



**GROCERY MANUFACTURERS OF AMERICA**  
MAKERS OF THE WORLD'S FAVORITE BRANDS OF  
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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January 24, 2005

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061 (HFA-305)  
Rockville, MD 20857

Re: Comments to the Draft Guidance for  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

Comments of the Grocery Manufacturers of America, Inc.

Dear Sir or Madam:

The Grocery Manufacturers of America, Inc. ("GMA") is pleased to have this opportunity to provide comments on the Draft Guidance for Records Access under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"). The Bioterrorism Act authorizes the Food and Drug Administration ("FDA" or the "Agency") to access and copy records related to a food in the event that the statutory criteria for a public health emergency is satisfied, and the Draft Guidance outlines the procedures the Agency will follow in such an emergency.

Grocery Manufacturers of America is the world's largest association of food, beverage and consumer product companies. Led by a board of 42 Chief Executive Officers, GMA applies legal, scientific and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

With U.S. sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states.

### *General Comments*

GMA commends the Agency for its achievements in implementing the Bioterrorism Act. The Bioterrorism Act has put food security among FDA's top priorities and GMA shares this goal with the Agency. GMA and its member companies have a deep obligation to American consumers and are strongly committed to ensuring that the nation's food supply is safe and secure.

The records access Draft Guidance is another step in enhancing the security of the food supply. The Draft Guidance appears to establish a process by which the appropriate FDA Centers, Offices and personnel may be actively involved in assessing whether records must be accessed. Input from these various entities appears to ensure that facts will be adequately reviewed and considered to determine whether the statutory criteria (i.e., there is reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals) for a public health emergency has been met. These factors are essential in light of the high threshold established by the Bioterrorism Act and the highly confidential information that may be provided to the Agency during a public health crisis.

The Draft Guidance, however, neglects to include important information that will assist the Agency and industry in understanding their obligations under the records access provision of the Bioterrorism Act. First, the Draft Guidance should clarify the standard "reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans and animals." Second, the written notification of a request to access or copy records should include additional information such as an explanation of how the statutory standard has been met, the records being requested, and the food that is the focus of the investigation. Third, the Draft Guidance should include procedures that notify the emergency contact listed on the company's facility registration of a written request for records in addition to the procedures currently identified. Finally, procedural and other safeguards for the treatment of confidential information that is provided to the Agency should be included in the Draft Guidance. These modifications are further discussed in the next section of these comments.

*Specific Comments*

1. Clarification of the Statutory Criteria

The Bioterrorism Act authorizes FDA to access and copy records related to an article of food if there is "reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals." Although the standard established by the Bioterrorism Act is high, the term "reasonable belief" is vague. A clear articulation of the standard is necessary to ensure that the requirements of the statute are satisfied and records are not unnecessarily accessed.

It is appropriate for FDA to expeditiously develop and include in the Draft Guidance a clear definition of "reasonable belief." Specifically, the Draft Guidance should specify that the Agency will rely on evidence such as laboratory analysis confirming the presence of an adulterant and/or affidavits sworn under penalty of perjury. The "reasonable belief" standard should be similar to that of "probable cause" and based on more than mere speculation or an anonymous telephone tip.

2. Notice for Access to Records should Explain how the Statutory Criteria has been met, Records being Requested, and Food under Investigation

The records access provision of the Bioterrorism Act greatly expanded FDA's authority in public health emergencies. To avoid confusion and ensure that companies cooperate to the fullest extent, written notifications for access to records should include information that: (1) explains how the statutory threshold has been satisfied; and (2) identifies the records being requested and the food that is the focus of the investigation.

The standard for accessing records is similar to the administrative detention provisions. In the administrative detention regulations, it specifies that the detention order must include "a brief, general statement for the detention." (21 C.F.R. § 1.393(b)(6)). Thus, the Agency should also provide information regarding how the statutory criteria have been met as part of the written notification for records access.

