4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0226]

Medical Device ISO 13485:2003 Voluntary Audit Report Pilot Program; Termination of Pilot Program; Announcement of the Medical Device Single Audit Program Operational Phase

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Medical Device ISO Voluntary Audit Report Pilot Program. This program allowed the submission of ISO audit reports performed by third parties, along with audit reports from the preceding 2 years, to determine if the owner or operator of the medical device establishment could be removed from FDA's routine inspection work plan for 1 year. FDA is also announcing its participation in the operational phase of the Medical Device Single Audit Program (MDSAP), which will allow third parties recognized by the MDSAP consortium to submit audit reports that FDA will utilize for routine inspections.

DATES: This notice is effective March 31, 2016.

FOR FURTHER INFORMATION CONTACT: Robert Ruff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3615, Silver Spring, MD 20993-0002, 301-796-6556.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 19, 2012 (77 FR 16036), FDA announced the availability of a final guidance entitled "Guidance for Industry, Third Parties and Food and Drug Administration Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program" (Ref. 1). This guidance document was effective on June 5, 2012, and as stated in the guidance was an interim measure while developing a single audit program, to implement section 228 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), which amended section 704(g)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(7)). The pilot allowed the owner or operator of the medical device establishment to be removed from FDA's routine inspection work plan for 1 year from the last day of the ISO 13485:2003 audit. The voluntary submitted ISO 13485:2003 audit report provides FDA some information on the conformance of the manufacturer with basic and fundamental quality management system requirements for medical devices.

In 2012, FDA started working on the MDSAP with other global regulators within the International Medical Device Regulators Forum (IMDRF) for purposes of leveraging work performed for other medical device regulators to meet its inspection obligations. On November 15, 2013 (78 FR 68853), FDA announced its participation within the MDSAP consortium's pilot program, which is effective January 1, 2014, through December 31, 2016.

After review of the MDSAP Mid-Pilot Report, which published in August 2015 (Ref. 2), FDA announced that it will participate with the other MDSAP Consortium regulators from Australia, Brazil, Canada, and Japan in the implementation of the operational phase of the program starting January 1, 2017. The MDSAP program provides FDA better assurances than the ISO 13485:2003 Voluntary Audit Report Submission Pilot because FDA's requirements

under 21 CFR 820 or other FDA regulations typically covered during FDA inspections are encompassed within the MDSAP audit model.

On January 1, 2017, MDSAP will become fully operational to include opening applications for additional auditing organizations beyond the limited eligible auditing organizations within the pilot phase. Each regulator within the consortium has committed to continuing to utilize the MDSAP audits during the pilot as well as during the operational phase as described in the MDSAP public announcements posted on FDA's Webpage (Ref. 3).

Also, Health Canada in a recent announcement laid out the timeframe for which they will terminate their Canadian Medical Device Conformity Assessment System (CMDCAS) program and utilize MDSAP as the means by which manufacturers will obtain a medical device license for distribution of medical devices in Canada (Ref. 4). As a result of the implementation of the MDSAP program, FDA will no longer accept ISO 13485:2003 Voluntary Audit Report Submissions after March 31, 2016, to assist transitioning manufacturers over to MDSAP.

II. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. FDA Guidance, Guidance for Industry, Third Parties and Food and Drug Administration Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Pilot Program, available at

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM212798.pdf.

2. Medical Device Single Audit Program (MDSAP) Mid-Pilot Status Report, January 2014-December 2016, available http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM461661.pdf.

3. Medical Device Single Audit Program (MDSAP) Pilot, available at http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/.

4. Health Canada's transition strategy from CMDCAS to MDSAP, available at http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/index-eng.php.

Dated: December 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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