THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

July 10, 2012

The Honorable Margaret A. Hamburg MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Submission of Food/Feed Facility Profile Information

Docket No. FDA-2012-N-0430

Dear Commissioner Hamburg:

On May 11, 2012, the Food and Drug Administration (FDA or the Agency) announced an opportunity for public comment on the proposed collection of certain food/feed facility (hereinafter food facility) profile information on a voluntary basis (Information Collection Request or ICR) in conjunction with food facility reregistration pursuant to the Bioterrorism Act[1] as amended by the FDA Food Safety Modernization Act (FSMA).[2] The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U.S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly $650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Its international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of its retail and wholesale members.

Background

FMI members own and operate a variety food facilities required to be registered under section 415 of the Federal Food, Drug and Cosmetic Act (FD&C Act). While retail stores themselves are not required to be registered, the distribution centers that service

[1] P.L. 107-188.
[2] P.L. 111-353.

them are. Most chain food retailers and all wholesalers operate distribution centers. The latest statistics indicate that 215 different food retailers operate distribution centers.[3] Many chains operate multiple distribution centers and large retailers may have 10, 20 or more than 30.[4] Nearly 1,200 food wholesalers operate in the U.S., and many of these wholesalers have multiple distribution centers. A number of FMI members also operate central dairy, deli and bakery facilities that are required to be registered under the FD&C Act.

As part of the required food facility registration process, FDA proposes to collect additional food facility profile information on a voluntary basis. According to the Agency, food facility profile information will assist FDA in determining whether a firm is high-risk or non-high-risk. The Agency states that the profile information will assist them in determining the frequency at which the firm will be inspected. FDA claims facilities that voluntarily submit the food facility profile information would benefit through interaction with better-informed investigators and potentially reduced inspection time.

The information FDA proposes to collect includes:

> (1) The facility type (e.g. manufacturer/processor, repacker/packer, or warehouse/holding facility);
>
> (2) The products, and hazards (e.g., biological, physical, chemical) and preventative controls measures associated with those products where either there is a regulation in place requiring identification of hazards and preventative control measures (e.g. seafood and juice), or the firm as a matter of its own business practices voluntarily identifies hazards and implements preventative controls measures; and
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> (3) Other facility information such as food safety training, facility size, operational schedule, and number of employees.

FDA proposes to give firms the option of providing or updating their profile information whenever the firm accesses the Food Facility Registration Module (e.g., when completing their initial registration process or when updating their registration information). FDA will also provide a direct URL that a firm may use to submit the facility profile information at a time when they are not registering or updating their registration information.

Pursuant to the Paperwork Reduction Act,[5] FDA invites comments on:

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[3] 2011 Chain Store Guide, Directory of Supermarket, Grocery and Convenience Store Chains.
[4] 2011 Chain Store Guide, Directory of Supermarket, Grocery and Convenience Store Chains.
[5] 44 U.S.C. 3506(c)(2)(A).

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validation of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) 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 technology.

Paperwork Reduction Act Analysis

1. Is the Proposed Collection of Information Necessary for the Proper Performance of FDA's Functions? Will the Information have Practical Utility?

FMI believes that certain information FDA has proposed to collect will have practical utility, while other information the Agency seeks to collect in the ICR will not.

A. Information with Practical Utility

FMI believes that certain information will have practical utility in that it will facilitate FDA's inspection process. This information includes:

(1) Facility type;

(2) For processing facilities, products handled by the facility OR for holding facilities, the types of storage (i.e. refrigerated, frozen, dry storage); and

It is essential for FDA to make the distinction between processing facilities and holding facilities like grocery distribution centers. FMI has reviewed FDA's draft Form 3797 (Draft Form) and in it the Agency provides a list of 27 types (plus a write in slot) of products the user of the form is to select from. As discussed later in these comments, the typical grocery distribution center handles nearly all of the 27 products types listed in Draft Form and should not be considered high-risk on the basis of merely handling a variety of items. FMI believes that supermarket distribution centers should generally be considered low-risk. These facilities only handle products, they do not process or pack them. FDA's existing Food Facility Registration Module contemplates the difference between processing and handling facilities and FMI believes the Draft Form should

contemplate this fact as well. Distribution centers should not be required to identify individual product categories. We believe information on the types of storage maintained by a distribution center is more useful to the Agency for purposes of achieving the goals of the ICR. If a user identifies a food facility as a holding facility, the Draft Form should automatically skip questions related to processing and inquire only on issues relevant to warehousing.

(3) Facility size based on areas where food is handled.

It is important for FDA to consider that facilities such as supermarket distribution centers may have truck washing and maintenance operations and tractor/trailer parking areas on-site. Assessing the size of a facility based on areas where food is handled rather than total area will provide the Agency with a more useful metric in preparing for inspections.

The previous information will provide FDA with the tools it needs to more effectively conduct inspections and notify facilities that might be affected by accidental or deliberate contamination of the food supply. The information will allow the Agency to better predict how long an inspection could take, the number of inspectors to send, and whether inspectors with particular expertise are needed.

B. Information Without Practical Utility

A number of the data points FDA seeks to collect will not provide the Agency with useful information and impose a very significant—and unnecessary—paperwork burden on the industry.

