THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

September 7, 2012

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

Re: Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories; Availability

Docket No. FDA-2012-D-0585

Dear Commissioner Hamburg:

On August 15, 2012 the Food and Drug Administration (FDA or the Agency) announced in the Federal Register the availability of draft guidance for industry entitled "Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories" ("Draft Guidance").[1] The Draft Guidance identifies additional food categories to be included in food facility registrations as determined appropriate by FDA. FDA has stated that "this guidance, if finalized. . .will have binding effect."[2] The Food Marketing Institute (FMI) comments on the binding effect of the Draft Guidance. 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.

[1] 77 Fed. Reg. 48990 (August 15, 2012).
[2] 77 Fed. Reg. 48991.

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 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.

Binding Guidance

FMI has concerns about the treatment of the Draft Guidance as binding. As a general principle throughout the federal government, and as expressed in FDA's good guidance practice (GGP) regulations,[5] guidances do not establish legally enforceable requirements. As such, FDA's GGP regulations require that guidances prominently display a statement of the document's nonbinding effect.[6] In the case of the Draft Guidance, FDA has made the determination that the document contains findings that serve as the predicate for binding requirements on industry. Because of this, FDA is purposely omitting a statement of nonbinding effect in the Draft Guidance.

While FMI appreciates this opportunity to comment on the Draft Guidance, the fact remains that because the agency is not following the notice and comment rulemaking requirements of the Administrative Procedure Act, FDA's process for crafting the list of new food categories will be less transparent and less informed.

> The rulemaking process prescribed by the APA insures a thorough exploration of the relevant issues. . . But when an agency promulgates a general statement of policy, the agency does not have the benefit of public exploration of the issues. Judicial review may be the first stage at which the policy is subjected to full criticism by interested parties.[7]

There is very little precedent for Congress to grant agencies authorization to establish binding requirements based on actions by guidance. While FMI does not seek to ascertain the intent of Congress in crafting 21 USC § 350d(2) in these comments, it is clear that no other provision of FSMA could conceivably be interpreted to grant FDA

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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] "Are you or FDA required to follow a guidance document? (1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA." 21 CFR 10.115(d).
[6] 21 CFR 10.115(i)(1)(iv).
[7] Pacific Gas & Electric Co. v. Federal Power Com., 506 F.2d 33, 40 (D.C. Cir. 1974).

authority to issue binding guidance. As such FDA should not create any binding requirements based on guidance for any other provision of FSMA and FDA's GGP should therefore apply.

It is important to note that while FDA is directed by Congress to make the determination of the necessity for general food categories (as identified under 21 CFR 170.3) to be included in food facility registrations through guidance, the agency is given the *option* of adding additional food categories through guidance or rulemaking.[8]

We urge the agency to consider conducting a rulemaking on adding the additional food categories to the registration process to ensure that the public is afforded a more significant opportunity to participate in the policymaking process, that the agency is better informed and that transparency is increased.

We appreciate your consideration of these comments.

Sincerely,

Erik R. Lieberman
Regulatory Counsel

[8] "An entity (referred to in this section as the "registrant") shall submit a registration under paragraph (1) to the Secretary containing information. . .when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations, or any other food categories as determined appropriate by the Secretary, *including by guidance*) of any food manufactured, processed, packed, or held at such facility." 21 USC § 350d(2) (emphasis added).