4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0984]

Specification of the Unique Facility Identifier System for Drug Establishment Registration; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration." This guidance specifies the UFI system for registration of domestic and foreign drug establishments. The guidance addresses provisions set forth in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). This guidance finalizes the draft guidance issued on September 6, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your

requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2262, Silver Spring, MD 20993-0002, edrls@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration." In July 2012, FDASIA was signed into law (Public Law 112-144). Sections 701 and 702 of FDASIA direct the Secretary of Health and Human Services (and by delegation, FDA) to specify the UFI system for registration of domestic and foreign drug establishments. Once the UFI system is specified, section 510 of the FD&C Act (21 U.S.C. 360), as amended, requires that each initial and annual drug establishment registration include a UFI (21 U.S.C. 360(b), (c), and (i)). This guidance is intended solely to address sections 701 and 702 of FDASIA. Although section 703 of FDASIA mandates the use of the same UFI system (specified for drug establishment registration) to identify excipient manufacturers in product listings, this guidance does not address implementation of section 703 of FDASIA.

This guidance specifies the UFI system for registration of domestic and foreign drug establishments. At this time, FDA's preferred UFI for a drug establishment is the Data

Universal Numbering System (DUNS) number, assigned and managed by Dun and Bradstreet. The DUNS number is available free of charge to all drug establishments and may be obtained by visiting Dun and Bradstreet's Web site at http://www.dnb.com/. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.) This guidance reflects the Agency's current thinking in light of data standards, information technology, and information management resources. As these variables change over time, FDA may revisit the guidance.

In the Federal Register of September 6, 2013 (78 FR 54899), FDA announced the availability of the draft guidance entitled "Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration." The notice gave the public an opportunity to comment by November 5, 2013. FDA carefully considered all comments received in preparing the guidance. No substantive changes were made in finalizing the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on specification of the UFI system for drug establishment registration. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information have been approved under OMB control number 0910-0045.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, or http://www.regulations.gov.

Dated: November 3, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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