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August 30, 2002

Docket No. 02N-0277
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Implementation of Section 306 (Recordkeeping) of Bioterrorism Act (Docket No. 02N-0277)

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 Agency's implementation of Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). As discussed more fully below, much of the information that FDA is considering requiring food retailers to maintain is already held by the industry and is routinely used to conduct efficient product investigations in recall situations. However, given the enormous volume of records involved, FDA's regulations should utilize the existing system, rather than requiring the food industry to develop new records specifically for purposes of this regulation. An undertaking of this nature would be inordinately expensive and would provide no additional protection against

[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.

bioterrorism. Rather, FDA's regulations should establish the basic requirements as set forth in the statute and allow the food industry to meet those standards in a manner that will not unnecessarily interfere with the food supply.

A. Legal Background

Section 306 adds a new Section 414 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) entitled, "Maintenance and Inspection of Records." See Pub. L. 107-188, § 306(a). In sum, Section 414(a) of the FD&C Act authorizes FDA to access and to copy food industry[2] records relating to an article of food when the Agency has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The purpose of the review is to determine whether the Agency's belief is legitimate, i.e., whether the food is actually adulterated and presents a serious threat to public health. The statute requires the records review to be made by an officer or employee, upon presentation of appropriate credentials and a written notice to the person holding the records. Review may only occur at reasonable times, within reasonable limits, and in a reasonable manner.

Section 306(d) of the Bioterrorism Act and Section 414(b) of the FD&C Act jointly require FDA to publish regulations requiring the food industry to maintain records to allow the Agency to identify "the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals." FDA cannot require records to be kept for more than two years. The Agency must consider the size of a business in promulgating regulations.

Section 414(d) prescribes important limitations on FDA's records access and maintenance authority. In relevant part, Section 414(d) prevents FDA from accessing or copying recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales). FDA must take appropriate measures to ensure that the Agency has effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by FDA pursuant to Section 414. Section 414(c).

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[2] Section 414 applies to many in the food industry. Specifically, paragraph (a) allows FDA to access records held by each person who manufactures, processes, packs, distributes, receives, holds or imports food that may be adulterated to the extent that it presents a threat of serious adverse health consequences or death; paragraph (b) adds transporters to the list of persons subject to FDA's records maintenance jurisdiction. Farms and restaurants are excluded. For simplicity, we here refer to the community that is subject to FDA's records jurisdiction as the "food industry."

B. Implementation of Section 306: Retail Issues

1. Information Necessary To Meet Standard

a. Immediate Previous Source

As noted above, Section 414(b) requires the food industry to maintain records sufficient to "identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging." In short, for the retail food industry, the information sufficient to identify immediate previous sources of food and packaging[3] is the name and address of the immediate supplier; we would expect FDA to have additional information on the supplier through the database that the Agency will be compiling pursuant to the registration requirements in Section 305 of the Bioterrorism Act. Accordingly, retailers should not be required to maintain records with more than the name and address of the supplier.

As to the particular entity to be identified, we understand the "immediate previous source" to refer to the separate legal entity that held title to the food immediately before title was transferred to the "person" who is required to maintain records under the statute. We understand the "person" on whom the requirement falls to be a single corporate entity, rather than individual facilities. Thus, for example, a distribution center (DC) held by the same corporate entity as a retail store would not be the "immediate previous source" of a food product; rather, in this case, the "immediate previous source" to the entity that held the retail store and the DC would be the supplier to the DC.

In contrast, if food is delivered to a retail store through a third party wholesaler or by direct store delivery (DSD), the immediate previous source of the food would be the wholesaler or the DSD supplier, respectively. In some cases, however, food is shipped to a retail store from a commercial warehouse, which has held product on behalf of the manufacturer until a suitable purchaser might be located. Although the commercial warehouse was the immediate previous *location* of the food, FDA should consider the immediate previous *source* of the food to be the manufacturer or other entity that held title to the food product before it became the property of the retailer. Although retailers will likely be able to identify the entity from whom they purchased the product, retailers may not know whether the supplier chooses to ship product from the plant or from a separate commercial warehouse facility at which the supplier chose to house some of the product until a suitable buyer was located.

Separate food retailers may also share truckloads of food products. For example, Retailer A may purchase a truckload of product from Manufacturer 1. Unable to use the entire truckload, Retailer A contracts with neighboring Retailer B for Retailer B to purchase half of the truckload. In that case, we expect that the immediate previous

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[3] As some food products, such as meat, poultry, and prepared foods, are packaged in store, retailers will be required to maintain records of their packaging suppliers, as well.

source for Retailer A would be Manufacturer 1, while the immediate previous source for Retailer B would be Retailer A.

