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MEMORANDUM

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Re: **FDA Finalizes Regulation Amending Food Facility Registration Regulations**

The Food and Drug Administration (FDA) recently published a final rule amending the agency's regulations for food facility registration (21 CFR Part 1, Subpart H). 1/ Many of the revisions codify facility registration-related provisions of the FDA Food Safety Modernization Act (FSMA). FDA also included provisions to "improve the utility" of the food facility registration database. This memorandum first provides background information about the FSMA amendments to facility registration and then summarizes the requirements of the final rule, noting the key changes from the proposed rule.

The most significant revisions to the facility registration requirements will:

- Require submission of a Unique Facility Identifier (UFI) starting during the registration renewal period beginning October 1, 2020. Through guidance, FDA expects to recognize D-U-N-S numbers as acceptable identifiers.

- Require the person making the registration submission to provide FDA with the email address of the individual who authorized the submission.

- Implement a verification step whereby FDA will compare the registration information submitted with the information associated with the UFI for each facility to confirm its accuracy, as well as confirm that the individual submitting the registration, update, or renewal is authorized to do so by the individual whose email address was provided as authorizing the submission.

- Permit FDA to unilaterally cancel a facility's registration under specified circumstances (e.g., when the facility failed to renew the registration).

- Require registrations and renewals to be submitted electronically starting January 4, 2020.

1/ 81 Fed. Reg. 45912 (July 14, 2016).

Background and Statutory Requirements

Section 415(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 350d) requires all domestic and foreign facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States to register with FDA. This requirement, which was adopted by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), has been in effect since December 2003.

Facility registration originally was just a one-time requirement, which functioned as a "directory" of sorts to assist the agency to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. However, FSMA considerably expanded the consequences of facility registration. 2/ Most significantly, FSMA provides that the preventive controls requirements apply to food facilities required to register with FDA under section 415. Additionally, FSMA also authorizes FDA to suspend a food facility's registration in certain circumstances, essentially withdrawing its license to operate.

Section 102 of FSMA included a number of amendments to the food facility registration requirements, which have been finalized in this rule. In particular:

- Facilities must renew their registrations with FDA every 2 years, between October 1 and December 31 of each even-numbered year; 3/
- FDA is directed to provide for an abbreviated registration renewal process for any registrant that has not had any changes to such information since its preceding registration was submitted;
- FDA is authorized to require that all food facility registrations be submitted in an electronic format, but this requirement could not take effect before January 4, 2016;
- FDA is directed to amend the definition of the term "retail food establishment" to make clarifications about direct sales to consumers through platforms like roadside stands, farmers' markets, or community supported agriculture (CSA) programs;
- Registrations for domestic facilities must contain the email address for the contact person of the facility (or for the U.S. agent for a foreign facility);
- All food facility registrations must contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FFDCA; and
- FDA is authorized "through guidance" to designate additional food product categories to be identified in a facility registration.

Some of these amendments are self-implementing and became effective upon enactment of FSMA. In April 2015, FDA proposed various amendments to the facility registration regulations to conform to FSMA and improve the registration database. 4/

Overview of the Rule and Key Changes from Proposed Rule

The final rule revises FDA's current facility registration regulations in two ways. First, FDA added new provisions to the current regulations to implement and codify certain provisions of FSMA section 102. Second, FDA has made changes to "improve the utility" of the food facility registration database by requiring certain additional data, implementing verification steps to confirm the accuracy

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2/ Prior to FSMA, the consequences of facility registration also were affected by the Food and Drug Administration Amendments Act of 2007 (FDAAA), which requires a "responsible party" (i.e., the person that submits a food facility registration), to submit reports to the Reportable Food Registry.

3/ The first registration renewal period was in 2014. Renewal will occur again this fall.

4/ 80 Fed. Reg. 19160 (April 9, 2015).

of the information submitted, and identifying the circumstances when FDA will cancel registrations. Each key provision, as well as any significant changes made to these provisions from the proposed rule, is discussed in detail below.

