October 28, 2013

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA Docket No. FDA-2013-D-0984: Draft Guidance for Industry on Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration; Availability

Dear Madam/Sir:

Hospira, Inc. (Hospira) hereby submits the attached comments to Docket No. FDA-2013-D-0984; Draft Guidance for Industry on Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration. Hospira is responding to the Request for Comments published on September 6, 2013.

Should you have any questions or require additional information, please contact the undersigned.

Sincerely,

Kathleen M. Lins 28 Oct 2013

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

Comments from Hospira, Inc.

Section III. Specification of the UFI System

This section states:

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-NS (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.

Hospira agrees that the DUNS Number should be used as the Unique Facility Identifier (UFI). Although, industry is having a very challenging time getting Establishment Registration Form Structured Product Labeling (ERF SPL) files to pass FDA validation due to discrepancies in the addresses that industry provides versus what appears in the Dun and Bradstreet database used for FDA validation. Foreign addresses are extremely challenging. Industry needs a way to verify the address that FDA sees prior to submitting the ERF SPL file to the FDA. If the address shows a discrepancy, and is incorrect in the Dun and Bradstreet database, industry will request Dun and Bradstreet to make correction in their database. Dun and Bradstreet has to expedite corrections to address discrepancies in their database so ERF SPL files will pass FDA validation the first time and not require a manual override from the FDA.

This challenge has been discussed at the SPL Working group meetings and many companies are having the same issue regarding failing ERF SPL files. Dun and Bradstreet offered the possibility of a portal that industry could use to see the addresses in the Dun and Bradstreet database that the FDA uses to validate the ERF SPL files. This portal, showing real time data, would help alleviate the issue as well as provide efficiencies for the Agency, as fewer manual overrides would be requested.