



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

1 5 31 2005

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Re: Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket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of making those regulations operate most efficiently, IDFA offers comments with respect to FDA's recently released draft guidance for records access.

IDFA is somewhat concerned that it will not be precisely clear to the regulated community when they are being subjected to a Section 306 records access request. We understand that FDA is in the process of modifying its existing FDA 482 to provide for records access, but it is not clear if the FDA 482 is being modified to specifically identify whether the records access is being requested due to a requisite Section 306 SAHCODHA threat or if records access is being requested under other FDA authority. Therefore, IDFA requests that the FDA 482 specifically and clearly identify whether or not the records access being sought falls under Section 306. We believe that a checkbox on the FDA 482 that states "Records

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Access Authorized by District Director under Section 306" would be sufficient to convey that information.

Thank you for the opportunity to share our thoughts in this matter and for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen", with a long horizontal line extending from the end of the signature.

Clay Detlefsen
Vice President & Counsel