FSMA-Directed Provisions

- Biennial Registration Renewal and Abbreviated Registration Renewal Process: The biennial registration renewal requirement in FSMA was self-executing, but FDA codified the requirement through this rulemaking. Additionally, FDA is adopting an abbreviated registration renewal process for any registration that has not had any changes to its registration information. Submission of an abbreviated renewal requires confirmation that no changes have been made and certification that the information submitted is truthful and accurate. FDA also specifies that a registration that is not renewed is considered to be expired and the facility will be considered to have failed to register.

- Email Address: FDA is requiring registrations to include the email address for the contact person of a domestic facility. Additionally, foreign facility registrations are required to contain an email address for the U.S. agent of the foreign facility.

- Assurance Statement: The final rule codifies the FSMA requirement that food facility registrations must contain an assurance that FDA would be permitted to inspect the facility at the times and in the manner permitted by the FFDCA.

- Mandatory Electronic Submission: FDA proposed requiring electronic submission of registration and renewals starting on January 4, 2016, but the final rule delays the effective date. This provision now will become effective January 4, 2020, unless a waiver has been granted for the registrant. FDA established procedures to request such waivers under 21 CFR § 1.245.

- U.S. Agent: FDA clarified in the preamble that it does not interpret the "U.S. agent" for the Foreign Supplier Verification Program (FSVP) 5/ to be the same "U.S. agent" designated by a foreign facility for food facility registration because the these U.S. agents serve different purposes under each regulation.

- "Retail Food Establishment" Definition: FDA has amended the definition of "retail food establishment" to provide that the definition includes certain farm-like operations selling food directly to consumers as their primary function. 6/ Their sales are considered to be directly to consumers when they occur at roadside stands, farmers' markets, through CSA programs, or any other direct sales platform.

5/ Under the FSVP final rule, the "importer" of food with no U.S. owner or consignee at the time of entry is the "U.S. agent or representative" of the foreign owner.

6/ "Retail food establishments" remain exempt from facility registration. Under the current definition, "retail food establishment" means "an establishment that sells food directly to consumers as its primary function," which occurs if the annual monetary value of sales of food directly to consumers exceeds the annual monetary value of sales of food to all other buyers. 21 CFR § 1.227(b)(11)

"Utility"-Related Provisions

- D-U-N-S Numbers and Verification Procedures: In the proposed rule, FDA sought to require facility registrations include D-U-N-S numbers. 7/ In the final rule, responding to comments opposing the use of D-U-N-S numbers, FDA adopted a requirement that the facility's registration must include a UFI that is "recognized as acceptable to FDA." 8/ FDA will issue guidance in the future regarding which specific UFIs or identifiers FDA recognizes as acceptable. Notably, the agency and expects to recognize D-U-N-S numbers as acceptable identifiers, though the preamble notes that the agency "will consider recognizing as acceptable UFIs other than D-U-N-S numbers."

  While FSMA does not explicitly require a UFI as part of food facility registrations, FDA believes that the lack of such a requirement does not prevent FDA from requiring identifiers. The preamble explains that a UFI system such as D-U-N-S allows the agency to leverage the information in the UFI system as a check that the information provided in the facility registration is accurate. FDA will not discontinue the use of registration numbers, but notes that the use of UFIs in conjunction with registration numbers may help the agency avoid the problem of "inspectional washouts" where an FDA investigator arrives for an unannounced inspection at a listed address that is no longer in business or no longer located at the address FDA has on file. During fiscal year 2015, FDA experienced 629 inspectional washouts; therefore, the agency expects the use of UFIs as verification of information submitted in registrations to increase inspectional efficiencies.

  The requirement to provide a UFI applies to all registrants, new and existing. In order to provide both domestic and foreign food facilities sufficient time to obtain a UFI, this provision will not be effective until the registration renewal period beginning October 1, 2020. FDA explains that this is an adequate timeframe for facilities to become familiar with the process of obtaining a D-U-N-S number, which can be acquired outside of the biennial registration renewal period.

