

Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation: Guidance for Industry

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**U.S. Department of Health and Human Services
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Center for Veterinary Medicine**

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Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) 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 specifies FDA’s current thinking on what unique facility identifier (UFI) FDA recognizes as acceptable for purposes of the Foreign Supplier Verification Programs (FSVP) regulation established in Title 21 of the Code of Federal Regulation, Part 1, subpart L as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). The pronoun “you” is used in this guidance to refer to the importer.

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.

II. Background

FDA issued the rule on FSVPs for importers of food for humans and animals on November 27, 2015 (80 FR 74225). The FSVP regulation, codified in 21 CFR 1.500 through 1.514, specifies the foods and importers to which the FSVP regulation applies and establishes various

¹ This guidance has been jointly prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Division of Import Operations in the Office of Regulatory Affairs at the U.S. Food and Drug Administration.

requirements, including the requirement for importer identification for food offered for entry into the United States (21 CFR 1.509(a)).

In the FSVP proposed rule, FDA initially proposed to require that for each line entry of food product offered for importation into the United States, the FSVP importer's name and Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number identifying the FSVP importer be provided (78 FR 45729 at 45762, July 29, 2013).

In response to comments, in the FSVP final rule we replaced this proposed provision with a requirement that for each line entry of food product offered for importation into the United States, the FSVP importer provide its UFI recognized as acceptable by FDA (21 CFR 1.509(a)). We stated in the final rule that we anticipated issuing guidance specifying which UFI(s) we recognized as acceptable and that we expected to recognize DUNS numbers as being acceptable (80 FR 74226 at 74301). In addition, the final rule requires that for each line entry of food product offered for importation into the United States, the FSVP importer must also provide the importer's name and electronic mail address (21 CFR 1.509(a)).

III. Recognition of Acceptable Unique Facility Identifier (UFI)

At this time, FDA recognizes the DUNS number, assigned and managed by D&B, as an acceptable UFI for the purpose of compliance with the FSVP regulation.

Currently, FDA finds the DUNS number appropriate to meet Agency needs to accurately identify FSVP importers so we can effectively implement, monitor compliance with, and enforce the FSVP requirements. The DUNS number is available free of charge to all importers, and can be obtained by contacting D&B by phone at 866-705-5711 or via email at govt@dnb.com, or by visiting D&B's Web sites at <http://www.dnb.com/duns-number.html> or <https://fdadunslookup.com>. Although a DUNS number may be obtained within a few business days, in some circumstances it could take up to 45 days or more.

If you anticipate being unable to provide a DUNS number to identify yourself as the FSVP importer of a food product at entry, you may contact FDA's Division of Import Operations at 1-301-796-0356 or via email at FDAImportsInquiry@fda.hhs.gov prior to offering your product for import into the United States.