Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–17898 Filed 7–29–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10433]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed. We are seeking emergency approval for modifications to the information collection request (ICR) currently approved under Office of Management and Budget (OMB) control number 0938–1187 to include account registration elements associated with submitting data through the Amazon Cloud EDGE Server or the On-Premise EDGE server. As a result of contractor changes and technical design changes to our distributed data collection (DDC) approach for implementing the risk adjustment and reinsurance programs, we must change the data elements that issuers will submit as part of the DDC information collection requirements. These modifications will permit us to register EDGE servers with the appropriate issuer accounts, permitting CMS to make risk adjustment and reinsurance payments to issuers.

DATES: Comments must be received by August 27, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10433/OMB Control Number 0938–1187, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10433 Initial Plan Data Collection To Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; *Use:* As required by the CMS–9989–F, Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange Establishment Rule), each Exchange must assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). In addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153, as established by CMS–9975–F, Patient Protection and Affordable Care Act; Standards for Reinsurance, Risk Corridors, and Risk Adjustment (77 FR 17220), have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs including the final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium

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).