publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the information collection requirements contained in consumer assessment surveys that are used by ACL to measure program performance for programs funded under Title III of the Older Americans Act.

DATES: Submit written or electronic comments on the collection of information by February 10, 2014.

ADDRESSES: Submit electronic comments on the collection of information to: *elena.fazio@acl.hhs.gov.*

Submit written comments on the collection of information to Elena Fazio, Administration for Community Living, Office of Performance and Evaluation, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Elena Fazio, 202–357–3583.

SUPPLEMENTARY INFORMATION: 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. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The National Survey of Older Americans Act (OAA) Participants information collection, which builds on earlier national pilot studies and surveys, as well as performance measurement tools developed by ACL grantees in the Performance Outcomes Measures Project (POMP), will include consumer assessment surveys for the Congregate and Home-delivered meal nutrition programs; Case Management, Homemaker, and Transportation Services; and the National Family Caregiver Support Program. This information will be used by ACL to track performance outcome measures; support budget requests; comply with GPRA Modernization Act of 2010 (GPRAMA) reporting requirements; provide national benchmark information; and inform program development and management initiatives. Descriptions of previous National Surveys of OAA Participants can be found under the section on OAA Performance Information on ACL's Web site at: *http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx.* Copies of the survey instruments and data from previous National Surveys of OAA Participants can be found and queried using the AGing Integrated Database (AGID) at *http://www.agid.acl.gov/.* The proposed Ninth National Survey entitled National Survey of OAA Participants draft 2013 may be found on the ACL Web site at *http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx.* ACL estimates the burden of this collection of information as follows: *Respondents:* Individuals; *Number of Respondents:* 6,250; *Number of Responses per Respondent:* one; *Average Burden per Response:* 6000 at 40 minutes, 250 at 4 hours; *Total Burden:* 5,000.

Dated: December 5, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013–29436 Filed 12–9–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0853]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices Current Good Manufacturing Practice Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by January 9, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices Current Good Manufacturing Practice Quality System Regulation—21 CFR Part 820 (OMB Control Number 0910–0073)—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety

and effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice (CGMP), as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the FD&C Act.

The CGMP/quality system (QS) regulation implementing authority provided by this statutory provision is found under part 820 (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The authority for this regulation is covered under sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, and 803 of the FD&C Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383). The CGMP/QS regulation includes requirements for purchasing and service controls, clarifies recordkeeping requirements for device failure and complaint investigations, clarifies requirements for verifying/validating production processes and process or product changes, and clarifies requirements for product acceptance activities quality data evaluations and corrections of nonconforming product/quality problems.

Requirements are compatible with specifications in the international standards ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.'' The CGMP/QS information collections will assist FDA inspections of manufacturers for compliance with QS requirements encompassing design, production, installation, and servicing processes.

Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review the following topics: (1) The quality policy, (2) the organizational structure, (3) the quality plan, and (4) the quality system procedures of the organization.

Section 820.22 requires the conduct and documentation of QS audits and re-audits. Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j) requires, in respective order, the establishment, maintenance, and/or documentation of the following topics: (1) Procedures to control design of class III and class II devices and certain class I devices as listed therein; (2) plans for design and development activities and updates; (3) procedures identifying, documenting, and approving design input requirements; (4) procedures defining design output, including acceptance criteria, and documentation of approved records; (5) procedures for formal review of design results and documentation of results in the design history file (DHF); (6) procedures for verifying device design and documentation of results and approvals in the DHF; (7) procedures for validating device design, including documentation of results in the DHF; (8) procedures for translating device design into production specifications; (9) procedures for documenting, verifying, and validating approved design changes before implementation of changes; and (10) the records and references constituting the DHF for each type of device.

Section 820.40 requires manufacturers to establish and maintain procedures controlling approval and distribution of required documents and document changes.

Section 820.40(a) and (b) requires the establishment and maintenance of procedures for the review, approval, issuance, and documentation of required records (documents) and changes to those records.

Section 820.50(a) and (b) requires the establishment and maintenance of procedures and requirements to ensure service and product quality, records of acceptable suppliers, and purchasing data describing specified requirements for products and services.

Sections 820.60 and 820.65 require, respectively, the establishment and maintenance of procedures for identifying all products from receipt to distribution and for using control numbers to track surgical implants and life-sustaining or supporting devices and their components.

