

I. Background

Section 801.45 (21 CFR 801.45) requires a device to be directly marked with a UDI when the device is intended to be used more than once and intended to be reprocessed before each use. However, “intended to be used more than once” and “intended to be reprocessed” are not defined in the UDI regulations. This guidance provides FDA’s interpretation of these terms, clarifies when direct marking of devices with a UDI is required, provides recommendations for how labelers should comply with the UDI direct marking requirements, and clarifies the criteria for exceptions to the direct marking requirement.

In the **Federal Register** of June 26, 2015, FDA published the notice of availability of “Draft Guidance for Industry and Food and Drug Administration Staff: Unique Device Identification: Direct Marking of Devices” (80 FR 36821) (the “Draft Guidance”). In the notice of availability, FDA also solicited feedback on two questions related to interpretation of “intended to be reprocessed”: (1) Should the definition of “reprocessing” for purposes of UDI direct marking requirements include cleaning alone without subsequent disinfection and/or sterilization of the device? and (2) what public health benefits would be served by requiring a UDI direct marking to be affixed to devices intended to be reused for which reprocessing instructions include cleaning only and not disinfection and/or sterilization? Interested persons were invited to comment by September 24, 2015. FDA considered the comments received on the draft guidance, including comments responding to the specific questions in the notice of availability, and revised the guidance as appropriate in response to these comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Unique Device Identification: Direct Marking of Devices.” It does not establish any rights for any person and 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the 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 <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <https://www.regulations.gov>. Persons unable to download an electronic copy of “Unique Device Identification: Direct Marking of Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400031 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information described 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 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 830 pertaining to GUIDID labeler accounts and data submissions addressed in this draft guidance document have been approved under OMB control number 0910–0720.

Dated: November 14, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Member Conflicts: Mental Health Services Research.

Date: December 7, 2017.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, gavinevanskm@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 13, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–24899 Filed 11–16–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the NHLBI Institutional Training Mechanism Review Committee.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Institutional Training Mechanism Review Committee.