Hazards and Preventative Controls

FMI believes that the information on hazards and preventative controls FDA seeks to collect lacks practical utility, will not serve to facilitate the inspection process, and will be extremely burdensome for food retailers to submit. The Draft Form provides a list of 27 types (plus a write in slot) of products the user of the form is to select from. For each product, the user is asked to identify potential hazard(s) from a list of 46 options, and select preventative controls implemented for each hazard from a list of 20 options. Many types of products will have multiple hazards and multiple controls.

Of the 27 products listed, the typical grocery distribution center will carry 26 of them. It is conceivable that one product category will have three, four or more potential hazards identified with multiple controls for each hazard. Completing the hazards and controls section on for a distribution center using the Draft Form will likely require hundreds of entries. We believe this information will be of little practical utility to the Agency while imposing tens of hours of paperwork burdens for each facility. Furthermore, all of this

information is generally available to inspectors when they conduct inspections. Requesting it to be disclosed in advance places a redundant paperwork burden on the supermarket industry.

FMI is concerned not only about the paperwork burden, but that the hazard and preventative control information could be misinterpreted. Risks can be managed effectively using different controls. FDA should not view differences in the controls applied in various facilities as an indication that one facility has better practices than another and thus should have a different risk-profile.

As an alternative, the Agency could consider asking in the form of yes/no questions as to whether a facility has one or more hazard analyses and HAACP plans available for review.

Number of Employees

FMI does not believe that information on the number of employees at a facility has practical utility to the Agency. The number of employees at grocery distribution centers fluctuates regularly. In addition, processes at distribution centers are becoming increasingly automated. Information submitted on facility size is more relevant to assisting the Agency in preparing for inspections.

Operational Schedules

Information on operational schedules should be limited only to the question FDA proposes in the Draft Form: whether a facility operates on a seasonal or year-round schedule. Any more detailed information may present the Agency with an inaccurate picture as operating schedules may change regularly. As such, this information would be of little practical utility to FDA.

2. The Accuracy of FDA's Estimate of the Burden of the Proposed Collection of Information

FDA has Grossly Underestimated the Burden

FDA estimates that submitting a new domestic food facility profile will take only 15 minutes. FMI believes this grossly underestimates the amount of time retailers will to respond to the form. As discussed earlier, the typical distribution center carries 26 of the 27 product categories listed in the Draft Form. Providing detail on the potential hazards and preventative controls implemented for each product will take retailers a total of 20-30 or more hours per facility. Most chain retailers have multiple facilities. A national retailer will easily have a dozen or more distribution centers. The largest food retailers will several dozen. It is conceivable that hundreds of hazard and preventative control entries will be required to be made for each distribution center to respond to the

Draft Form. The typical large distribution center carries more than 16,000 different stock keeping units of food.[6] Completing the form itself will require several hours due to all of the entries. Compiling the information for each facility will take 20-30 hours. Under the Paperwork Reduction Act, FDA is required to consider not only the time it takes to complete the form, but also the time it takes to compile the information.[7] FDA must revise its estimate of the burden imposed by the ICR.

3. Ways to Enhance the Quality, Utility, and Clarity of the Information to be Collected

As discussed previously, FMI believes that FDA's proposal to collect hazard and preventative control information will not provide the Agency with clear, useful or relevant information. To enhance the quality, utility and clarity of the ICR, the Agency should eliminate this section of the Draft Form. FMI also believes that the question on the number of employees in the Draft Form should be eliminated for the reasons discussed previously.

4. Ways to Minimize the Burden of the Collection of Information on Respondents

Grocery Distribution Centers Should Generally be Considered Low-Risk

While grocery distribution centers handle a wide range of products, the vast majority of these products are enclosed in packaging and no processing occurs within the facility. FDA should contemplate this fact and generally consider distribution centers to be in a low-risk category. Focusing FDA resources on distribution centers at the expense of inspecting other categories of facilities would only serve to diminish the effectiveness of the Agency's efforts to strengthen food safety regulation and be inconsistent with the objectives of FSMA. Generally classifying grocery distribution centers as low-risk will minimize the burden of the ICR on the supermarket industry.

Information on Preventative Controls

FMI has concerns regarding FDA's proposal to collect information on hazards and preventative control measures implemented at each facility. The Draft Form directs users to select from lists of hazards categorized as biological, chemical and physical, as well as lists of process controls. As discussed previously, completing this section will impose a burden on industry of 20-30 hours or more per facility. FMI does not believe the Agency should request this documentation as it would impose an enormous paperwork burden on retailers without being of practical utility to FDA. This information is currently available to the Agency upon inspection. Furthermore, the Agency enjoys expanded authority to access records under FSMA. Various controls can be effective in

[6] FMI 2007 Transportation Benchmarks Study.
[7] 5 C.F.R. Part 1320.

managing risk and the Agency should not be making risk assessments on the basis of this information. Eliminating this section of the Draft Form would minimize the burden of the ICR.

