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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Enforcement Policy for Providing an Acceptable Unique Facility Identifier (UFI) for the 2020 Food Facility Registration Biennial Renewal Period: Guidance for Industry[1]

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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.

This guidance supersedes the guidance of the same title dated December 2020. This guidance revises section III. to extend the period of the enforcement policy for the rest of the 2020 biennial registration renewal cycle for facilities that are unable, or anticipate that they will be temporarily unable, to provide a DUNS number with their registration or renewal. This guidance also describes our intent not to enforce the associated verification requirements for the remainder of this 2020 biennial registration renewal cycle.

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.

[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.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA's guidance documents, including this guidance, 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. 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 addition, 21 CFR 1.231(a)(3) and (b)(5) of the Food Facility Registration regulation provides that FDA will not confirm a facility's registration or registration renewal until FDA verifies the accuracy of its UFI and verifies that the facility-specific address associated with the UFI is the same address associated with the facility's registration. The Food Facility Regulation provides that FDA will not confirm a registration or provide a facility with a registration number until FDA verifies the accuracy of the facility's UFI and verifies that the facility-specific address associated with the UFI is the same address associated with the registration. 21 CFR 1.231(a)(3); 1.231(b)(5).

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 were 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, 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. In addition, FDA intends not to enforce the requirement in 21 CFR 1.231(a)(3) and (b)(5) to verify the accuracy of the UFI submitted by registrants. Upon submission, the registrant will have until December 31, 2022,[3] to update their registration with their DUNS number. Failure to update the registration with a valid DUNS number by the end of the next biennial registrational renewal cycle 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.

[2] The UFI field is in Section 2 – Facility Name/Address Information of Form FDA 3537.
[3] FDA initially provided this enforcement discretion for 90 days. But upon hearing from stakeholders that additional time may be required to obtain DUNS numbers, FDA is extending this policy until December 31, 2022.