4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1306]

International Medical Device Regulators Forum; Medical Device Single Audit Program International Coalition Pilot Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing participation in the Medical Device Single Audit Program International Coalition Pilot Program. The Medical Device Single Audit Program (MDSAP) was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the diverse international regulatory requirements of medical devices quality management systems and other specific regulatory requirements of the regulatory authorities participating in the pilot program. FDA will be participating in the MDSAP and will accept the resulting audit reports as a substitute for routine Agency inspections.

ADDRESSES: Submit electronic comments on the MDSAP International Coalition Pilot Program 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: Kimberly A. Trautman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5400, Silver Spring, MD 20993-0002, 301-796-5515, Kimberly.Trautman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The International Medical Device Regulators Forum (IMDRF) was conceived in 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world, which includes FDA, who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices. The purpose of the IMDRF is to accelerate international medical device regulatory harmonization and convergence. See http://www.imdrf.org/.

The IMDRF recognizes the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices. The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group (WG) to develop specific documents for advancing the concept of the MDSAP. See http://www.imdrf.org/.

This global approach opens possibilities and pathways to support the development of an international initiative of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in a pilot program starting in January 2014. The international partners for the MDSAP pilot, Therapeutic Goods Administration of Australia, Brazil's Agência Nacional de Vigilância Sanitária, Health Canada, FDA, and Japan's Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency, are official observers and active participants in the pilot program's Regulatory Authority Council and subject matter expert groups.

The mission of the participants in the MDSAP International Coalition is to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers. The development of the

MDSAP includes the use of third party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates. Recognizing the increasingly global nature and number of medical device manufacturers, the use of third party auditors in addition to regulatory authority inspectorates, allows greater coverage in auditing manufacturers as opposed to relying solely on the government resources of individual countries. The government resources can then be focused on high risk or problematic medical devices, manufacturers that are not in compliance with the regulations, and oversight of the third party auditing organizations. The MDSAP Pilot is intended to allow MDSAP-recognized auditing organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot.

The regulatory authorities involved in the pilot will base their recognition and assessment process on the following final IMDRF MDSAP documents:

- IMDRF MDSAP WG N3--"Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition;"
- IMDRF MDSAP WG N4--"Competence and Training Requirements for Auditing Organizations;"
- IMDRF MDSAP WG N5--"Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations;" and
- IMDRF MDSAP WG N6--"Regulatory Authority Assessor Competency and Training Requirements."

Each of these documents was proposed in draft by the IMDRF and comments were solicited. IMDRF is in the process of revising these documents based on comments received.

The IMDRF MDSAP Working Group has submitted the four proposed final documents for the IMDRF Management Committee meeting in Brussels on November 12 to14, 2013.

The proposed drafts for each document are not available during the revision process. When final, these documents will be available on the IMDRF Web site (see http://www.imdrf.org/).

In addition, the MDSAP International Coalition has also developed several documents in order to implement the pilot. As documents are finalized by the MDSAP International Coalition Regulatory Authority Council, the documents will be posted on FDA's Web site.

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements of medical devices. FDA will accept the MDSAP audit reports as a substitute for routine Agency inspections. Inspections conducted "For Cause" or "Compliance Followup" by FDA will not be affected by this program. Moreover, this MDSAP Pilot would not apply to any necessary preapproval or postapproval inspections for Premarket Approval (PMA) applications or to decisions under section 513(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

III. Electronic Access

Additional information on the IMDRF MDSAP can be found at: http://www.imdrf.org/ and at http://www.fda.gov/MedicalDevices/.

V. Comments

Interested persons may submit either electronic comments regarding the MDSAP International Coalition Pilot Program 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: November 8, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013-27358 Filed 11/14/2013 at 8:45 am; Publication Date: 11/15/2013]