FOOD MARKETING INSTITUTE

January 8, 2010

Submitted Electronically and via First Class Mail

Mr. David Horowitz
Assistant Commissioner for Policy
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Agency Information Collection Request on Third Party Disclosure and Recordkeeping Requirements for Reportable Food Registry (Docket No. FDA-2009-N-0501)

Dear Mr. Horowitz,

The Food Marketing Institute[1] is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the collection of information associated with the Reportable Food Registry (RFR). 74 Fed. Reg. 53746. In particular, FDA has asked for information on (1) the accuracy of the Agency's estimated burden; (2) ways to enhance the quality, utility and clarity of the information to be collected; and (3) ways "to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology." As discussed more fully below, a relatively modest technological amendment to the RFR will allow it to harness information available via the Rapid Recall Exchange™, thereby maximizing efficiency of FDA's program and minimizing burden.

[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.

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As discussed more fully in the Federal Register notice, Section 1005 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) requires the establishment of the RFR through which responsible parties are required to notify FDA of reportable foods. A "reportable food" is one 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." The FDAAA also permits FDA to require responsible parties to notify their immediate previous sources and immediate subsequent recipients of a reportable food.

FDA estimates that 1200 reports will be submitted via the RFR next year and that the Agency will require all responsible parties to notify their immediate previous and immediate subsequent sources of the food. The Agency estimates that each such notification will take 0.6 hours for a total of 2,880 hours in 2010. FDA estimates that the associated recordkeeping burden would be 15 minutes per report, for a total of 450 hours per year. The notice does not assign a cost to the burden.

FMI understands that the FDAAA statutorily imposes certain unavoidable disclosure and recordkeeping burdens. Nonetheless, we believe that the Agency has significantly underestimated the amount of time required to comply with these burdens. Although we have not conducted a survey of our members, those that have reported their experiences with the RFR have indicated that filing took at least 4 hours per notification. The current system is extremely labor-intensive, requiring manual input of a large quantity of data. Moreover, the current system does not save drafts. Therefore, the notifications of members who are still pulling together information as they are preparing the notification may "time out," meaning that all of the information entered will disappear requiring the member to re-key all of the data all over again.

Moreover, current technology could be utilized to both enhance the quality of information and streamline the burden associated with the third party disclosure requirements. Specifically, the Food Marketing Institute, the Grocery Manufacturers Association, the National Grocers Association and GS1 US have developed the Rapid Recall Exchange™[2] (RRE) to facilitate communication between suppliers and the food distribution industry in the event a food that has entered the supply chain must be recalled. RRE applies industry expertise and best practices to standardize product recall and withdrawal notifications between retailers/wholesalers and suppliers. The online service enables prompt and accurate information exchange.

FDA's current guidance document on the use of the RFR expressly allows electronic communication mechanisms to share the information among trading partners that is required by the FDAAA. However, a relatively simple technological amendment to both the RFR and the RRE would greatly enhance and simplify communication.

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[2] Additional information about the RRE can be obtained from this website: http://www.rapidrecallexchange.org/.

Specifically, much of the information that is transmitted via the RFR and RRE is identical. Both programs include the following data elements: (1) description of the food; (2) extent and nature of adulteration; (3) disposition of the article of food; (4) product information found on the packaging; and (5) contact information for the responsible party. Communication will be significantly streamlined if the information submitted via the RRE could pre-populate the fields required for RFR submission.

We understand that FDA is updating the RFR and that the Agency intends to use the HL7/ICSR standard for electronic data transfer. However, to our knowledge, the Agency has not publicly confirmed either the electronic data transfer or an associated timeline. The RRE can be updated to allow it to transfer information to the RFR; however, our work on this end will be useless unless FDA provides a comparable capability within the RFR.

We strongly encourage the timely development of this capability within the FDA's RFR to enhance the congressionally-identified purpose of the RFR in a manner that maximizes efficiency and minimizes burden. If you have any questions regarding this matter, we would be pleased to discuss this issue with you further.

Sincerely,

Deborah R. White

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Senior Vice President and
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