Further, providing companies with additional information in the written notice will facilitate recovery or speedy resolution of certain facts. For example, if specific information about the identity of the food product being investigated is provided, companies can quickly determine whether the suspected product was in fact produced at the facility where the Agency is requesting access. It is not uncommon for confusion to exist about where the food originated. Food companies may receive quality complaints from consumers only to discover that, after obtaining the product lot code, the company did not manufacture that particular product. In a public health emergency, immediate identification of the actual manufacturer of a product will save the Agency valuable time and resources.

During recent meetings to explain the record maintenance regulations, FDA stated that detailed information about the records being requested and the food under investigation would be shared with the company so long as national security is not compromised. FDA should memorialize this commitment and modify the Draft Guidance to reflect its position that it will share information with companies in the event that records must be accessed.

### 3. Notification of the Company's Emergency Contact

As provided in the Draft Guidance, FDA intends to present appropriate identification and documents to company personnel at the location where the documents will likely be maintained. Although it is understandable for FDA to seek the documents at local facilities, many of GMA's members are large companies that have offices and facilities in multiple geographical locations across the country. The person most familiar with the requested documents or best equipped to coordinate the company's resources may not be located at the local facility. In addition, company officials with the authority to ensure that a request for records is responded to promptly and appropriately may not be properly notified of the urgent situation. Therefore, to facilitate a timely response, FDA should provide notification of its requests for records under the Bioterrorism Act to the emergency contact listed on the company's facility registration.

FDA may incorporate the notice to the company's emergency contact as a measure in addition to the currently identified procedures of the FDA inspector's presentation of the FDA Form 482 to the facility. The company

would thereby receive two notifications from FDA requesting access to documents. In light of the serious health consequences that must exist in order for the Agency to access records under the Bioterrorism Act, this additional step is a minor modification to the Draft Guidance that will provide FDA and the food industry with assurances that a public health emergency will be addressed in an effective manner.

#### 4. Safeguards for Handling Confidential or Trade Secret Information

FDA addresses only briefly the procedures that it will implement to maintain confidentiality of protected information in the records it obtains from the records access provision of the Bioterrorism Act. The food industry recognizes that there are several statutes and regulations that govern the Agency's disclosure of confidential information. Nonetheless, because of the serious consequences if confidential or trade secret information is inadvertently released to the public, there are reservations regarding the manner in which FDA will adequately protect this information. It is important to note that FDA's regulations require that if there are any situations where confidentiality is uncertain, the Agency is required to consult with the person who has submitted or divulged the data or information or who would be affected by its disclosure. (21 C.F.R. § 20.47).

In addition to the Agency's existing regulations, GMA also suggests that FDA provide further instructions on how confidential or trade secret information will be handled within the Agency and shared with other federal, state, and local authorities. For example, certain legislation requires that manufacturers of cigarettes and smokeless tobacco products disclose to the Center for Disease Control and Prevention ("CDC") the list of ingredients used in these products. (See, Federal Cigarette Labeling and Advertising Act (Pub. L. 98-474), and Comprehensive Smokeless Tobacco Health Education Act of 1986 (Pub. L. 99-252)). To address confidentiality concerns, CDC published in the *Federal Register* notices that set forth its policy on document access, accountability, protection, reproduction and disposition of confidential information submitted in accordance with these acts. (See, 50 Fed. Reg. 49617 (Dec. 3, 1985; 59 Fed. Reg. 4714 (Feb. 1, 1994)).

Likewise, FDA should also establish specific procedures such as limiting access to confidential documents to only necessary personnel and identifying how documents will be checked-out, controlled, location verified, and reported

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lost. These additional measures will provide assurances that confidential information will be handled appropriately by the Agency and documents adequately protected. The consequences of the inadvertent release to the public of highly confidential company information cannot be understated.

*Conclusion*

Industry cooperation is essential to effectively address a public health emergency that involves the food supply. Accordingly, GMA respectfully requests the Agency to modify the Draft Guidance consistent with these comments. The above-suggested modifications will provide further clarity to FDA's authority under the Bioterrorism Act and ensure that industry is actively engaged to immediately assist the Agency in an urgent situation.

Sincerely,

A handwritten signature in black ink that reads "Susan M. Stout". The signature is written in a cursive, flowing style.

Susan Stout  
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