As evidenced by the foregoing examples, the food distribution system is quite complex. It will be helpful for FDA to define the term "immediate previous source." We believe a suitable definition is the person or legal entity from whom legal title to the food product was obtained.

b. Immediate Subsequent Recipient

The immediate subsequent recipients of food from food retail establishments are primarily individual consumers. Food retailers should not be required to maintain records to identify which consumers bought specific food products. FDA's regulations should explicitly exempt food retailers from the requirement to maintain records on the immediate subsequent recipients of food products.

c. Specificity of Supplier Identification

The food industry should be responsible for identifying the possible immediate previous sources for a particular food item, rather than identifying an individual supply source for a particular item. Specifically, much of the food industry – including the retail sector – relies on multiple sourcing for many different food products in a variety of contexts. Multiple sourcing is highly efficient and allows the food industry to ensure supplies adequate to provide consumers with the products that they want. For example, a company that bakes cookies may source flour from five different companies and sugar from three different sources, rather than depending on single suppliers. The flour and sugar are utilized in the cookies without regard to their sources so that it is not possible to determine for any given cookie the specific source of the flour and sugar in the cookie.

Similarly, particularly in the bulk agricultural commodity context, retailers source products through their distribution centers from a variety of suppliers. So, for example, a retailer might order lettuce from three different suppliers, all of which will be held in a single bin at the distribution center. The DC will fill orders for forty or fifty stores, without regard to the exact source of the lettuce that is destined for each store. FDA's regulations should clarify that the ability to provide the Agency with information on the possible immediate previous sources of a food product is sufficient to meet the records maintenance requirements of Section 414(b).

2. Sources of Information

Section 414 is silent with respect to the types of records that may be kept to satisfy the requirement that the food industry maintain records to identify the immediate previous source and subsequent recipient of food products. Rather then requiring the creation of an entirely new set of records, we recommend that FDA rely on the extensive records that many in the food industry already maintain that are used efficiently and

effectively in product recall and traceback situations on a daily basis.[4] Requiring the establishment and maintenance of an entirely new set of records would require substantial resources without any concomitant benefit.

For example, a typical supermarket stocks approximately 40,000 different "stock-keeping units" or SKU's of merchandise. Although the allocation between food and non-food products varies with store formats, 50-70% of a store's SKU's are likely to be devoted to food products. Developing a new system that would require the creation of a new record for each different item would require an enormous allocation of resources that would clearly be disproportionate to any possible benefit.

Instead, FDA should build upon the systems that are currently in place that retailers use to identify the immediate previous source of food products. For example, our members advise that purchase orders, bills of lading, and invoices are documents that may already be maintained by food retailers for business purposes that contain information sufficient to identify the immediate previous source of food products.[5] We recommend that FDA's proposed regulation identify these (and any other) documents currently maintained by the food industry as examples of the types of records that may satisfy FDA's records maintenance regulations.[6] The regulation should clearly state, however, that these are illustrative examples of adequate records and that other types of records may also be sufficient.

3. Format and Location of Information

FDA's regulations should also provide for flexibility with respect to the format and location of the required records. Our members' recordkeeping practices vary widely, but each company expects to be able to utilize its current system to identify the immediate previous source of food products and, indeed, most regularly use their systems for this purpose to respond to product recall situations.

With respect to the format, many companies maintain records solely in electronic form, although some stores, particularly smaller companies, still maintain some paper

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[4] One larger retailer advised that his company addresses an average of 7 to 9 product retrievals (including market withdrawals, class I through III recalls) each week involving products regulated by FDA, USDA or CPSC. The extensive records maintenance system that they have implemented allows them to perform product tracebacks on a daily basis efficiently and effectively.

[5] An individual purchase order may contain information on an entire tractor load of items. Despite this consolidation of information, a member that operates 115 stores estimates that they receive 35,000 purchase orders per year. Invoices often attach to individual products. One member, which operates 140 supermarkets in the mid-Atlantic region, estimates that they receive 10,000 invoices per day. A large food retailer with more than 3000 retail locations tracks paperwork by the trailer-load. As each trailer will include food products and each store averages three to five trailer-loads per day, the company conservatively estimates that they receive 12,000 records per day on incoming food items.

[6] As discussed more fully below, these records may well contain confidential information. Adequate controls must be implemented to ensure that the information is not disclosed and the food industry should be given sufficient flexibility to generate reports that include only the information necessary to achieve FDA's public health objective from the primary records.

records or retain older records on microfiche or microfilm. Moreover, even those companies that maintain information electronically rely on paper documentation originally that is eventually entered into an electronic system. Accordingly, the regulations should permit records to be maintained in electronic, paper, microfilm, microfiche, or any other suitable form.

