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Supplemental Questions and Answers Regarding Food Facility Registration: Draft Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2012-D-1002 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact FDA’s Technical Assistance Network by submitting the form available at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www/regulations.gov>. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2012-D-1002 listed in the notice of availability that publishes in the *Federal Register*.

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Food and Drug Administration
Office of Foods and Veterinary Medicine
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
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Table of Contents

I. INTRODUCTION3

II. QUESTIONS AND ANSWERS.....4

A. Who Must Register?.....4

Supplemental Questions and Answers Regarding Food Facility Registration: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your information at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

I. INTRODUCTION

On October 10, 2003, the Food and Drug Administration (FDA or we) issued an interim final rule to implement amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (Pub. L. 107-188) (68 FR 58894). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. This guidance was developed to answer frequently asked questions relating to the registration requirements of section 415 of the FD&C Act.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended the food facility registration requirements in section 415 of the FD&C Act.

FDA first issued a guidance document with questions and answers regarding food facility registration requirements on December 4, 2003. That guidance was issued as Level 2 guidance pursuant to Title 21, Code of Federal Regulations (CFR), Section 10.115 (21 CFR 10.115). The most recent edition of the guidance (the Seventh Edition) was issued as Level 1 guidance pursuant to 21 CFR 10.115 in August 2018, and includes updated questions and answers relating to food facility registration.

¹ This guidance has been jointly prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Office of Regulatory Affairs at the U.S. Food and Drug Administration

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We are issuing these supplemental questions and answers as draft guidance pursuant to 21 CFR 10.115. We are issuing this supplement because FDA continues to receive questions that highlight the need to provide guidance on registration requirements in situations where multiple entities are involved in the use of shared physical space, such as where one entity owns a building and lessees manufacture/process, pack or hold food in the building. FDA has drafted several questions and answers to clarify our thinking about who should register in these situations. We intend to finalize this guidance by incorporating these questions and answers into a future edition of the Questions and Answers Regarding Food Facility Registration: Guidance for Industry.

“I,” “you,” “your” or “registrant” are used in this guidance to refer to the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. QUESTIONS AND ANSWERS

A. Who Must Register?

A.2² If a manufacturer leases the building where it manufactures food, is the manufacturer required to register? Is the owner of the building where the food is manufactured required to register the building?

An establishment under one ownership at one general physical location that manufactures/processes food in a leased space is a food facility. Therefore, food manufacturers are required to register even if the physical location where they conduct manufacturing is leased. If the building owner/lessor never has physical control over the food, then the owner/lessor is not manufacturing/processing, packing, or holding food. Consequently, the building owner/lessor is not required to register the building as a facility.

A.3 If a manufacturer stores food in a self-storage warehouse, is the manufacturer required to register its storage unit? Is the warehouse required to be registered? Is the answer different if the food is stored in a third-party logistics warehouse?

Manufacturer Storing Food in Self-Storage Warehouse

An establishment under one ownership at one general physical location that holds food in a leased space is a facility required to register. If the manufacturer keeps physical control over the food in

² We start the numbering here at A.2 because question A.1 already exists in the Seventh Edition of the Questions and Answers Regarding Food Facility Registration Guidance.

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its storage unit, the manufacturer is holding food and is required to register the self-storage unit as a facility.

Owner of a Self-Storage Warehouse

In a typical self-storage warehouse, the owner of the warehouse/lessor has no physical control over the food and therefore is not holding food. Consequently, the warehouse owner/lessor is not required to register the warehouse as a facility.

Third-Party Logistics Warehouse

In contrast, a typical third-party logistics warehouse has sole physical control over the food stored in the warehouse. In this case the warehouse is a structure (or establishment) under one ownership at one general physical location that holds food. Therefore, the owner, operator, or agent in charge of the warehouse must register the warehouse as a facility.

A.4 Some manufacturers use a commercial communal kitchen that is used by multiple manufacturers that share responsibility with the landlord for maintenance of common facility infrastructure and common equipment. Who is required to register?

Each manufacturer using the kitchen is an establishment under one ownership at one general physical location that manufactures/processes, packs, or holds food and therefore is a facility required to register. In addition, a landlord/lessor that has physical control over food at any time (e.g., responsibility for food in a common storage area in a communal kitchen) is required to register because it is an establishment or structure under one ownership at one general physical location holding food.