Enforcement Policy for Providing an Acceptable Unique Facility Identifier (UFI) for the 2020 Food Facility Registration Biennial Renewal Period: Guidance for Industry

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This guidance represents the current thinking of the Food and Drug Administration (FDA, we, or the Agency) 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 the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides information on how you may comply with FDA's requirement to provide a unique facility identifier (UFI) recognized as acceptable by FDA when you submit your food facility registration or renewal in the Food Facility Registration Module (FFRM). This guidance also provides information on what to do if you are unable to timely obtain a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number prior to the end of the biennial renewal period, December 31, 2020.

In this guidance, the terms "you," "your," or "registrant," are used 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 the Agency's 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.

[1] This guidance has been prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Background

Section 415 of the Federal Food, Drug, and Cosmetic Act (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. 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 to require domestic and foreign facilities submit certain additional new information to FDA and to renew their registrations every other year, during the period beginning on October 1 and ending on December 31 of each even-numbered year. FDA issued a final rule that revised FDA's Food Facility Registration regulation on July 14, 2016 (81 FR 45912).

The Food Facility Registration regulation was established in Title 21 of the Code of Federal Regulations, Part 1, subpart H, and specifies who the Food Facility Registration requirements apply to and establishes various requirements. Among other requirements, 21 CFR 1.232(a)(2) of the Food Facility Registration regulation requires that starting October 1, 2020, facilities are required to provide a UFI recognized as acceptable by FDA.

In August 2018, FDA issued guidance recognizing the DUNS number as an acceptable UFI for the Food Facility Registration regulation (see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition).

This guidance provides information on how registrants may obtain and provide a UFI even if they are unable to obtain a UFI before December 31, 2020.

III. Discussion

Following the implementation of the UFI requirement on October 1, 2020, FDA received feedback from stakeholders of their concerns with obtaining the DUNS number before the conclusion of the 2020 biennial renewal period on December 31 for those registrants whose registration(s) are due for renewal.

While FDA expects all registrants to provide their DUNS number with their registration or renewal submission before December 31, 2020, the Agency recognizes that there may be a delay in obtaining a DUNS number. To address stakeholder concerns with obtaining a DUNS number in a timely manner, FDA intends to allow registrants who anticipate that they will be temporarily unable to provide a DUNS number with their registration or renewal to enter "PENDING" in the UFI field[2] of their registration. This temporary entry will allow for registrations and renewals to be submitted even if the registrant has not yet provided a DUNS number. Upon submission, the registrant will have 90 calendar days to update their registration with their DUNS number. Users will be reminded via email that their registration needs to be updated with a DUNS number within 90 calendar days, with reminder notifications to follow. Failure to update the registration with a valid DUNS number within 90 calendar days of submitting a registration or renewal with

[2] The UFI field is in Section 2 – Facility Name/Address Information of Form FDA 3537.

“PENDING” in the UFI field will result in cancellation of the registration for failure to renew in accordance with 21 CFR 1.230(b).

The DUNS number can be obtained by contacting D&B by phone at 866-705-5711 or by visiting D&B’s website at http://www.dnb.com/duns-number.html.