April 4, 2016

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2015-D-4048: Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

To Whom It May Concern:

On behalf of the Health Industry Distributors Association (HIDA), which represents the interests of 600 medical surgical healthcare products distributor companies across the country, I write in response to the Food and Drug Administration’s (FDA) Unique Device Identification: Convenience Kits; Draft Guidance for Industry and FDA Staff.

HIDA’s members deliver lifesaving healthcare products to more than 295,000 points of care including 210,000 physician offices, 6,500 hospitals, and 44,000 nursing home and extended care facilities throughout the nation. HIDA’s members are also committed to promoting safety and cost savings within the healthcare supply chain.

HIDA supports the intent of the FDA’s Unique Device Identification (UDI) program and its goal of helping reduce medical errors, facilitating device recalls, improving adverse event reporting, and helping ensure product integrity. However, several considerations must be made with regard to the agency’s proposed approach to the UDI labeling exception and medical convenience kits. Clearly communicated expectations of what is required for labelers of medical convenience kits are critical for the supply chain to effectively execute a UDI program.

As such, HIDA recommends the following:

1. The adoption of an appropriate term that defines a collection of devices that is subject to UDI but, for the purpose of UDI labeling compliance, is not considered a convenience kit; and
2. The use of regulatory enforcement discretion through September 20, 2021 to ensure that all Class I devices and any grandfathered inventory that may be subject to UDI labeling requirements as a result of the new convenience kit criteria are appropriately labeled by their respective manufacturer prior to being assembled into a convenience kit.
Medical Convenience Kits

HIDA encourages the FDA to develop clear and concise guidance with regard to the application of UDI and medical convenience kits. Many of HIDA’s member companies are labelers of thousands of unique medical convenience kits. The vast majority of these kits are for specific procedures at a hospital or surgery center. These highly customizable packaging configurations allow our members to package together a variety of finished medical products required for a given operation. Absent such a service, healthcare personnel would be required to assemble these kits themselves—pulling stock from various sources throughout a facility. Such a process would be incredibly labor intensive and costly. We believe that the current systems and processes in place are working well—delivering products to patients and providers safely and efficiently.

Definitions

It appears that the intent in narrowing the definition of convenience kit is to limit the use of the convenience kit exception outlined in the final rule. We recognize that by narrowing the definition of convenience kit to include “only medical devices that are packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user” is more in line with the overarching objective of the UDI rule, as required by section 519(f) of the FD&C Act “to provide a system to adequately identify medical devices through distribution and use.” That said, a clear understanding of what is expected for labelers of medical convenience kits is critical for those in the supply chain to effectively execute a UDI program.

HIDA recommends that the FDA clearly define what constitutes a group of medical devices packaged together for the convenience of the user for the purposes of compliance with UDI labeling requirement. This designation is needed in order to clarify the distinction between:

1. Convenience kits as defined at CFR 801.3 that meet the new UDI kitting exception criteria outlined in the draft guidance (i.e., convenience kits whose devices remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user) where a UDI label on the immediate container serves to adequately identify the devices through distribution and use; and
2. A group of medical devices packaged together for the convenience of the user that do not meet the UDI kitting exception criteria (i.e., devices packaged together for the convenience of the user where they are not intended to remain packaged together and/or are intended to be replaced, substituted, sterilized, or otherwise processed or modified before the devices are used) where a UDI label is required on each individual device within the group.

Historically the FDA has defined convenience kits as “two or more finished medical devices packaged together for the convenience of the user.” The products contained within convenience kits are “in finished form held for
sale to an end user . . . [and] suitable for use or capable of functioning, whether or not . . . packaged, labeled or sterilized.” Because the FDA is proposing to alter how it intends to apply the UDI kit exception to convenience kits, the agency needs to define and use an appropriate term for a collection of devices that is subject to UDI but is not, for the purposes of UDI compliance, a “convenience kit.” The term “medical convenience kit” is also used and defined in The Drug Supply Chain Security Act (21 USC 353) as “a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user.” HIDA suggests the FDA utilize this definition when referring to a group of medical devices packaged together for the convenience of the user that do not meet the UDI kitting exception criteria.

**Enforcement Discretion**

The success of the UDI program is reliant upon a practical implementation timeline. Given the proposed change to the FDA’s approach to the UDI labeling exception for convenience kits, the current timeline is unworkable for industry and raises serious concerns regarding the costs and changes in business practices necessary to be compliant. We ask the FDA to fully consider the potential effects on the supply chain before issuing final guidance and consider exercising enforcement discretion against convenience kit labelers through September 20, 2021. This timeline will ensure that any existing Class I device inventory is fully compliant with the UDI requirements.

**Existing Timeline’s Impact on Convenience Kit Labelers**

Labelers of convenience kits must adhere to the UDI compliance timeline associated with the highest level of device within the kit they are assembling. A majority of convenience kits contain Class II devices. As such, any convenience kit (containing a Class II device) not already in commercial distribution must be UDI compliant per the final rule by September 20, 2016. Less than six months is not a suitable timeline for implementation given the FDA’s new interpretation of which types of convenience kits meet the UDI labeling exception outlined in the final rule. Furthermore, the current September 20, 2016 timeline that a majority of convenience kit labelers must adhere to is made more problematic because most convenience kits also contain Class I devices. Class I devices are not required to be UDI compliant until September 20, 2018. This creates a situation where a convenience kit labeler could potentially be responsible for placing a UDI label on another manufacturer’s Class I product if the convenience kit that is being assembled does not meet the new UDI kitting exception criteria (i.e., the convenience kit’s devices remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user).

HIDA believes that the use of enforcement discretion through September 24, 2021 is a suitable timeline for convenience kit labelers to ensure compliance with the new UDI labeling criteria for convenience kits. Such a timeline will ensure that all Class I devices and any grandfathered inventory that may be subject to UDI labeling requirements as a result of the new convenience kit criteria are appropriately labeled by their respective manufacturer prior to being assembled into a convenience kit.
HIDA strongly supports a UDI system that is relevant and cost effective for the wide range of medical products used in varied healthcare settings. However, we encourage the FDA to fully consider the potential effects on the supply chain before finalizing this guidance.

On behalf of HIDA and its members, thank you in advance for your consideration of our comments and recommendations.

Sincerely,

Linda Rouse O’Neill
Vice President, Government Affairs
Health Industry Distributors Association