



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4048]

Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff." This proposed guidance document is intended to outline the Agency's current thinking that for purposes of Unique Device Identification (UDI) labeling and data submission requirements, the term "convenience kit" applies solely to 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. This draft guidance is not final nor is it in effect at this time. When finalized, this guidance document will constitute a change in policy.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-4048 for "Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3303, Silver Spring, MD 20993-0002, 301-796-5995, email: gudidsupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 and section 614 of the Food and Drug Administration Safety and Innovation Act amended the Federal Food,

Drug, and Cosmetic Act (the FD&C Act) to add and amend section 519(f) (21 U.S.C. 360i(f)), which directs FDA to publish regulations establishing a unique device identification system for medical devices. The UDI system final rule was published on September 24, 2013 (78 FR 58786) (the UDI Rule).

The overarching objective of the UDI Rule, as required by section 519(f) of the FD&C Act, is to provide a system to adequately identify medical devices through distribution and use. We interpret this to mean that the form of a UDI should, in conformity with 21 CFR 801.40, be available to identify a device in both easily readable plain-text and in a form that can be entered into an electronic patient record or other computer system via an automated process when the device is used by an end user.

The term "convenience kit" is defined at 21 CFR 801.3 as "two or more different medical devices packaged together for the convenience of the user." Under 21 CFR 801.30(a)(11), individual devices packaged within a convenience kit are excepted from the UDI labeling requirements, provided the UDI is on the label of the immediate container of the convenience kit. The preamble to the UDI Rule expressed our thinking at the time that medical procedure kits, including orthopedic procedure kits, are convenience kits.

Since the publication of the UDI Rule, we have determined that interpreting the term "convenience kit" at § 801.3 to include implantable devices and instruments that are provided by the labeler in sets or trays as non-sterile and repeatedly reconfigured and sterilized (or cleaned and sterilized) prior to use would be inconsistent with the purpose of the exceptions at § 801.30 and the UDI Rule generally. In this draft guidance, FDA proposes to interpret the term "convenience kit" at § 801.3 as applying solely to 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.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the Agency's current thinking on Unique Device Identification for Convenience Kits. It does not establish any rights for any person is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of "Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500010 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 801, subpart B have been approved under OMB control number 0910-0720.

Dated: December 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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