4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0350]

Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.'" FDA has developed this guidance document to assist industry in preparing premarket applications (PMAs), humanitarian device exemptions (HDEs), investigational device applications (IDEs), premarket notifications (510(k)s), and de novo requests for medical devices that come into direct or indirect contact with the human body in order to determine the potential toxicity resulting from contact of the component materials of the device with the body.

The purpose of this guidance is to provide further clarification and updated information on the use of the Office of Device Evaluation (ODE) General Program Memorandum #G95-1 entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" dated May 1, 1995. When final, this guidance will therefore replace #G95-1.

This draft guidance is not final nor is it in effect at this time.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft 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:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this guidance document to assist industry in preparing PMAs, HDEs, IDEs, 510(k)s, and de novo requests for medical devices that come into direct or indirect contact with the human body in order to determine the potential toxicity resulting from contact of the component materials of the device with the body.

The purpose of this guidance is to provide further clarification and updated information on the use of ODE General Program Memorandum #G95-1 entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" dated May 1, 1995. When final, this guidance will therefore replace #G95-1. This guidance document also incorporates several new considerations, including assessment of known or potentially toxic chemicals (e.g., color additives), and sample preparation for submicron or nanotechnology components, in situ polymerizing, and bioabsorbable materials, which were not previously discussed in #G95-1. The scope of this document is limited to the biological evaluation of sterile and nonsterile medical devices that come into direct or indirect contact with the human body. This document addresses the following issues: (1) Test selection; (2) general testing considerations, including sample preparation; (3) specific considerations for the following testing: Cytotoxicity, sensitization, hemocompatibility, pyrogenicity, implantation, genotoxicity, carcinogenicity, reproductive and developmental toxicity, and biodegradation; (4) use of animal safety studies to justify omission of specific biocompatibility tests; (5) assessment of known or potentially toxic chemical entities; and (6) contents of a biocompatibility test report.

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 the use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." 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 draft guidance may do so by using 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.regulations.gov.

To receive "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1811 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 part 807, subpart E, have been approved under

OMB control number 0910-0120; the collections of information in 21 CFR part 814, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332; and the collections of information in 21 CFR part 812, have been approved under OMB control number 0910-0078.

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: April 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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