From: U.S. Food & Drug Administration (FDA) [mailto:fda@service.govdelivery.com]
Sent: Thursday, December 18, 2014 11:05 AM
Subject: Update on UDI Implementation for Registered Medical Device Establishments

Having passed the first Unique Device Identification System compliance date of September 24, 2014 (for Class III devices and devices licensed under the Public Health Service Act), the FDA's Center for Devices and Radiological Health (CDRH) would like to take this opportunity to summarize recent and upcoming UDI activities and deadlines. The next two compliance dates for UDI requirements are:

- September 24, 2015 for non-class III implantable, life-supporting, and life-sustaining (I/LS/LS) devices
- September 24, 2016 for class II devices

Global Unique Device Identification Database (GUDID) Data Submission:

- In January 2015, we will begin accepting GUDID account requests from labelers of I/LS/LS devices. Later in 2015, we plan to accept GUDID account requests from labelers of class II devices. We strongly encourage all device labelers to take steps to ensure their readiness to meet UDI requirements well before actual data submission to GUDID. This will provide labelers with ample opportunity to assess their ability to meet requirements, including data submission to the GUDID, by their deadline and to work with us if they have any difficulties coming into compliance. Suggested steps are included on the UDI website.

- Also in January, we will host a webinar to help Class II and I/LS/LS device labelers prepare to comply with the UDI rule. Notification of webinar specifics will be sent directly to these device labelers in early January. The webinar will include overviews of UDI requirements and how to get started with the GUDID.

UDI Policy:

- We continue to work with industry on UDI implementation issues that surfaced in 2014, including GUDID data submission for contact lenses/IOLs and development of approaches to ensure the UDI is available at the point of use for non-sterile implants. We recognize there are several other policy issues that are of significant interest to industry; we hope to address a number them in 2015, such as UDI direct marking requirements, convenience kits, posting of decisions on UDI exceptions and alternatives, and issuance of additional Frequently Asked Questions (FAQs).

- The use of National Health Related Items Code (NHRIC) and National Drug Code (NDC) numbers for devices is being phased out over a time period that corresponds with the compliance dates for UDI requirements. Device labelers that want to retain the use of FDA-issued NHRIC or NDC labeler codes under a system for the issuance of UDIs were required to request such continued use by September 24, 2014. If you intend to retain the use of a previously issued FDA labeler code within your UDI system but have not made such a request, we urge you to do so as soon as possible.

UDI Adoption and Use:

- We continue to collaborate with stakeholders, such as the Pew Charitable Trusts, the Office of the National Coordinator for Health IT (ONC), and the Brookings Institution to promote and facilitate UDI adoption in health care settings.
- We are working with the National Library of Medicine (NLM) to give the public search and download access to published records in the GUDID in the spring of 2015. GUDID search will allow published GUDID data to be retrieved based on parameters of interest to the user. The GUDID download function will let users download all published GUDID data at once.

Finally, we'd like to reaffirm our plans to implement this important system over several years—and underscore the fact that we fully intend to be flexible during this time. Our main focus is getting the system implemented correctly and actively helping companies comply with system requirements. As with the implementation of many new systems, it can take time to understand and comply with new requirements—widespread, strict enforcement of associated deadlines and requirements is not necessarily the best way to achieve compliance at this time.

To date, industry has been very willing to work with CDRH, and we have experienced excellent efforts and strong feedback. We urge labelers that are having difficulty fulfilling UDI requirements to let us know through the FDA UDI Help Desk.

We will continue to work diligently to give the medical device industry, health care systems, clinicians and patients the assistance and information needed to implement and use UDI successfully. For additional information, please see www.fda.gov/udi or contact us at the FDA UDI Help Desk.

Food and Drug Administration
Center for Devices and Radiological Health