FOOD MARKETING INSTITUTE

September 1, 2009

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

Re: Comments on Draft Reportable Food Registry (RFR) Guidance; Docket No. FDA-2009-D-0260

Dear Sir or Madam,

The Food Marketing Institute[1] (FMI) appreciates the opportunity to provide written comments on the Food and Drug Administration's (FDA's) "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007" (June 2009), hereinafter "Guidance Document." 74 Fed. Reg. 27803 (June 11, 2009). As discussed more fully below, FMI encourages FDA to ensure that the Reportable Food Registry (RFR) is an efficient and effective tool that utilizes and complements available industry systems to increase the safety of the overall food supply. In this spirit, we offer the following comments.

A. Background

Section 417 of the Federal Food, Drug and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007, requires FDA to develop an electronic system to receive reports of "reportable foods" from "responsible parties" and to list and evaluate certain of those reports in a Reportable Food Registry (RFR). A responsible party is one who is required to register a "facility" under section 415(a) of the FD&C Act. The term "facility" is

[1] FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 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 and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food 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 more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

HEADQUARTERS:
2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801
T 202.452.8444
F 202.429.4519

WASHINGTON OFFICE:
50 F Street, NW, 6th Floor
Washington, DC 20001-1530
T 202.452.8444
F 202.220.0873

www.fmi.org
fmi@fmi.org

further defined in the FD&C Act as "any factory, warehouse, or establishment that manufactures, processes, packs or holds food," but "does not include farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer" or certain fishing vessels. A "reportable food" is an article of food for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals.

In response to the statutory amendments, FDA has developed a Reportable Food electronic portal and a Reportable Food Registry, which the Agency is planning to launch on September 8, 2009. In preparation for such launch, FDA held a series of public meetings and issued a draft Guidance Document, organized in "question & answer" format.

FMI believes that both of these outreach steps are essential to the development of a system that the public can properly utilize and that will provide meaningful information to the Agency. FMI was pleased to participate in the July 23, 2009 public meeting and provides comments below on the Guidance Document.

B. Comments on Guidance Document

1. Definition of "responsible party"

Q&A 7 addresses the concept of a "responsible party" and reiterates the statutory definition. As FDA knows, the statutory definition is complex because it cross-references two previous amendments to the FD&C Act, which expressly carve out certain types of facilities from the statutory definition. Accordingly, to ensure that the Guidance Document is clear, we recommend that FDA amend the answer to question 7 to state expressly that the "responsible party" definition does not include retail stores, restaurants or farms.

As a related matter, the guidance document is unclear regarding the number of reports that must be submitted. For example, although retail food stores are not required to submit reports, such companies often own multiple distribution centers. A recall that involves a nationally braded product might be held in distribution centers across the country. Owners of multiple sites should be able to submit a single report that identifies all of the facilities at which the product is located.

2. "Reportable food"

One of the most difficult issues that users of the new FDA program will face is determining when an incident must be reported to the Agency thru the Reportable Food electronic portal (RFep). Q&A 9 reiterates the statutory definition of a "reportable food" as an article of food for which "there is a reasonable probability" that the use of or exposure to will cause serious adverse health consequences or death. Q&A 13 states that instances of reportable food must be submitted "as soon

as practicable but in no case later than 24 hours *after determining* that an article of food is a reportable food." (emphasis added).

The legal standard is vague and it would be helpful for FDA to provide further guidance, such as examples, in the next guidance document. The examples should recognize that the act of determining that an article of food is a reportable food is more than simple receipt of a test report, but requires an assessment of the significance of test results or any other data that may underpin a responsible party's ability to determine whether an article of food actually constitutes a "reportable food." Thus, the 24-hour "clock" should start when the appropriate person has made the necessary determination and not before.

3. "Transfer of food" Standard

Q&A 15 describes when an instance of otherwise "reportable food" does not need to be reported to FDA. Specifically, the Guidance Document reiterates the statutory standard that a report is not required if: (1) the adulteration originated with the responsible party; (2) the responsible party detected the adulteration *prior to any transfer to another person*; and (3) the responsible party corrected the adulteration or destroyed the article of food.

The issue of whether or not an article of food has been transferred to another person is an important one in the food industry. For example, manufacturers or distributors may send food to be held at another physical location, although no transfer of legal title of the food has occurred. Accordingly, we recommend that FDA clarify in the Guidance Document that "transfer" means that title to the product has transferred rather than just physical control.

4. Responsible Party Notifications to Trading Partners

The statute requires responsible parties to notify their trading partners in certain circumstances that the responsible party has submitted a reportable food report to FDA and to provide the unique report number assigned by FDA to those trading partners. Q&A 26 outlines various methods that a responsible party may use to notify its trading partners, including e-mail, fax, text messaging, telegrams, mailgrams, and first class letters. In addition, we would like to call your attention to electronic recall information exchange programs that are being developed by industry to speed the communication of information among trading partners in the event of a product recall.

