IFDA
international foodservice distributors association

CONNECTING THE FOODSERVICE INDUSTRY

January 24, 2005

BY ELECTRONIC AND U.S. MAIL

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

Re: Docket No. 2004G-0381

The International Foodservice Distributors Association (IFDA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) draft guidance for industry and agency staff on FDA's records access authority under section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

IFDA is a trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 135 members include broadline and specialty foodservice distributors that supply food and related products to restaurants, institutions, and other food away from home foodservice operations. IFDA members operate more than 550 facilities, and sell more than $75 billion in food and related products to the fastest growing sector in the food industry.

The records access authority under section 306 is one of the most substantial changes to the Food, Drug, and Cosmetic (FD&C) Act since its original 1938 passage. IFDA supports the exercise of this authority under the narrow but grave circumstances Congress intended for its use. In the event of a foodborne disease outbreak or terrorist attack on the food supply, the food distribution industry has not only the legal obligation but also the moral responsibility to assist public health authorities in determining the causes and extent of the situation. IFDA is concerned that the extraordinary authority FDA now possesses must be properly invoked so that both regulators and the regulated industry fully understand the seriousness of such a situation. Accordingly, IFDA supports the procedure described in the draft guidance that FDA must present credentials and a FDA Form 482, Notice of Inspection, when invoking section 306. FDA should, however, amend the draft guidance and its procedures to explicitly provide that the Form 482 clearly state in writing that the conditions necessary for reliance on section 306 have been met and that the agency is proceeding under section 306 authority.

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In addition, IFDA believes that the draft guidance does not provide sufficient protection for trade secret and confidential commercial information that may come into FDA's possession in the exercise of its new records access authority. We urge FDA to add the kinds of procedural protections envisioned by Congress when it passed the Bioterrorism Act.

Section 306 of the Bioterrorism Act greatly expanded FDA's pre-existing records access authority. Under the Bioterrorism Act and FDA's implementing regulation, whenever the statutory criteria for records access are satisfied, FDA will have access to detailed information about the article of food being investigated, including information that many companies consider confidential. Such information includes, for example, all suppliers of foods and food ingredients, all customers to which product is shipped, and all ingredients used to manufacture that food. Moreover, in the emergency situations in which FDA will be exercising this authority, additional records containing other trade secret and confidential information are likely to be swept up and to enter the agency's files.

In granting this expanded authority, Congress directed FDA to provide additional protections for trade secret and confidential information that will come into the agency's possession. Congress was quite clear about the kinds of internal procedural protections it had in mind:

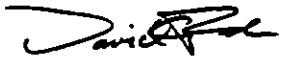
> .... the Secretary would be required to take appropriate measures, presumably through rulemaking and assuredly with the benefit of comments from record keepers, to prevent the unauthorized disclosure of trade secret or confidential information obtained by the Secretary. The managers envision procedures whereby no agency personnel will have access to records without a specific need for such access, possession of all copies of records will be strictly controlled, and detailed records regarding all handling and access to these records will be kept. Shortcomings in such procedures or lapses in adherence to them should be viewed as a presumption of unlawful release of the records. Such record protections are to be in place prior to FDA exercising new records access authority.

House Manager's Report, May 22, 2002.

The draft guidance does not include the kinds of protections for trade secret and confidential commercial information that Congress directed FDA to put in place. It merely refers to existing statutory and regulatory protections. However, FDA's regulations governing disclosure of information (21 C.F.R. Part 20 and 21) do not contain the protections that Congress believed are necessary (*e.g.*, strict control over all copies of records obtained by the agency, a log listing all agency personnel with access to the records, and policies limiting access to the records to agency personnel with a need for such access).

IFDA is concerned that trade secret and confidential information obtained by FDA may be inadvertently disclosed. We urge FDA to revise the draft guidance to add the protections envisioned by Congress. Such internal agency policies and procedures should be published for public comment, insofar as the policies and procedures will deal with the handling not of internal agency records, but rather records obtained from regulated companies.

Respectfully submitted,



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