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).