- Email Address for Authorizing Party: The final rule requires the person submitting the registration or renewal to provide FDA with the email address of the individual who authorized the submission, unless a waiver has been granted. In addition, each electronic registration renewal must include the name of the individual submitting the renewal.

- Verification by FDA: After the registration-related submission is made to FDA, the agency will verify the accuracy of the facility's UFI and that the facility-specific address associated with the UFI is the same address associated with the registration. Likewise, FDA also will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility. FDA will not confirm the registration or provide a registration number until these steps are complete. The new verification steps are intended to address a problem FDA has encountered with unauthorized third-party registration submissions. These provisions also apply to the submission of an abbreviated

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7/ A D-U-N-S number is a unique 9-digit identifier provided by Dun & Bradstreet that can be specific for each site. As part of the Foreign Supplier Verification Program rulemaking, FDA proposed requiring importers to provide their D-U-N-S number for each line of entry of food. 78 Fed. Reg. 45730, 45777 (Proposed 21 CFR § 1.509(b), (c)). In the final rule, FDA required importers to provide a "unique facility identifier recognized as acceptable by FDA," and indicated it anticipated issuing a guidance document that recognizes D-U-N-S numbers as being acceptable facility identifiers. 80 Fed. Reg. 74226, 74299 (Nov. 27, 2015).

8/ 81 Fed. Reg. 45912, 45929 (July 14, 2016).

registration renewal. FDA plans to issue guidance with more detailed information on how FDA will conduct the authorization verification step.

- Timing for Updates and Cancellations: In response to the comments submitted on the proposed rule, FDA did not shorten the time period for food facilities to update or cancel their registration from 60 calendar days to 30 calendar days. Therefore food facilities continue to have 60 calendar days to update or cancel their registration.

- FDA-Initiated Cancellations: The final rule provides that FDA will cancel a registration in situations where the agency independently verifies that:

    - The facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration;
    - FDA determines that the registration is for a facility that does not exist, is not required to register, or where the information about the facility's address was not updated in a timely manner or the registration was submitted by a person not authorized to make the submission; or
    - The facility has failed to renew its registration.

  Prior to cancelling a registration, FDA will send notice to a facility indicating the intent to cancel the registration and the basis for doing so. If a facility facing cancellation of its registration sufficiently corrects the issue warranting cancellation within 30 days, FDA will not cancel the registration. FDA's believes that its independent verification of the circumstances will ensure registrations are not cancelled as a result of an inadvertent technical mistake.

- Food Product Categories: Registrations are required to provide information on the type of activity conducted at the facility for each product category identified, consistent with the categories set forth in FDA's Food Product Categories guidance document. 9/ This guidance document is unique because it is binding, as FSMA explicitly directs creation of binding requirements based on findings in guidance; therefore, the Food Product Categories guidance document is not subject to the usual restrictions in FDA's Good Guidance Practices regulations, such as the requirements that a guidance document not establish legally enforceable responsibilities and that it must contain a statement of the guidance document's nonbinding nature.

  FDA recognizes that it may be necessary for warehouse facilities engaged in operations that frequently change the types of foods held to frequently update their registrations to update the food product categories. FDA advises that warehouses engaged in ongoing operations may select all of the food product categories that are normally a part of their operations. If the warehouse has any updates to the food product categories that it handles, it is required to update its registration. FDA is considering possible IT solutions to reduce the burden associated with selection of food product category information.

- U.S. Agent Voluntary Identification System: FDA plans to implement a U.S. Agent Voluntary Identification System (VIS) that will be designed to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which

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9/ U.S. Food and Drug Administration, Guidance for Industry, Necessity of the Use of Food Product Categories and Updates to Food Product Categories, October 2012, *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM324792.pdf. FDA intends to update the Food Product Categories guidance to add several additional food product categories for animal food and to replace certain food product categories that relate to animal food.

the agent has agreed to serve. FDA will provide further information and details about the system in future guidance.

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Should you have any questions, please do not hesitate to contact us.