Specifically, FMI in conjunction with the Grocery Manufacturers of America, GS1 and others has developed a program called the Rapid Recall Exchange™ (RRE). RRE standardizes product recall and withdrawal notifications between retailers, wholesalers and their suppliers, enabling the prompt, consistent and accurate exchange of recall information. RRE maintains records of who has been notified and when those notifications were received and can issue reports

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2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801
T 202.452.8444
F 202.429.4519

WASHINGTON OFFICE:
50 F Street, NW, 6th Floor
Washington, DC 20001-1530
T 202.452.8444
F 202.220.0873

www.fmi.org
fmi@fmi.org

of recipients that can be included in the subsequent reports that are required to be sent to the RFep regarding notification progress. RRE will be launched on September 21 and was recently modified to include a field for the unique report number assigned by the FDA RFep. Accordingly, to ensure that the public is fully aware of all of the options for notifying their trading partners, we recommend that FDA modify the guidance document to include "electronic recall information exchange programs" as an acceptable mechanism for notifying trading partners in the answer to Question 26.

5. Ability To Correct Existing Reports or Reports Filed by Others

We strongly encourage FDA to provide a mechanism that will allow persons to know if a report has been filed about a food that the person manufactured or that was held at the person's facility so that the person can investigate the situation and take actions necessary to remediate the situation. In some cases, information may be submitted that would clarify a situation or explain why a food was improperly characterized by another person as a "reportable food." The RFep should have a mechanism thru which such additional information may be submitted and inaccurate reports can be removed.

6. Recordkeeping Obligations

The statute requires and the Guidance Document reiterates that responsible parties must maintain records related to reports received, notifications made, and reports submitted to the RFep for two years. Neither source provides additional information regarding the location at which those records must be maintained or the form of the records.

Given the statutory silence on the issue, we encourage FDA to clarify in the guidance document that records may be maintained in any form and at any location from which they may be retrieved within the standard set forth in Section 414 of the FD&C Act. For example, the Rapid Recall Exchange can maintain information regarding notifications made, as well as the receiving parties, in electronic format for as long as necessary. Responsible parties and their trading partners should be allowed to use existing systems where feasible rather than required to develop new ones.

7. Security of Registry and Portal

We strongly encourage FDA to ensure that all security measures necessary to protect the integrity of the data submitted to FDA via the RFep and maintained in the Reportable Food Registry are employed and in place before the programs are launched. FDA requires a broad range of information to be submitted in reportable food reports, some of which may be submitted out of an abundance of caution or that includes sensitive information related to trading partners. Given the significant ramifications for the food supply, individual companies, and consumer confidence, every effort should be made to protect the information that FDA is collecting for its use in identifying and controlling outbreaks of foodborne illness.

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T 202.452.8444
F 202.429.4519

WASHINGTON OFFICE:
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8. Functionality of Portal

Given the importance and time sensitivity of the data that must be provided thru the RFep, we encourage FDA to ensure that the system works as efficiently as possible. For example, the RFep should accept attachments in other formats so that reports that are being generated by companies using existing technology can be included with or attached to the reports that are submitted into FDA via the RFep rather than re-keying in the information. Similarly, interoperability between the systems underlying the RFep and other existing programs would increase the efficiency at which information could be transferred from existing systems into the FDA programs.

9. State and Local Official Submissions

The statute requires FDA to permit state and local officials to submit instances of reportable food into the RFep and the Guidance Document reflects this fact. Although we recognize that state and local officials may have important information to provide, we do have some concerns.

First, such officials should only submit reports on food that they have an independent basis to make a determination that the food itself meets the "reportable food" definition in accordance with the statutory standard. For example, a consumer reporting illness after eating a food product should not be sufficient. Likewise, testing products that have been in consumers' possession should not be a basis for a report into the RFep. PulseNet is the appropriate vehicle for public health officials to submit data on foodborne illness and we recommend that you encourage such officials to understand the difference and to use the appropriate vehicle.

Second, the official should be strongly encouraged, if not required, to notify a facility from which it sampled food in the course of an inspection or other regulatory activities that the official will submit a report into the RFep. In fact, the facility should be told immediately -- even before the official submits the report -- if the official believes that the facility has "reportable food" so that the appropriate steps can be taken as quickly as possible to secure the food. As noted above, the RFep should also have a mechanism for correcting erroneous reports and for closing out completed investigations.

C. Conclusion

We appreciate the opportunity to provide the foregoing comments and encourage FDA to continue to accept feedback on the Guidance Document and the overall system itself as everyone -- agency and industry alike -- gain experience with the program. FDA has received important information during the comment period, which we encourage the Agency to take into account when it issues an updated Guidance Document.

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We look forward to working with you as the program develops. In the interim, if we may be of assistance in any way, please do not hesitate to call on us.

Sincerely,

Deborah R. White
Senior Vice President &
Chief Legal Officer

Cc:
Faye Feldstein
Center for Food Safety & Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

HEADQUARTERS:
2345 Crystal Drive, Suite 800
Arlington, VA 22202-4801
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F 202.429.4519

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