



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0126]

Draft Compliance Policy Guide Sec. 100.250 Food Facility Registration--Human and Animal Food; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft Compliance Policy Guide Sec. 100.250 Food Facility Registration--Human and Animal Food (the draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on issues related to food facility registration under a section of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration.

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 comments on this draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug

Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft CPG.

Submit electronic comments on the draft CPG 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:

Mischelle B. Ledet,
Center for Food Safety and Applied Nutrition (HFS-615),
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740,
240-205-1165; or

Kim R. Young,
Center for Veterinary Medicine (HFV-230),
Food and Drug Administration,
7519 Standish Pl.,
Rockville, MD 20855,
240-276-9200.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft CPG entitled “Compliance Policy Guide Sec. 100.250 Food Facility Registration--Human and Animal Food.” The draft CPG is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will replace “Compliance Policy Guide Sec. 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.”

Section 415 of the FD&C Act (21 U.S.C. 350d) requires owners, operators, or agents in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their facilities with FDA, unless an exception applies (see 21 CFR 1.226 and 1.227). The FDA Food Safety Modernization Act (FSMA) (Public Law 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, and to require facilities required to register with FDA to renew such registrations biennially. FSMA also amended section 415 of the FD&C Act to provide FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that: (1) Created, caused, or was otherwise responsible for such reasonable probability; or (2) knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

The draft CPG is intended to provide guidance for FDA staff regarding enforcement of the food facility registration provisions of section 415 of the FD&C Act, including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration. The draft CPG also contains information that may be useful for the regulated industry and to the public.

The draft CPG, when finalized, will represent the Agency's current thinking on food facility registration requirements of section 415 of the FD&C Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and section 415 of the FD&C Act. 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 21 CFR 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB Control No. 0910-0502.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). 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 CPG from FDA's Office of Regulatory Affairs history page. It may be accessed at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

Dated: March 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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