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.

FOR FURTHER INFORMATION CONTACT: Raphaela Simon, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3379, Silver Spring, MD 20993–0002, 301–796–9169, *Raphaela.Simon@fda.hhs.gov*.

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.

[FR Doc. 2016–02545 Filed 2–8–16; 8:45 am]

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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.*

Mammography Systems-Premarket Notification (510(k)) Submissions,'' issued on May 30, 2008. 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 of 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 May 9, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–0270 for ''Display Devices for Diagnostic Radiology; Draft Guidance for Industry and Food and Drug Administration Staff; Availability''. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Display Devices for Diagnostic Radiology'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Mary Pastel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4312, Silver Spring, MD 20993–0002, 301–796–6887.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance, when finalized, will apply to display devices intended for diagnostic radiology as identified in section III ''Scope'' of the guidance, and currently classified under 21 CFR 892.2050 as class II devices according to section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360c(a)(1)) with the assigned product code PGY. This draft guidance is intended to assist industry in preparing a 510(k) for display devices intended for use in diagnostic radiology. This draft guidance provides recommendations for the types of information to provide in 510(k) submissions for display devices intended for diagnostic radiology. This information supplements the requirements for a 510(k) submission found in 21 CFR part 807, subpart E, as well as recommendations provided in other FDA guidance documents concerning the specific content of a 510(k) submission.

This guidance, when finalized, will apply to workstation medical image displays for diagnostic radiology. These devices are classified as class II devices that are intended to be used in controlled viewing conditions to display and view digital images for primary image interpretation. Display devices for diagnostic radiology may also be referred to as soft-copy displays or medical grade monitors.

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 current thinking of FDA on display devices for diagnostic radiology. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from

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.* Persons unable to download an electronic copy of ''Display Devices for Diagnostic Radiology'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500022 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The 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 have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: February 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02521 Filed 2–8–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–4040–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before March 10, 2016.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.Collection Clearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–4040–New–30D for reference.

Information Collection Request Title: DATA Act Sec. 5. ''Simplifying Federal Award Reporting'' Grants Pilot

Abstract: Public Law 113–101, The Digital Accountability and Transparency Act of 2014 (DATA Act) expands the Federal Funding Accountability and Transparency Act of 2006 by increasing accountability and transparency in Federal spending. Section 5 of the DATA Act (''Sec. 5. Simplifying Federal Award Reporting'') tasks the Director of the Office of Management and Budget (OMB) to establish a pilot program (Sec. 5 (b)).

OMB has designated the Department of Health and Human Services (HHS) as the executing agent of the pilot program. Within HHS, the DATA Act Program Management Office (PMO) (DAP) has been established under the Office of the Assistant Secretary for Financial Resources (ASFR) in order to implement this pilot program. ASFR/DAP, in coordination with Grants.gov, is requesting a generic clearance for the purpose of conducting tests under the pilot program to obtain qualitative and quantitative data and gain an understanding of the burden imposed on Federal recipients.

The DAP has designed several test models to evaluate recipient burden and assess quality of data. The goal of these test models is to determine whether new technology, data standards, processes, and forms aid in reducing recipient burden and increase the accuracy and quality of the data submitted. Under this clearance, a variety of methods (surveys, focus groups, etc.) could be used to collect data, with the exact nature of the questions currently undetermined. DAP expects these questions to include, but not be limited to, topics pertaining to the Standard Form (SF) 424, the Consolidated Federal Financial Reports, and the expanded Single Audit form (SF–SAC). If this data is not collected, the requirements of the DATA Act Section 5 pilot will not be met. The types of collections that this generic clearance covers include, but are not limited to:

- Surveys,
- Focus Groups,
- Other qualitative methods such as interviews, small discussion groups, and case studies.

Likely Respondents: Recipients of Federal contracts, grants, and sub-awards.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Estimated annual reporting burden				
Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Surveys, Focus Groups, and other qualitative methods	300	1	56.25	16,875
Total	300			16,875

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2016–02472 Filed 2–8–16; 8:45 am]

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