



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

2004G-0381

January 27, 2005

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

Re: Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 2004G-0381]

Dear Sir/Madam:

The International Dairy Foods Association (IDFA) is the leading trade association representing the dairy processing industry. IDFA's approximately 500 member companies manufacture the entire range of dairy products and include processors, manufacturers, marketers, distributors, and suppliers. IDFA consists of three constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. Member companies in these groups account for 85 percent of the dairy products consumed in the United States.

IDFA supports FDA's efforts in promulgating the required regulations under the Bioterrorism Act and commends FDA for the extensive stakeholder outreach throughout the promulgation process. In support of making those regulations operate most efficiently, IDFA offers comments with respect to FDA's recently released draft guidance for records access. Overall, IDFA supports what is written, as is, with the exception that we believe Section III, E., of the guidance, needs to be modified to be consistent with FDA's Bioterrorism Act registration regulation.

In FDA's registration regulation, FDA requires the disclosure of an emergency contact phone number and allows for the disclosure of an emergency contact person for matters relating to that registered facility. FDA has acknowledged that the registered facility has discretion in identifying the appropriate contact number and a specific person, if a facility chooses to identify a specific person. As a matter of practice, we believe that FDA has encouraged the

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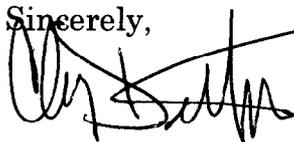
appropriate point of contact, regardless of whether that contact is at the facility or not.

Further we believe that FDA should encourage the voluntary identification of an individual as it will likely facilitate efficient and timely communications when time is of the essence. IDFA believes that facilities and companies who identify individuals when it is not required by the regulation are doing so after giving the matter appropriate consideration and are doing so in the best interests of all concerned. Considering the totality of circumstances we believe that FDA has crafted the registration contact requirements appropriately.

Turning to the records access guidance, IDFA understands that the guidance indicates that FDA will not look to the registration information to identify the emergency contact, but rather FDA will directly contact the registered facility regardless of what was entered into the registration database. We view this as inconsistent and believe that it would be inappropriate for FDA to provide this option under the registration regulation and then ignore a facility's choice when it comes to records access. Given that it is clear that records access is only appropriate when a SAHCODHA threat exists and a SAHCODHA threat by its very nature is an emergency, the appropriate point of contact must be the emergency contact (phone number or individual) identified in the facility's registration.

Given the above, IDFA respectfully requests that FDA modify its draft guidance to require direct and immediate notification of a facility's emergency contact in the event of a request for records access under the Bioterrorism Act. By doing so, IDFA firmly believes the agency will be acting in the best interests of all concerned. Thank you for the opportunity to share our thoughts in this matter and for your consideration.

Sincerely,



Clay Detlefsen
Vice President & Counsel