needs clarity and specificity in order for the affected parties to ensure proper records are retained if and when such conditions arise. If FDA is primarily interested in establishing supply chain custody and access for possible adulteration, other records would seem to be of lesser or no interest. FedEx recommends that FDA clarify this section to provide examples of what records would be of interest, and those that may not be of interest. Question B in this section also states that FDA's authority under section 414 and 704(a) may apply to "some or all" records required by 414(b). While recognizing that circumstances of a particular event will vary, as accurately stated by FDA, FedEx recommends that FDA provide some examples of what documents would and would not be required in such an event.

Comment No.3

Section III, Question D addresses the procedures that FDA intends to follow before requesting access to records. However, there is no mention in this discussion of this process being publicly accessible, or if the affected parties will be given any advance notice before FDA submits the written Notice of Inspection to the record keeper. FedEx recommends that this process be readily accessible to all affected parties, and that maximum possible advance notice be provided to the record keeper to allow as much time as possible to retrieve the required records, which will benefit both the record keeper and FDA.

FedEx would like to reiterate our support of the FDA in their efforts to secure the U.S. food supply chain, and for the opportunity to submit comments to this Guidance Document.

Sincerely,

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