Supplemental Information on Preventative Controls, Food Safety and Food Defense Training

FMI seeks clarification that the Agency only intends to have users identify hazards and preventative controls from the lists provided on the Draft Form and not request the vast records of HAACP plans, standard operating procedures (SOPs) and prerequisite programs (PRPs) of facilities pursuant to the ICR. Similarly, FMI seeks clarification on the level of detail FDA intends to request regarding food safety and food defense training. Records on HAACP plans, SOPs and PRPs are vast and retailers have reams of materials related to food safety and food defense training. Requiring such information to be submitted to FDA would be extremely burdensome while providing the Agency with information that has little or no practical utility. This information is available to the Agency upon inspection. In the Draft Form, the Agency poses food safety and food defense training questions in simply a yes/no format. We believe the inquiry should remain in that format or be stricken entirely. FMI does not believe any of the above mentioned supplemental information should be requested by the Agency in conjunction with this ICR or any in the future as it would impose an enormous paperwork burden on retailers; be very cumbersome to submit; and, provide the Agency with little useful information.

Allowing Partially Completed Forms to be Submitted

While some facilities may wish to respond to all inquiries FDA is proposing to collect information on, others may wish to only respond to certain questions. FMI believes that facilities that wish to voluntarily submit the information FDA is seeking to collect pursuant to the ICR be able to selectively respond to the fields they wish to rather than being required to complete the form in its entirely, or not fill it out at all. Permitting a partially completed form to be submitted is likely to increase the number of responses received by FDA and would ease the burden associated with the ICR. FDA should not penalize firms in any way for submitting partially completed forms. Users should also be able to save the data they have entered into the system before submitting it to the Agency.

Pilot Program

Several FMI members have indicated interest in accessing the new reregistration system before the October 1, 2012-Dcember 31, 2012 reregistration period. To the extent feasible, FDA should provide the industry with the ability to see the new forms and/or use the new system in advance of October 1. This will ease the transition into the new registration system as FDA will not be inundated with questions from regulated

entities on October 1. This will also better allow industry associations such as FMI to educate and provide assistance to businesses in regards to responding to the ICR.

Education and Outreach

FMI encourages the Agency to conduct education and outreach in regards to the ICR and the overall registration process. Providing clear and concise educational materials, hosting webinars and participating in industry events would make the transition to the new system easier for industry.

Voluntary Nature of Information Collection Request

FMI appreciates that FDA is proposing to collect the information associated with the ICR on a voluntary basis; however, we seek clarification from the Agency whether the submission is truly voluntary. Namely, will facilities that choose not to submit the information FDA is proposing to collect be automatically placed in a category (high-risk or otherwise) that subjects them to increased inspections? FMI strongly believes this should not be the case for this ICR or any other voluntary ICR implemented by the Agency. Not classifying facilities as high-risk because they choose to not respond to the ICR would minimize burdens. FDA should also make clear on the website and all related materials that submission of the information associated with the ICR is strictly voluntary, so that businesses do not mistakenly believe it is required. Firms should not be penalized in any way for making inadvertent mistakes in responding to the ICR.

Confidentiality

FMI seeks clarification from FDA as to how information submitted pursuant to the ICR will be maintained confidentially and also whether the Agency intends to share such information with other entities, including governmental entities at the federal, state and local level. If the Agency does seek to share information with other entities, FMI seeks clarification as to which types of entities and the manner in which the information will be shared, including steps taken to ensure the security of such data. FMI believes that such information should be shared solely for the purposes of food safety related inspections and notifying facilities that might be affected by a deliberate or accidental contamination of the food supply. FMI believes information obtained in connection with the ICR should be treated as confidential and be protected from disclosure under the Freedom of Information Act.

Quantitative Information Format

It will be less burdensome if the reregistration module allows quantitative information to be submitted in ranges rather than requiring submission of an exact number.

Obligation to Update Information

The number of employees at a facility and types of products handled may vary over the course of one or two years. If a facility choses to provide information on a voluntary basis and begins handling a new type of product, or significantly changes the number of employees before it is due to reregister with the Agency, would it be obligated to update the information? FMI strongly believes information should only be required to be updated in conjunction with the compulsory biennial mandatory registration schedule. Food facilities should not be penalized for failing to update information provided on a voluntary basis pursuant to the ICR. Requiring updates only in conjunction with the mandatory biennial registration process would ease the burden of the ICR.

Eliminating Redundant Disclosures

On June 22, 2012, Cass Sunstein, the Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget, sent a memorandum to the heads of executive departments and agencies regarding reducing reporting and paperwork burdens. The memo directed agencies to "take meaningful steps to reduce paperwork and reporting burdens on the American people" by, among other things, "Eliminating redundant or unnecessary collections."

The ICR does contain redundant collections. Namely, the existing Food Facility Registration Module requests information on facility type and products handled while the ICR seeks the same information.[8] FMI believes the Agency should minimize redundancies to the greatest extent possible and use the information it already has. As such, the Agency should not be requesting information on facility type, products handled and, if it decides to as we recommend, types of storage, through this ICR. All of these data points are already collected by the existing Food Facility Registration Module.

[8] http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/ucm073706.htm#section1

We appreciate your consideration of these comments.

Sincerely,

Erik R. Lieberman
Regulatory Counsel