Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014, and the final HHS Notice of Benefit and Payment Parameters for 2015 provide further reporting requirements.

Form Number: CMS–10433 (OMB control number: 0938–1187); *Frequency:* Once; *Affected Public:* Individuals and Households, Private sector—Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments; *Number of Respondents:* 2400; *Total Annual Responses:* 9,600; *Total Annual Hours:* 600. (For policy questions regarding this collection contact Jaya Ghildiyal 301–492–5149).

We are requesting OMB review and approval of this collection by August 27, 2014, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the date and address noted below.

Dated: July 25, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–17971 Filed 7–29–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; FDA Safety Communication Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''FDA Safety Communication Readership Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 21, 2014, the Agency submitted a proposed collection of information entitled ''FDA Safety Communication Readership Survey'' 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 0910–0341. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17891 Filed 7–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0501]

Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A; Guidance for Industry and Food and Drug Administration Staff

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A.'' This document provides CDRH's interpretation of key provisions of section 517A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which were added by the FDA Safety and Innovation Act (FDASIA), as these provisions pertain to requests for documentation of rationales for significant decisions and requests for supervisory review of regulatory decisions and actions taken by CDRH.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: 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 copy of the guidance document entitled ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A'' to the Office of the Center Director, Guidance and Policy Development, CDRH, 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.

Submit electronic comments on the 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: Ruth Fischer, CDRH, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5400, Silver Spring, MD 20993–0002, 301–796–5735.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, section 517A of the FD&C Act (21 U.S.C. 360g–l) was added by section 603 of FDASIA (Pub. L. 112–114). CDRH developed this guidance as a companion document to the final guidance entitled ''Center for Devices and Radiological Health Appeals Processes,'' which was issued on May 17, 2013. The guidance ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A'' provides CDRH's interpretation of key provisions of section 517A of the FD&C Act as these provisions pertain to requests for documentation of rationales for significant decisions and requests for supervisory review of regulatory decisions and actions taken by CDRH. In particular, this document provides interpretations surrounding the statutory terms ''significant decision'' and ''substantive summary.'' It also addresses who may request documentation of significant decisions under section 517A of the FD&C Act, and how this provision relates to requests under the Freedom of Information Act.

In the **Federal Register** of May 17, 2013 (78 FR 29140), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by August 15, 2013. FDA considered the public comments received and revised the guidance, as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The guidance represents the Agency's current thinking on Center for Devices and Radiological Health's Appeals Processes: Questions and Answers About 517A. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH 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 ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1821 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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, subpart E have been approved under OMB control number 0910–0120; the collections of information found in 21 CFR part 814 have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332. The collections of information in the guidance document ''Center for Devices and Radiological Health Appeals Processes'' have been approved under OMB control number 0910–0738.

V. Comments

Interested persons may submit either electronic comments regarding this document 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: July 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17901 Filed 7–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Medical Device User Fee Rates for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2012 (MDUFA III), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2015, which apply from October 1, 2014, through September 30, 2015. To avoid delay in the review of your application, you should pay the standard fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before making your submission to FDA; if you do not qualify as a small business before making your submission to FDA, you will have to pay the higher standard fee. Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2015, you should not submit a FY 2015 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2015 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT: *For information on Medical Device User Fees:* Visit FDA's Web site at *http://www.fda.gov/mdufa*.

For questions relating to this notice: David Miller, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202E), Silver Spring, MD 20993–0002, 301–796–7103.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, and notices (for simplicity, this document refers to these collectively as ''submissions'' or ''applications''); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee. (See 21 U.S.C. 379j(d) and (e).) Additionally, the Secretary of Health and Human Services (the Secretary) may, at the Secretary's sole discretion, grant a fee waiver or reduction if the Secretary finds that such waiver or reduction is in the interest of public health. (See 21 U.S.C. 379j(f).)

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2013 through FY 2017; the base fee for a premarket application received by FDA during FY 2015 is $258,019. From this starting point, this document establishes FY 2015 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2013 through FY 2017; the base fee for an establishment registration in FY 2015 is $3,750. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.