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Years of Leadership

August 30, 2002

Docket No. 02N-0276
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Implementation of Section 305 (Registration) of Bioterrorism Act (Docket No. 02N-0276)

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 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). As discussed more fully below, the regulations should provide for a flexible system that permits registration either electronically or by first class mail, and allows facilities to decide whether to file a single registration from corporate headquarters to cover all commonly held facilities or individual registrations from separate facilities. Registration should be required only once, with amendments as necessary to reflect significant changes in the information contained in the registration. No fees should be assessed. FDA's implementing regulations should reflect the scope of the facility definition provided in the statute as clarified by the legislative history. Specifically, retail food establishments, including supermarkets, grocery stores, super centers, club stores, and their attendant facilities, should be explicitly exempted from the facility definition.

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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.

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A. Legal Background

Section 305 adds a new Section 415 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) that requires facilities that engage in manufacturing, processing, packing, or holding food intended for consumption in the United States to be registered with FDA. Registration requires the submission to FDA of the facility's name and address, as well as all trade names under which the registrant conducts business. If FDA deems it necessary, registrations must also include the "general food category" as identified under 21 C.F.R. § 170.3 of any food manufactured, processed, packed, or held at the facility. Registrants must notify FDA "in a timely manner of changes" to the registration information. The conference report states that Section 415 is intended to require one-time registration, rather than annual registration of such facilities. 148 Cong. Rec. H2691, H2726 (May 21, 2002). No registration fee should be assessed. See 148 Cong. Rec. E2387, E2388 (Dec. 20, 2001) (section does not impose a registration fee and calls for a one-time registration).

The registration requirement applies to "facilities" as that term is defined in the statute and further explained by the legislative history. Specifically, "facility" includes any factory, warehouse, or establishment that manufactures, processes, packs or holds food, but does not include farms, restaurants, other retail food establishments, certain nonprofit food establishments, or fishing vessels. 21 U.S.C. § 415(b). The conference report explains that the term "retail food establishments" includes establishments that store, prepare, package, serve or otherwise provide articles of food directly to the retail consumer for human consumption. Examples cited include grocery stores, convenience stores, cafeterias, lunch rooms, food stands, and other similar establishments. The conference report states that the term does not include a warehouse that does not provide articles of food directly to a retail consumer as its primary function. 148 Cong. Rec. at H2726. Nonetheless, the legislative history states that the category 'other retail food establishments' that are exempt from registration includes "facilities attendant to their [retail food establishments'] operations, which are under the same ownership or management." 148 Cong. Rec. at H2858 (May 22, 2002).

Upon receipt of each registration, FDA is required to notify the registrant that the registration was received and to assign a registration number to each facility. The Agency is further required to compile and maintain an up-to-date list of facilities that are registered under Section 415. The list and registration documents are not subject to disclosure under the Freedom of Information Act, nor is any information derived from the list or registration documents to the extent that such derivative information would disclose the identity or location of a specific registered person. See 21 U.S.C. § 415(a)(4).

B. Implementation of Section 305: Retail Issues

1. Scope of Facility Definition

As noted above, facilities that hold food are required to register with FDA, except that certain of such establishments are expressly exempt from the facility definition and, therefore, the statute's registration requirement. 21 U.S.C. § 415(b). "Other retail food establishments" are defined in the legislative history as establishments that store, prepare, package, serve or otherwise provide articles of food directly to the retail consumer for human consumption; grocery and convenience stores are cited examples of "other retail food establishments. 148 Cong. Rec. at H2726. Clearly, then grocery stores and supermarkets are exempt from the registration requirement, as are other retail food establishments, such as super centers or club stores, which also provide articles of food directly to the retail consumer for human consumption.

"Retail food establishments" are often more than the immediate retail store, however, and the legislative history recognizes this fact. Specifically, the legislative history explicitly states that the term "other retail food establishment" includes "facilities attendant to their operations, which are under the same ownership or management." 148 Cong. Reg. at H2858. In the case of supermarkets or grocery stores, such attendant facilities might include distribution centers or central kitchens. FDA's implementing regulations should include a definition of "facility" that explicitly exempts supermarkets, grocery stores, super centers, club stores, and their attendant facilities (such as distribution centers or central kitchens) from the registration requirement.

Similarly, as the statute and the legislative history focus the determination of whether a facility constitutes a retail establishment on whether the facility provides food for consumption directly to retail consumers, the fact that some retail facilities process foods, such as juice, on-site should not render the retailer a "processor." FDA's regulations should provide an affirmative determination in this regard, as well.

