FDA Releases Draft Guidance on UDI Requirements for Convenience Kits

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On January 4, 2016, the Food and Drug Administration (FDA) released a draft guidance intended to clarify the Unique Device Identifier (UDI) labeling requirements for certain medical devices packaged together as "convenience kits.[1]" The draft guidance, while not legally binding, attempts to explain FDA's current thinking on the regulatory exception to the UDI Final Rule, whereby devices packaged within the immediate container of a convenience kit are exempted from UDI labeling requirements, if the label of the convenience kit contains a UDI.

As background, the UDI final rule, published on September 24, 2013, requires that a medical device label and package include an individual UDI, unless an exception or alternative applies. The agency rule, codified at 21 C.F.R. § 801.20, is intended to identify a device through its distribution and use, thereby improving patient safety and post-market surveillance. However, FDA provides exceptions to the UDI requirement, such as the aforementioned convenience kit exception, described at 21 C.F.R. § 801.30.

Highlights of the Draft Guidance

- The draft guidance explains that when the UDI final rule was issued, FDA grouped all medical procedure kits (e.g., kits containing implants and reusable instruments) together as convenience kits. FDA now proposes to define a "convenience kit," for UDI purposes, as a kit containing "two or more different medical devices 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." No additional processing or modification of the devices may occur before their use.
    - FDA interprets "packaged together" as: "packed (i.e., wrapped or sealed) in a single container that is not intended to be unwrapped or unsealed before it is used by an end user)."
    - FDA interprets "medical devices" as finished devices and not device components.
- According to FDA, interpreting the term convenience kit to include devices and instruments that are provided by the labeler in sets or trays as "non-sterile and repeatedly reconfigured and sterilized" prior to use would be "inconsistent with the purpose of the exceptions."
- The new interpretation draws a distinction between convenience kits where the kit contents are not intended to be altered prior to use compared to kits where the devices are intended to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before use by the end user.

1 The guidance, "Unique Device Identification: Convenience Kits: Draft Guidance for Industry and Food and Drug Administration Staff "

- FDA explains that, because medical devices contained in certain medical procedure kits may not remain together until end use, a single UDI on the kit package may not adequately identify the devices through distribution and use. In addition, the agency noted other anticipated benefits in requiring UDIs on the individual devices within such kits, such as more rapid identification of adverse events, more expeditious and efficient resolution of device recalls, and improved inventory management and detection of counterfeit devices.

- A common first aid kit, available at many retail stores, is an example of a "convenience kit" for the purposes of UDI compliance. The items contained in a typical first-aid kit may consist of a number of different medical devices (e.g., bandages, tape, gauze), which are intended to be used without first being modified; therefore, the individual devices contained in the kit would not be required to bear an UDI. A single UDI for the kit will be sufficient. Labelers may choose to place UDIs on the individual devices within the kit, but it is not required.

- In contrast, a non-sterile orthopedic procedure tray or set is not a convenience kit. It contains a number of items that, while packaged together, are intended to be removed and sterilized prior to use. Therefore, each item contained in the kit must include an individual UDI. Similarly, reusable medical devices packaged together do not qualify as convenience kits and, thus, are not exempted. The products, according to FDA, are not intended to remain packaged together, and each is intended to be sterilized before use by the end user. Therefore, each device must comply with the applicable UDI requirements.

- A company must assign a new Device Identifier if a change to a device results in a new version or model (i.e., the change requires documentation in the device master record).

AGG Observations

- The UDI convenience kit exemption is narrowed. FDA's draft guidance seems to now limit the definition of convenience kits to exclude any devices that may go through further processing once packaging is opened by the end user.

- FDA's new interpretation seems to draw distinctions between kits that will be modified prior to use. For example, in a Q&A section of the draft guidance, the agency states that all devices in the kit need not be consumed in a single use or used at the same time for it to qualify as a "convenience kit" for UDI purposes. Citing the first aid kit example, the agency explains that, while all items may not be used at one time, they are "intended to remain packaged together." However, the guidance later states that "the immediate container cannot be intended to be opened and the individual devices replaced, substituted, repackaged, sterilized, or otherwise processed or modified before being used by an end user." Again citing the first aid example, the agency states that, "although the purchaser may replace devices consumed over time, such as bandages, this replacement is not intended by the labeler to occur prior to use by an end user."

- Companies that previously considered their products to qualify as convenience kits should re-evaluate, based on the new draft guidance, whether their assessment might change.

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