

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2012-D-0049]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleman, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [daniel.gittleman@fda.hhs.gov](mailto:daniel.gittleman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On August 1, 2012, the Agency submitted a proposed collection of information entitled "Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0732. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: April 15, 2013.

**Leslie Kux,***Assistant Commissioner for Policy.*

[FR Doc. 2013-09480 Filed 4-22-13; 8:45 am]

**BILLING CODE 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**Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"; Draft Guidance for Industry and Food and Drug Administration Staff; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.'"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 July 22, 2013.

**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:**

Jennifer Goode, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1212, Silver Spring, MD 20993-0002, 301-796-6374.

**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](mailto: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.*

[FR Doc. 2013-09479 Filed 4-22-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0788]

#### Pilot Program for Early Feasibility Study Investigational Device Exemption Applications; Extending the Duration of the Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the extension of the Early Feasibility Study Investigational Device Exemption (IDE) Applications pilot program to May 8, 2014, for sponsors who have already been accepted for the program.

**DATES:** This notice is effective April 23, 2013.

**FOR FURTHER INFORMATION CONTACT:** Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1676, Silver Spring, MD 20993-0002, 301-796-5640, [sheila.brown@fda.hhs.gov](mailto:sheila.brown@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 10, 2011 (76 FR 70150), FDA announced the availability of a draft guidance entitled "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies." This guidance document is intended to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Concurrent with the publication of the draft guidance, FDA

also announced an Early Feasibility Study IDE Pilot Program (76 FR 70152; November 10, 2011) intended to collect information and experience on the application of the draft guidance in order to inform the final guidance document.

In the pilot program notice, FDA stated its intention to accept nominations to participate in the pilot program until May 8, 2012, and stated that the pilot program would terminate on May 8, 2012. In the **Federal Register** notice announcing the pilot program, FDA also stated its intention to limit the pilot program to nine candidates.

FDA began accepting nominations for the pilot program on December 12, 2011. After reviewing the nominations received in response to the pilot program notice, FDA accepted nine appropriate candidates for the pilot program. In the **Federal Register** of March 6, 2012 (77 FR 13343), FDA terminated the acceptance of applications into the program and extended the pilot program for the nine accepted sponsors until May 8, 2013. The pilot program will be further extended for the nine accepted sponsors until May 8, 2014.

Dated: April 18, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-09528 Filed 4-22-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

**Name:** Advisory Committee on Infant Mortality (ACIM).

**Dates and Times:** April 24, 2013, 8:00 a.m.-5:00 p.m., April 25, 2013, 8:00 a.m.-3:00 p.m.

**Place:** Virtual via Webinar.

**Status:** The meeting is open to the public. For more information on registration and webinar details, please visit the ACIM Web site: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality>.

Adobe Connect: <https://hrsa.connectsolutions.com/infantmortality/>.

Teleconference Number: (888) 790-1958. Participant passcode: 461-8352.

**Purpose:** The Committee provides advice and recommendations to the Secretary of