



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0293]

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling;
Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.” This guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices. This guidance document also provides recommendations for the content and review procedures for premarket notification (510(k)) submissions, premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, de novo requests, and investigational device exemption (IDE) applications, concerning the labeling instructions for reprocessing reusable medical devices. This guidance reflects the scientific advances in knowledge and technology involved in reprocessing reusable medical devices, especially more complex, reusable medical device designs that are more difficult to reprocess.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: 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 guidance document entitled “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Angela C. Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1666, Silver Spring, MD 20993-0002, 301-796-6380; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, there has been a significant advance in knowledge and technology involved in reprocessing reusable medical devices. Additionally, there has been an evolution

towards more complex medical device designs that are more difficult to clean, disinfect, and sterilize. This guidance reflects the scientific advances in these areas. Under section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to reprocess (i.e., clean, disinfect, and sterilize) a reusable device are critical to ensure that the device is appropriately prepared for its next use.

In the Federal Register of May 2, 2011 (76 FR 24494), FDA announced the availability of the draft guidance. Interested persons were invited to comment by August 1, 2011. FDA reviewed and considered all the public comments we received and revised several sections of the guidance, where applicable. On June 8 and 9, 2011, FDA held a public workshop entitled “Reprocessing of Reusable Medical Devices Workshop.” The purpose of the workshop was to discuss factors affecting the reprocessing of reusable medical devices and FDA’s plans to address the identified issues. The discussion during this workshop and the comments received were considered before revising the guidance. This final guidance supersedes “Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance” dated April 1996.

This final guidance contains the addition of “Appendix E: Devices for which a 510(k) Should Contain Data to Validate Reprocessing Instructions,” which includes a subset of medical devices that FDA has identified that pose a greater likelihood of microbial transmission and represent a high risk of infection if they are not adequately reprocessed. Because of this greater public health risk, 510(k) submissions for these devices should include protocols and complete test reports of the validation of the reprocessing instructions so that FDA has the information it needs to evaluate substantial equivalence.

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 Agency's current thinking on reprocessing validation methods and labeling for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH 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/Guidances/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1748 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 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485 (medical device labeling); the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120 (premarket notification);

the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078 (investigational device exemption); the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910-0231 (premarket approval); the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332 (humanitarian use devices); and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073 (quality system regulation).

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-06029 Filed: 3/16/2015 08:45 am; Publication Date: 3/17/2015]