DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. FDA-2012-D-1002]

Questions and Answers Regarding Food Facility Registration (Sixth Edition); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Sixth Edition)." The guidance includes one additional question and answer regarding FDA's policy regarding food facility registration for farms that also pack or hold raw agricultural commodities grown on a farm under different ownership in light of other ongoing FDA Food Safety Modernization Act (FSMA) rulemakings.

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

ADDRESSES: 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. Submit written requests for single copies of the 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 two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Amy Barringer, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1988.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Sixth Edition) available on FDA's website at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm." We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). In accordance with § 10.115(g)(2), we are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate. The guidance represents a less burdensome policy consistent with the public health. Although this guidance document is immediately in effect, FDA will accept comments at any time.

Section 102 of FSMA (Public Law 111-353), signed into law on January 4, 2011, amends section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) (the FD&C Act) regarding requirements for food facility registration. Further, section 102(a)(3) of FSMA amends section 415 of the FD&C Act to provide that food facilities required to register with FDA must renew their registrations with FDA every 2 years, between October 1 and December 31 of each even-numbered year, by submitting registrations renewals to FDA.

In addition to amending section 415 of the FD&C Act, FSMA also amended the FD&C Act such that section 415 functions in connection with other food safety provisions. For

instance, FSMA added section 418 of the FD&C Act (21 U.S.C. 350g), which establishes certain preventive control requirements for food facilities that are required to register under section 415 of the FD&C Act. In general, section 418(a) of the FD&C Act requires the owner, operator, or agent in charge of a "facility" to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. The term "facility" is defined in section 418(o)(2) of the FD&C Act as "a domestic facility or a foreign facility that is required to register under section 415."

As part of the rulemaking to implement section 418 of the FD&C Act, on September 29, 2014 (79 FR 58524), we published a supplemental notice of proposed rulemaking in the Federal Register, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (preventive controls for human food). In that supplemental proposed rule, we proposed, inter alia, certain changes to the definition of the term "farm" in 21 CFR 1.227 (§ 1.227). If implemented, these changes would impact food facility registration because the food facility registration requirements of section 415 of the FD&C Act do not apply to an establishment that meets the definition of "farm." The current definition of a "farm" under § 1.227 describes a farm in relevant part as a facility devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Although that definition of "farm" then provides that farms also pack or hold food, it limits facilities that fall within the definition of "farm" to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Thus, under the current definition, an establishment that is devoted to the growing and harvesting of crops, but also packs and holds food not grown or raised on that farm or on another farm under the same ownership, would fall outside the

definition of "farm" and be required to register as a food facility. In the supplemental notice of proposed rulemaking for preventive controls for human food, FDA proposed to revise the "farm" definition in relevant part so that it would no longer limit establishments that fall within the "farm" definition to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Under the revised "farm" definition, an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the "farm" definition (and, thus, not be subject to the FD&C Act section 415 registration regulations) even if it packs and holds raw agricultural commodities grown on another farm.

In light of this ongoing rulemaking, we are announcing our policy regarding food facility registration for farms that also pack or hold raw agricultural commodities grown on a farm under different ownership and that would no longer be required to register if the proposed amendments to the "farm" definition are finalized as proposed. Under this policy, as discussed in the guidance, FDA does not intend to prioritize enforcing the registration requirement for such establishments. This policy is a less burdensome policy consistent with the public health. FDA intends to make further updates to this guidance once certain FSMA rulemakings are final in order to make sure questions and answers, key terms, and definitions are consistent and accurate with regard to the registration of food facility requirements.

The guidance represents our 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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 §§ 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB control number 0910–0502.

III. Comments

Interested persons may submit either electronic comments regarding this guidance 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 document at either http://www.fda.gov/RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov. Always access an FDA guidance document by using FDA's Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 13, 2014.

Leslie Kux,

Associate Commissioner for Policy.

4164-01-P

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