Guidance for Industry

Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments 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. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact Paul Loebach eDRLS@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Office of Regulatory Affairs (ORA)

September 2013
Procedural
Guidance for Industry

Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration

Additional copies are available from:
Office of Communications
Division of Drug Information, WO51, Room 2201
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Silver Spring, MD 20993
Phone: 301-796-3400; Fax: 301-847-8714
druginfo@fda.hhs.gov
and/or
Office of Communication, Outreach and Development, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Rockville, MD 20852-1448
(Tel) 800-835-4709 or 301-827-1800
and/or
Communications Staff, HFV-12
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, Rockville, MD 20855
(Tel) 240-276-9300
http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm
and/or
Office of Policy
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Ave. Silver Spring, MD 20993
Phone: 301-796-4830

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Office of Regulatory Affairs (ORA)

September 2013
Procedural
TABLE OF CONTENTS

I. INTRODUCTION............................................................................................................. 1
II. BACKGROUND ............................................................................................................... 1
   A. Food and Drug Administration Safety and Innovation Act....................................................... 1
   B. Scope of this Guidance......................................................................................................... 2
III. SPECIFICATION OF THE UNIQUE FACILITY IDENTIFIER SYSTEM ........... 2
I. INTRODUCTION

This guidance specifies the unique facility identifier (UFI) system for registration of domestic and foreign drug establishments. This guidance is intended to address provisions set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), regarding the specification of the UFI system.

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

A. Food and Drug Administration Safety and Innovation Act

In July 2012, FDASIA was signed into law. Sections 701 and 702 of FDASIA direct the Secretary 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, as amended, requires that each initial and annual drug establishment registration include a UFI (21 U.S.C. 360(b), (c), and (i)).
B. Scope of This Guidance

This guidance is intended solely to address the provisions in sections 701 and 702 of FDASIA that direct the Secretary to specify the UFI system for registration of domestic and foreign drug establishments. This guidance reflects current thinking in light of data standards, information technology, and information management resources. As these variables change over time, the FDA may revisit this guidance and the specification made in section III of this guidance.

III. SPECIFICATION OF THE UFI SYSTEM

For drug establishment registration, FDA is specifying the following UFI System. At this time, FDA’s preferred UFI for a drug establishment is the Data Universal Numbering System D-U-N-S (DUNS) number, assigned and managed by Dun and Bradstreet. The FDA has been using the DUNS number as a registration number for drug establishments since the implementation of electronic drug registration and listing (for information on the electronic submission of registration and listing data, see http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm ). Currently, the FDA finds the DUNS number appropriate to meet Agency needs for a data standard for drug establishment registration UFI. The DUNS number is available free of charge to all drug establishments, and further information is available on the FDA Web site at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162544.htm. If you want to use an alternative identifier for your drug establishment, contact FDA via email at eDRLS@fda.hhs.gov.