DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1504]

Independent Assessment of the Process for the Review of Device Submissions; Implementation Evaluation Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing Booz Allen Hamilton's final evaluation report submitted as part of their independent assessment of the process for the review of medical device submissions. The evaluation is part of the FDA performance commitments relating to the Medical Device User Fee Amendments of 2012 (MDUFA III), which reauthorized device user fees for fiscal years 2013 through 2017. The assessment is described in section V, Independent Assessment of Review Process Management, of the commitment letter entitled ''MDUFA Performance Goals and Procedures'' (MDUFA III Commitment Letter). The evaluation has been conducted as the second phase (Phase 2) and is the last of a series of deliverables, as outlined in the contract statement of work.

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SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA).[1] Title II of FDASIA is the Medical Device User Fee Amendments of 2012 (MDUFA III), which gives FDA the authority to collect device user fees from industry for fiscal years 2013 through 2017. MDUFA III took effect on October 1, 2012, and will continue through September 30, 2017.

Device user fees were first established by Congress in 2002. Medical device companies pay fees to FDA when they register their establishment and list their devices with the Agency, whenever they submit an application or a notification to market a new medical device in the United States, and for certain other types of submissions. Under MDUFA III, FDA is authorized to collect user fees that will total approximately $595 million (plus adjustments for inflation) over 5 years. With this additional funding, FDA will be able to hire more than 200 full-time-equivalent workers over the course of MDUFA III. In exchange, FDA has committed to meet certain performance goals outlined in the MDUFA III Commitment Letter.[2]

II. Assessment of FDA's Process for the Review of Device Submissions

Section V of the MDUFA III Commitment Letter states that FDA and the device industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry. The assessment will be conducted in two phases by a private, independent consulting firm, under contract with FDA, that is capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment as described in the MDUFA III Commitment Letter.

FDA awarded the contract in June 2013 to the consulting firm Booz Allen Hamilton. Findings on high-priority recommendations (*i.e.*, those likely to have a significant impact on review times) were published in December 2013.[3] Final comprehensive findings and recommendations were scheduled to be published within 1 year of the contract award and are included in the report available at *www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM426392.pdf*. FDA agreed to publish an implementation plan within 1 year of the final findings and recommendations. The final implementation plan, ''Plan of Action,'' was published December 2014 and is available at *www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM426392.pdf*. Examination of the final comprehensive findings and recommendations report led FDA to conclude that the recommendations could be expanded to further enhance the efficiency of premarket reviews. Those actions were also outlined in the Plan of Action. To distinguish actions in direct response to the recommendations from additional actions to further improve the premarket review process, FDA used a ''Stage'' approach. In the Plan of Action ''Stage 1'' actions directly addressed the recommendations in the independent assessment and ''Stage 2'' actions outlined additional long-term actions the Agency intended to implement to further enhance the premarket review process. In addition, FDA has publicly stated in the ''Plan of Action'' that the Agency intended to complete all Stage 1 actions by December 31, 2015.

For Phase 2 of the independent assessment, the contractor evaluated the implementation of recommendations, described under Stage 1 in the ''Plan of Action,'' and is publishing its written assessment [4] no later than February 1, 2016.

FDA has implemented all Stage 1 actions outlined in the Plan of Action, and incorporated the resulting enhancements into the management of the premarket review program. Resources permitting, the Center for Devices and Radiological Health will continue to implement Stage 2 actions. FDA will monitor implemented improvements for accomplishment of intended results and the process for the review of device submissions for additional improvement opportunities.

Dated: February 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0270]

Display Devices for Diagnostic Radiology; 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 or Agency) is announcing the availability of the draft guidance entitled ''Display Devices for Diagnostic Radiology''. This draft guidance document provides recommendations for the types of information you should provide in your premarket notification submission (510(k)) for display devices intended for diagnostic radiology with the assigned product code PGY. This guidance, when finalized, will replace a previously issued final guidance entitled ''Display Accessories for Full-Field Digital

[1] *https://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.*

[2] *www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*

[3] *www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM378202.pdf.*

[4] *http://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM484146.pdf.*