Food retailers currently have a variety of systems for locating records. Some companies have centralized records access, so that only those at corporate headquarters can access the records of interest to FDA; smaller companies may not have a central headquarters. Mid-sized companies may store records with buyers located at regional or divisional offices. One retailer indicated that, an attempt to access stored records at the retail level would result in immediate notification to corporate headquarters. Given the multitude of current practices for locating records and the very large number of records that might be necessary to identify the immediate previous source of each food product at a retail store, FDA should not require the maintenance of records at each retail store location. Rather, and consistent with the records inspection authority in Section 414(a), FDA's records maintenance regulations should allow for storage of records wherever they may be accessed within a reasonable time following a request for access made by the Agency pursuant to Section 414(a).[7]

4. Protection of Trade Secret or Confidential Information

Paragraphs (c) and (d)(4) of Section 414 recognize the importance of information deemed to be trade secret or confidential to the food industry and specifically place such information beyond the scope of FDA's Section 414 records access and maintenance authority. Specifically, Section 414(d) states that the Agency's authority shall not extend to "recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales)." Section 414(c) requires FDA to implement measures "to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section."

As discussed more fully above, several existing forms of records already contain the information that FDA may require food retailers to retain regarding the immediate previous source of food products. However, these same documents may include information that is deemed highly confidential by the food industry. For example, purchase orders may include pricing data, information on the quantity of the product received, and product specifications, particularly for private label products. This information falls within the information to which FDA's records maintenance and access

[7] FDA permits infant formula manufacturers to maintain consumer complaints for an entire firm at a central location, provided that records are available within 24 hours of an FDA request for inspection of the facility. See 21 C.F.R. § 106.100(k)(6). Off-site storage of records is likewise permitted under the juice HACCP regulation if the records can be accessed within 24 hours of the request. See 21 C.F.R. § 120.12(d)(2).

authority does not extend under Section 414(d) and is further protected by Section 552 of the Freedom of Information Act (FOIA).

Specifically, product specifications are akin to recipes for food in that they provide detailed information on the properties of products that is as important to the quality of the finished product as the recipe is. In many instances, the quantity of the product received is analogous to sales data in the retail context because it reflects the amount of product that is necessary to replace product previously sold; food industry analysts can use product sales data to determine velocity of product sales, which is valuable information in the highly competitive food retail industry. Pricing data is explicitly enumerated as information to which FDA's authority does not extend.

To protect this information from disclosure to FDA, FDA's regulations must allow the food industry to generate reports of the specific information required to be maintained under Section 414(b) to the extent that it is necessary to serve the Agency's public health mission. Thus, if a retailer retains the requisite information on the immediate previous supplier through the purchase orders currently maintained, the retailer should be allowed to provide the information on the immediate previous supplier to FDA by a separate record created to respond to a specific request generated by the Agency when the public health need arises, rather than relinquishing control of the actual purchase order to FDA, since the purchase order may well include information to which Section 414(d) denies the Agency access. Indeed, the creation of a record of this nature would be analogous to a situation in which FDA's regulations prescribed that the food industry create separate records stating the immediate previous source information for each food product. However, rather than creating records of this nature for all foods – which would entail an inordinate and unjustified allocation of resources – the food industry would create the necessary records for FDA when the public health need arose.

Even if the food industry has the opportunity to provide tailored records, not all companies will choose or be able to do so. Accordingly, as an alternative, the food industry should be provided sufficient time to redact the records so that confidential information can be removed before the records are provided to the Agency. As noted above, Section 414(d) prevents FDA from accessing confidential information. To ensure that FDA does not overstep the records access authority of the statute, it will be necessary to allow companies to remove information that the Agency is not authorized to receive. Of course, FDA would need to receive the redacted records within an amount of time reasonable to address the public health needs.

Despite these precautions, FDA may well receive information that is considered trade secret or confidential and, therefore, as required by Section 414(c), the Agency must implement effective procedures to prevent the unauthorized disclosure of such information. The regulations that FDA promulgates to implement Section 414 should explicitly state that pricing data, sales data and product specifications are confidential, trade secret, commercial or financial information within the meaning of the Agency's Public Information regulations. 21 C.F.R., Part 20. See 21 C.F.R. § 20.61. Such

protection from public disclosure must extend to any other confidential trade secret, commercial or financial information that may be included on documents that the food industry maintains in order to comply with Section 414(b). Moreover, FDA should amend Section 20.100 to establish that trade secret, commercial or financial data – such as product specifications, pricing data, or sales data – obtained pursuant to the Agency's Section 414 authority will not be disclosable under FOIA.

