4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories." The draft guidance identifies additional food categories to be included in food facility registrations as determined appropriate by FDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration,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 one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories." This draft guidance sets forth FDA's determination of the necessity for additional food categories and sets forth the additional food categories to be included as mandatory fields in food facility registrations as determined appropriate by FDA.

The FDA Food Safety Modernization Act (FSMA), enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d). 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 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 draft guidance sets forth FDA's determination of the necessity for additional food categories and the other food categories to be included in food facility registrations as determined appropriate by FDA. The inclusion of these additional food categories in food facility registrations will help FDA provide a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency.

FDA is interested in comments regarding including the other food categories as mandatory fields in food facility registrations. FDA intends to issue a final guidance that identifies the additional food categories that will be included as mandatory fields in food facility registration forms before the first biennial registration renewal period, which begins on October 1, 2012.

Section 415(a)(2) of the FD&C Act provides in relevant part that a food facility is required to submit to FDA a registration containing information about the general food category (as identified listed 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 the Agency determines "through guidance" that such information is necessary. Because of Congress' explicit statutory authorization in section 415(a)(2) to establish 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 the Agency's guidances also ordinarily include language similar to the following paragraph:

This guidance represents the Food and Drug Administration'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.

FDA is not including this standard language in this draft 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 implemented, in part, section 415, as added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, it contains FDA's finding 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 draft 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 draft

guidance sets forth the other food 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, if finalized, modifies food categories for food facility registration under section 415 of the FD&C Act, it will have binding effect. For these reasons, FDA is not including the standard guidance paragraph in this draft guidance.

II. The Paperwork Reduction Act of 1995

This draft guidance contains a collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). FDA intends to submit the collection of information to OMB in the near future for emergency clearance processing under 5 CFR 1320.13. The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 1.230-1.235 have been approved under OMB control number 0910-0502.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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 draft guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Always access an FDA

document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: August 6, 2012

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-20038 Filed 08/14/2012 at 8:45 am; Publication Date: 08/15/2012]