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Regulatory Alert: FDA Releases Draft Guidance on Questions and Answers Regarding Food Facility Registration

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In November 2016, the U.S. Food and Drug Administration (FDA) published draft guidance for industry on Questions and Answers Regarding Food Facility Registration (Seventh Edition).

Pursuant to section 415 of the Food, Drug and Cosmetic Act (FDCA),[1] all U.S. and foreign facilities that process, pack and hold food for consumption in the U.S. must registered with FDA. Foreign facilities must appoint an agent in the U.S. to serve as a point of contact for FDA among other things. The Food Safety Modernization Act (FSMA)[2] added a new requirement for food facilities to renew their registration on every even-numbered year between October 1 and December 31.

The draft guidance may be found here. The draft guidance adds new questions and answers, the key ones of which are summarized below.

Do new food facilities need to wait until October 1 of a biennial renewal year to register?

No. The owner, operator, or agent in charge of a facility that begins to manufacture/process, pack or hold food for consumption in the United States must register before the facility begins such activities. If the initial registration is submitted prior to October 1 of a biennial renewal year, a renewal still must be submitted for the facility during the period beginning on October 1 and ending on December 31.

Will a food facility be issued a new registration number during the registration renewal process?

No.

Will facilities have to resubmit all registration information when a registration is renewed?

No. FDA is providing for an abbreviated renewal process for facilities that do not have information changes since the submission of the preceding registration, renewal or update.

The abbreviated registration renewal process confirms that no changes have been made since the preceding registration, renewal or update, and certify that the information submitted is truthful and accurate. Each electronic abbreviated registration renewal must include the name

[1] 21 USC 350d

[2] P.L. 111-353

of the individual submitting the abbreviated renewal and for abbreviated renewals not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the abbreviated renewal must be provided unless FDA has granted a waiver.

How will FDA conduct the verification process for the unique facility identifier (UFI) required in the facility's registration?

Under 21 CFR 1.232(a)(2), domestic and foreign facilities must submit a unique facility identifier (UFI) recognized as acceptable to FDA in the facility's registration. FDA has announced it expects to recognize DUNS numbers (Dun & Bradstreet Data Universal Numbering System) as acceptable for purposes of the UFI.

Please note that the UFI requirement will not begin until October 1, 2020.

FDA intends to verify UFIs as follows:

- For electronic registrations and renewal, after the registration or renewal is submitted, FDA will verify the accuracy of the UFI and that the address associated with the UFI is the same address associated with the registration or renewal. FDA will not confirm a registration or renewal until the accuracy of the UFI and address information is verified.

How will FDA conduct the verification process for submissions not made by the owner, operator, or agent in charge of the facility?

For registrations or renewals not submitted by the owner, operator, or agent in charge of the facility, FDA will verify that the individual identified as having authorized the submission on behalf of the facility in fact did so. FDA will not confirm a registration, provide a registration number, or provide confirmation of a registration renewal until that individual confirms that he or she authorized the submission. In most circumstances this will be done via an automated email.

For updates and cancellations, FDA will not provide a confirmation of the registration update or cancellation until the individual confirms that he or she authorized the submission. FDA will provide the owner, operator, or agent in charge of the facility 30 calendar days to respond to FDA's verification request. Failure to respond within 30 days will cause the renewal, update or cancellation to be removed from the database.

How will FDA conduct the verification process for U.S. agents?

For registrations, registration renewals, and updates to information about U.S. agents, FDA will verify that the period identified as the U.S. agent for the foreign facility agreed to serve as the U.S. agent. FDA will not confirm a registration or registration renewal or provide a registration

number until the person identified as the U.S. agent confirms that they have indeed agreed to serve as such. FDA will generally conduct the verification via email.

If the person listed as the U.S. agent informs FDA that they have not agreed to serve as the facility's U.S. agent, FDA will inform the facility of that fact and request that the facility amend the registration to designate a person who has affirmatively agreed to serve as the facility's U.S. agent.

If incorrect information is provided at the time the registration or registration renewal is submitted, does the submission need to be updated immediately?

Yes.

Will FDA allow for UFIs to be submitted in advance of October 1, 2020?

Possibly. FDA is considering adding an optional field to allow for voluntary submission of the UFI in advance of October 1, 2020.

Do owners, operators or agents in charge of multiple food facilities need to submit multiple UFIs?

Yes. The registration for each facility must have its own UFI. Businesses currently with one DUNS number for the entire organization will have to get DUNS numbers for each food facility they own, operate or serve as the agent in charge of.

Are facilities required to provide information about food product categories in registration submissions?

Yes

Must distribution centers/warehouses or other holding facilities need to constantly update their food product categories in their registrations if their information frequently changes?

For warehouse facilities engaged in ongoing operations that frequently change food product categories, these facilities may select all of the food product categories that are normally part of their operations. If the warehouse has updates to the food product categories it handles, the facility is required to update its registration.

Should facilities submit food product category information about the ingredients they use for manufacturing finished foods, or the finished foods the facility manufactures?

Manufacturers/processors should provide food product category information about the finished foods manufactured, not the ingredients used in the manufacturing/processing.

Do facilities that send human food byproducts to other facilities for production into animal food need to provide animal food product category information in their registration?

Yes.

Are facilities required to provide activity type information in their registrations?

Yes. Food facilities must include information about the type of activity conducted for each food product category identified. Activity types include: ambient human food storage warehouse/holding; contract sterilizer; manufacturer/processor and acidified food processor to name a few.

Do foreign facilities have to provide activity type information about all foods associated with the facility, or only about foods exported for consumption in the United States?

Foreign facilities that are required to register are only required to provide activity type information about food that the facility manufactures/process, packs, or holds for consumption in the U.S.

A facility has changes to my registration information. Must the registration be updated immediately, can it wait until the beginning of the biennial registration renewal period beginning on October 1 of each even-numbered year?

The owner, operator, or agent in charge of a facility is required to submit an update to a facility's registration to FDA within 60 calendar days of a change to any of the required registration information previously submitted.

Can FDA cancel a registration?

Yes, FDA will cancel a registration if FDA independently verifies:

- The facility is no longer in business
- The facility had changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration
- The registration is for a facility that does not exist
- The facility is not required to register
- The information about the facility's address was not updated in a timely manner
- The registration was submitted to FDA by an unauthorized person

In addition, FDA will consider a registration for a food facility to be expired if the registration is not renewed, and FDA will consider a food facility with an expired registration to have to register. Furthermore, FDA will cancel a registration if the registration has expired because the facility failed to renew it.

If a foreign facility has not renewed its registration by December 31 of a biennial renewal period, will the facility still be able to import food into the U.S?

If a foreign facility required to register does not renew its registration by December 31 of a biennial renewal period, the registration for the facility will be considered expired and FDA will cancel the registration. Food exported to the U.S. from a facility that has failed to renew its registration is subject to being held at the port of entry.

Are qualified facilities that are exempt from the Preventive Controls for Human or Animal Food final rules still required to register?

Yes. Qualified facilities, as defined in 21 CFR 117.3 (human food) or 21 CFR 507.3 (animal food), are food facilities that are required to register under section 415 of FD&C Act.

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