Agency disclosure of trade secrets obtained pursuant to FDA's Section 414 authority is a criminal offense. Section 306(c)(2) of the Bioterrorism Act; see, also, 148 Cong. Rec. H2691, H2726 (May 21, 2002). Moreover, the conference report states Congress's expectation that FDA will implement procedures so that "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 by the Agency." The conference report requires FDA to ensure that protections of this nature are in place before the Agency exercises its new records access authority. Rep. Shimkus opined that shortcomings in these procedures or lapses in adherence to them should be viewed as a presumption of unlawful release of the records; we urge FDA to adopt the same view in its implementing regulations. See 148 Cong. Rec. H2858 (May 22, 2002).

5. Required Records Maintenance Time

Section 414(b) allows FDA to require the food industry to maintain records that identify the immediate previous source and subsequent recipient of food products for up to two years. Given the large number of food products held at food retail locations and the differing amounts of time for which those products may be held or offered for sale – days in the case of fresh produce to years in the case of some canned goods – the need for holding all such records for two years is not apparent. Indeed, we recommend that FDA divide the food products that are subject to the record maintenance requirements into two categories – perishable and non-perishable products – and establish separate recordkeeping requirements for each.

We would consider perishable products to be those products with a shelf life of 6 months or less and recommend that FDA require the food industry to maintain records for perishable products for up to one year. (Using this definition, records would be retained for at least twice the shelf life for this class of products.) Non-perishable products might be subject to the full two year record maintenance requirement. This approach is consistent with FDA's current regulations for record maintenance under both the seafood and juice hazard analysis critical control point (HACCP) regulations. See 21 CFR § 123.9(b) (records for refrigerated seafood products must be retained for one year; records for frozen, preserved, or shelf-stable products must be retained for two years); 21 C.F.R. § 120.12(d) (required records must be maintained for 1 year for refrigerated or perishable juices and two years for frozen, preserved, or shelf-stable products).

6. Size of Business

Section 414(b) requires FDA to consider the size of businesses in promulgating regulations pursuant to Section 414. Small businesses are disproportionately impacted by recordkeeping requirements and have a smaller overall impact on the food supply. Therefore, we urge FDA to exempt small businesses from the records maintenance regulations.

C. Implementation of Section 306 – Records Access Authority

Section 414(a) authorizes the Secretary to access and to copy specific records related to food, if the Secretary has a "reasonable belief" that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The Secretary is allowed to inspect and copy those records "relating to such article that are needed to assist the Secretary in determining" whether the food is so adulterated. An officer or employee duly designated by the Secretary may inspect such records upon presentation of appropriate credentials and a written notice at reasonable times, within reasonable limits, and in a reasonable manner.

Although FDA's notice did not specify that the Agency intends to conduct rulemaking on the scope or extent of FDA's records access authority under Section 414(a), we believe it is an important provision that deserves comment from the public and an interpretation from the Agency as it relates directly to FDA's records maintenance authority under paragraph (b). In particular, we encourage FDA to recognize the explicit public health limitation on the Agency's authority both to access and require maintenance of records.

That is, FDA is only authorized to inspect and to require the food industry to maintain those records that are necessary to address credible threats of serious adverse health consequences or death to humans or animals. The statute thus requires FDA to reach a threshold determination that a particular food product is likely to be adulterated to the extent that it would have serious public health consequences *before* the Agency accesses food industry records. Section 414(a) allows FDA to inspect and to copy those records directly related to that food product, but does not authorize the Agency to look for, inspect, or copy records unrelated to the specific food product or the specific situation about which FDA has developed a credible belief regarding the severity of the food's adulteration. The Agency should affirmatively state its intention not to use the new authorities – which Congress granted for the express purpose of protecting the food supply against bioterrorism – as a basis to conduct routine inspections or "fishing expeditions."

The conference report states that the determination that the food is adulterated and presents a threat of serious adverse health consequences should be made under the direct supervision of senior FDA officials. Although the individual determination of the Agency's reasonable belief that a food may be significantly adulterated may not be made

publicly, FDA should render the process as transparent as possible and, thus, promulgate regulations that include the Agency's process for making that determination, as well as an appeal procedure for record holders who wish to challenge the Agency's determination.

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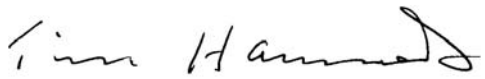
We hope that you will find the foregoing recommendations useful as you develop regulations to implement Section 414 of the FD&C Act. If we may provide any additional information in this regard, or if we may be of assistance in any other way, please do not hesitate to contact Deborah White (202/220-0614) or myself.

Sincerely,



Tim Hammonds
President and CEO

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