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ADVISORY

Guidelines on 2022 Food Facility Biennial Registration Renewal with US-FDA

(October 1, 2022, 12:01 AM through December 31, 2022, 11:59 PM)

To All Concerned Stakeholders:

Please be advised that the renewal of registration of food facilities with the U.S. Food and Drug Administration (FDA) will begin on October 01, 2022. Under the U.S. Bioterrorism Act, **‘all domestic and foreign food facilities that manufacture/process, pack, or hold food for human or animal consumption** in the United States must register with the FDA.’ Section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires registered food facilities to renew their registrations beginning **October 1** and ending on **December 31** of each even-numbered year, with 2022 being the renewal year.

Specifically, the owner, operator, or agent in charge of the facility should provide information such as the facility’s name, address, and food category handled by the facility. For foreign facilities, the information of the US agent for the facility should be included. Failure to renew their registration as required by 11:59 PM on December 31, 2022 shall be considered expired by FDA. Owners and operators of facilities can renew their registration through the **FDA industry Systems Account (FDIS)**, which can be accessed at <https://www.access.fda.gov/>.

In addition, all facilities must include a unique facility identifier (UFI) with their registration. To date, the FDA recognizes the Data Universal Numbering System (DUNS) number as an acceptable UFI. The DUNS number is assigned and managed by Dun & Bradstreet, and can be obtained or verified through the D&B’s website at <https://importregistration.dnb.com/>.

A webinar to explain the registration procedures and required UFI was held. During the webinar, it was explained that the information in the Dunn's number should match the information in Section 2 of the facility registration (facility name/location information). However, it was announced that it will extend the transitional measures established for the input of UFI until December 31, 2022, and for this renewal, it is allowed to apply by entering "PENDING" in the UFI item. FDA has released a guideline regarding the enforcement of UFI. (link No. 7).

You may also refer to the information on updating of registered facilities provided by JETRO (link No.8)

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For the further details on the registration procedures, and required UFI, kindly access the following links:

1. Food Facility Registration User Guide: Biennial Registration Renewal:
<https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-user-guide-biennial-registration-renewal>
2. Food Facility Biennial Registration Renewal Fact Sheet
<https://www.fda.gov/media/160352/download>
3. Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition>
4. Draft Guidance for Industry: Supplemental Questions and Answers Regarding Food Facility Registration
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-supplemental-questions-and-answers-regarding-food-facility-registration>
5. Registration of Food Facilities and Other Submissions
<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions>
6. Webinar on Food Facility Registration (FFR), Biennial Renewal and Unique Facility Identifiers
<https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-food-facility-registration-ffr-biennial-renewal-and-unique-facility-identifiers-ufi-08112022>
7. Enforcement Policy for Providing an Acceptable UFI for the 2020 Food Facility Registration Biennial Renewal Period: Guidance for Industry:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-enforcement-policy-providing-acceptable-unique-facility-identifier-ufi-2020-food>
8. Information on the Bioterrorism Act
https://www.jetro.go.jp/world/n_america/us/foods/bioterrorism.html

For your information. Thank you.