



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0585]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories.” FDA has developed this guidance in response to amendments made by the FDA Food Safety Modernization Act (FSMA) to the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance contains FDA’s determination that information about food product categories in food facility registrations is necessary for a quick, accurate, and focused response to a food safety related issue or incident, an actual or potential bioterrorist incident, or other food-related emergency. The guidance also identifies the additional food product categories included as mandatory fields in food facility registrations, as determined appropriate by FDA.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your

request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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5100 Paint Branch Pkwy.,
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240-402-1988.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled “Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories.” FDA has developed this guidance in response to amendments made by section 102 of FSMA (Public Law 111-353) to section 415(a)(2) of the FD&C Act (21 U.S.C. 350d(a)(2)).

FSMA, enacted on January 4, 2011, amended the food facility registration requirements of section 415 of the FD&C Act. Section 415(a)(2) of the FD&C Act, as amended by section 102 of FSMA, provides in relevant part that, when determined necessary by FDA through guidance, a registrant is required to submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in § 170.3 (21 CFR 170.3) or

any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. This guidance contains FDA's determination that information about food product categories as identified in § 170.3 and the other food product categories is necessary for a quick, accurate, and focused response to a food safety related issue or incident, an actual or potential bioterrorist incident, or other food-related emergency. The guidance also identifies the additional food product categories included as mandatory fields in food facility registrations, as determined appropriate by FDA under section 102 of FSMA.

In the Federal Register of August 15, 2012 (77 FR 48990), we made available a draft guidance entitled "Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories" and gave interested parties an opportunity to submit comments to us by September 14, 2012, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance. We reviewed and evaluated these comments and have modified the final guidance where appropriate. Changes to the guidance include amending a typographical error in the fishery/seafood product categories. We also added the word "nutritional" to the pet supplements category in the food for animal consumption food product categories to clarify that the category applies to "pet nutritional supplements." The guidance announced in this notice finalizes the draft guidance dated August 2012.

As noted previously, section 415(a)(2) of the FD&C Act provides, in relevant part, that a food facility must submit to FDA a registration containing information about the general food category (as identified in § 170.3 or any other food category as determined appropriate by FDA, including "by guidance") of a food manufactured/processed, packed or held at such facility, if we

determine “through guidance” that such information is a necessary. Because of Congress’s explicit statutory authorization in section 415(a)(2) of the FD&C Act to effectuate binding requirements based on actions by guidance, this document is not subject to the usual restrictions in FDA’s good guidance practice (GGP) regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document’s nonbinding effect. See 21 CFR 10.115(d)(i).

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited, and our guidances also ordinarily include the following standard paragraph:

“This guidance represents FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.”

We are not including this standard language in this guidance because it is not an accurate description of the effect of this guidance. This guidance contains findings that serve as the predicates for binding requirements on industry. As stated in “Guidance for Industry on Necessity of the Use of Food Product Categories in Registration of Food Facilities” (2003), which was issued under section 415 of the FD&C Act, as added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188),

we found that inclusion of the food categories in § 170.3 in food facility registrations is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency. Based in part on this finding, FDA's regulations for the registration of food facilities in 21 CFR part 1, subpart H currently require that a food facility submit a registration to FDA containing information on applicable food product categories as identified in § 170.3 for food manufactured/processed, packed, or held at such facility. As provided in section 102 of FSMA, this guidance contains FDA's finding that inclusion of other food categories in food facility registrations is also necessary to facilitate such rapid communications. In addition, this guidance sets forth the other food product categories to be included in food facility registrations determined to be appropriate by FDA for the purposes of food facility registration. Insofar as this guidance modifies food product categories for food facility registration under section 415 of the FD&C Act, it has binding effect. For these reasons, we are not including the standard guidance paragraph in this guidance.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in §§ 1.230 through 1.235 have been approved under OMB Control No. 0910-0502.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify

comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: October 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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