FOOD MARKETING INSTITUTE

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Division of Dockets Management (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Re: Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam,

The Food Marketing Institute[1] (FMI) is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the "Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." 69 Fed. Reg. 71657 (Dec. 9, 2004).

Section 414 of the Bioterrorism Act grants FDA expansive new authority both in terms of the records the Agency can require the food industry to maintain as well as the access that FDA now has to those records. FMI and its members commented extensively throughout the regulatory process on the rules that FDA issued to implement the records maintenance provisions of Section 414.

Although the Bioterrorism Act does not require FDA to interpret the records access provision through rulemaking or any other public process, as part of the comment process on the records maintenance provision, we encouraged FDA to issue a public interpretation of the records access provision as well. We are pleased that FDA has done so and believe this step will help lend clarity to the records access process in the future.

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[1] FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

With respect to the particulars of the guidance document itself, we have the following concerns.

First, the specific records to be accessed should be identified on Form 482 before it is presented to a company. Although we realize that it may not be possible to specify the exact records, FDA should make every effort to ensure that the scope of the records to be accessed as determined by officials at the Center for Food Safety and Applied Nutrition, the Office of Enforcement, and the Office of the General Counsel through the process outlined in Section III.D. of the guidance document is fixed and adhered to by the inspector who ultimately presents the request to access records.

Second, to the extent possible, the specific legal basis for the request should be stated and the analysis that FDA undertook to reach the conclusion that the Agency had a "reasonable belief that food was adulterated and presented a threat of serious adverse health consequences or death to humans or other animals" should be made available.

Third, the retail food industry as a whole has been highly responsive when asked for records related to a food safety crisis, even without the new access authority granted under the Bioterrorism Act. However, there may be instances in which a particular company does not believe that the Agency has an adequate legal basis to request the records or that the scope of the records requested is excessive (either for the particular alleged incident or because the request includes records to which Congress specifically denied FDA access). Accordingly, FDA should include guidance on the appellate process that may be used if an inspector presents a request for records that the recipient believes is inappropriate.

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We appreciate the opportunity to provide you with comments on the draft records access document. If you have any questions regarding our suggestion or if we may be of assistance in any other way, please do not hesitate to contact me at 202 220 0614.

Sincerely,

Deborah R. White
Associate General Counsel,
Regulatory Affairs