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 Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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.

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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Use of International Standard ISO–10993, ''Biological Evaluation of Medical Devices Part 1: Evaluation and Testing''; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Use of International Standard ISO–10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.'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