2. Information To Be Included in Registration

a. Identifying Information

Section 415(a)(2) requires registrations to include the "name and address of each facility at which, and trade names under which, the registrant conducts business." Accordingly, FDA's regulations should identify the foregoing as information required to be included in a facility registration.

b. General Food Categories

In rather unusual language, Section 415(a)(2) also allows the Secretary to require registrations to include the "general food category" of any food manufactured, processed, packed, or held at such facility "when determined necessary by the Secretary through guidance." Section 415 (a)(2). Section 170.3(n) identifies 43 general food categories that the Agency established to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. FDA stated that individual food products would be included within the categories in accordance with detailed classification lists contained in a 1972 National Academy of Sciences report on the use of "generally recognized as safe" (or GRAS) substances in food. Section 170.3 pre-dates the 1977 re-codification of FDA's regulations.

As noted above, Section 415 does not mandate FDA to require registrations to include "general food category" information; instead, the statute directs the Agency to first determine whether such information is necessary. Given the age of the regulations and their relative attenuation to foods produced today, FDA may well decide that the regulatory "general food categories" are not particularly relevant and, therefore, not necessary for inclusion on the registration form.

Nonetheless, if FDA decides that registrants must identify the general food categories relevant to their facilities on registrations, the Agency should also provide a mechanism for those facilities at which all general food categories are relevant to respond. Specifically, FDA should allow facilities that handle all general food categories to state "All" in lieu of identifying individual food categories on the registration. A situation in which a facility that normally carries all food categories has run out of products in a specific food category, but intends to re-stock the items, should not require amendment of the registration or subject the facility to penalties.

3. Registration Validity

The legislative history clearly expresses the intent of Congress that facilities perform a one-time (rather than an annual) registration and that such registration will serve to fulfill the statutory registration requirement. See 148 Cong. Rec. at H2726. Accordingly, FDA's regulations should require that facilities subject to the registration requirement submit a single, one-time registration.

The statute is equally clear, however, that the registrant must notify FDA "in a timely manner of changes" to the information contained in the registration. We would expect such change to include changes in the facility's ownership or significant changes in the products distributed, manufactured, handled or processed at the facility. Although no precedent exists for timely notification in the food context, FDA may look to the drug regulations for guidance. Specifically, drug listings must be updated every June or December if a new drug is manufactured or discontinued in the facility during the previous six months. See 21 C.F.R., Subpart C, e.g., § 207.30. FDA should consider six

months to be adequate in the food context, as well. Moreover, temporary changes in the general food categories held or processed at the facility should not require notification to FDA.

4. Registration Process

The statute does not prescribe a process by which FDA should implement the registration requirement – beyond a preference expressed for electronic registration – but instead, leaves the process development phase to the Agency's discretion. Although primarily a logistical conundrum for FDA, we recommend that the process eventually designed allow for maximum flexibility to reflect the varied nature of the food industry that will be required to submit registrations.

Specifically, FDA should permit registrations to be filed with the Agency either electronically or via paper. We expect that many in the food industry will prefer electronic filing, but that some – particularly some small businesses – may not yet have that capability. To the extent that FDA establishes an electronic registration system, the Agency should consider methods to protect the system's integrity. For example, although the system should be easy to use, FDA should incorporate safeguards to prevent the system from being used fraudulently or otherwise abused. That is, without some safeguards, persons intent on disrupting the food supply might enter fraudulent facility information for a targeted company or companies. We expect that the experts that FDA will retain to develop an electronic registration system will be able to incorporate suitable safeguards for the system.

Registration numbers should be assigned to facilities promptly; an immediate confirmation number may be generated electronically, and a return letter with a registration number should be mailed as quickly as possible to those who choose to register through first class mail. Similarly, provided that each facility is registered with the Agency, FDA should permit multiple facilities that are owned by a common entity to register individually or centrally, through the entity of common ownership.[2]

5. Protection of Information

As discussed more fully above, Section 415(a)(4) requires FDA to develop and maintain an up-to-date list of registered facilities, but protects the list, underlying registration documents, and any identifying derivative information from public disclosure. FDA's implementing regulations, as well as the Agency's public information regulations in 21 C.F.R., Part 20, should reflect the protected status of these records.

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[2] The approach recommended here is supported by the legislative history. See 148 Cong. Rec. E2387, E2388 ("registration should be made as simple as possible (such as permitting both electronic and paper registration, as well as permitting a headquarters to register on behalf of all establishments of a company").

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We hope that you will consider foregoing recommendations as you develop regulations to implement the registration requirements of Section 415 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

cc: Mr. L. Robert Lake, Esq.
Ms. Leslye M. Fraser, Esq.