Section 820.70(a) through (e), (g)(1) through (g)(3), (h), and (i) requires the establishment, maintenance, and/or documentation of the following topics: (1) Process control procedures; (2) procedures for verifying or validating changes to specification, method, process, or procedure; (3) procedures to control environmental conditions and inspection result records; (4) requirements for personnel hygiene; (5) procedures for preventing contamination of equipment and products; (6) equipment adjustment, cleaning, and maintenance schedules; (7) equipment inspection records; (8) equipment tolerance postings, procedures for utilizing manufacturing materials expected to have an adverse effect on product quality; and (9) validation protocols and validation records for computer software and software changes.

Sections 820.72(a), (b)(1), and (b)(2) and 820.75(a) through (c) require, respectively, the establishment, maintenance, and/or documentation of the following topics: (1) Equipment calibration and inspection procedures; (2) national, international, or in-house calibration standards; (3) records that identify calibrated equipment and next calibration dates; (4) validation procedures and validation results for processes not verifiable by inspections and tests; (5) procedures for keeping validated processes within specified limits; (6) records for monitoring and controlling validated processes; and (7) records of the results of revalidation where necessitated by process changes or deviations.

Sections 820.80(a) through (e) and 820.86, respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Procedures for incoming acceptance by inspection, test, or other verification; (2) procedures for ensuring that in process products meet specified requirements and the control of product until inspection and tests are completed; (3) procedures for, and records that show, incoming acceptance or rejection is conducted by inspections, tests or other verifications; (4) procedures for, and records that show, finished devices meet acceptance criteria and are not distributed until device master record (DMR) activities are completed; (5) records in the device history record (DHR) showing acceptance dates, results, and equipment used; and (6) the acceptance/rejection identification of products from receipt to installation and servicing.

Sections 820.90(a), (b)(1), and (b)(2) and 820.100 require, respectively, the establishment, maintenance and/or documentation of the following topics: (1) Procedures for identifying, recording, evaluating, and disposing of nonconforming product; (2) procedures for reviewing and recording concessions made for, and disposition of, nonconforming product; (3) procedures for reworking products, evaluating possible adverse rework effect and recording results in the DHR; (4) procedures and requirements for corrective and preventive actions, including analysis, investigation, identification and review of data, records, causes, and results; and (5) records for all corrective and preventive action activities.

Section 820.100(a)(1) through (a)(7) states that procedures and requirements shall be established and maintained for corrective/preventive actions, including the following: (1) Analysis of data from process, work, quality, servicing

records, investigation of nonconformance causes; (2) identification of corrections and their effectiveness; (3) recording of changes made; and (4) appropriate distribution and managerial review of corrective and preventive action information. Section 820.120 states that manufacturers shall establish/maintain procedures to control labeling storage/application; and examination/release for storage and use, and document those procedures.

Sections 820.120(b) and (d), 820.130, 820.140, 820.150(a) and (b), 820.160(a) and (b), and 820.170(a) and (b), respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Procedures for controlling and recording the storage, examination, release, and use of labeling; (2) the filing of labels/labeling used in the DHR; (3) procedures for controlling product storage areas and receipt/dispatch authorizations; (4) procedures controlling the release of products for distribution; (5) distribution records that identify consignee, product, date, and control numbers; and (6) instructions, inspection and test procedures that are made available, and the recording of results for devices requiring installation.

Sections 820.180(b) and (c), 820.181(a) through (e), 820.184(a) through (f), and 820.186 require, respectively, the maintenance of records that are: (1) Retained at prescribed site(s), made readily available and accessible to FDA and retained for the device's life expectancy or for 2 years; (2) contained or referenced in a DMR consisting of device, process, quality assurance, packaging and labeling, and installation, maintenance, and servicing specifications and procedures; (3) contained in a DHR and demonstrate the manufacture of each unit, lot, or batch of product in conformance with DMR and regulatory requirements, include manufacturing and distribution dates, quantities, acceptance documents, labels and labeling, control numbers; and (4) contained in a quality system record, consisting of references, documents, procedures, and activities not specific to particular devices.

Sections 820.198(a) through (c) and 820.200(a) through (d), respectively, require the establishment, maintenance, and/or documentation of the following topics: (1) Complaint files and procedures for receiving, reviewing, and evaluating complaints; (2) complaint investigation records identifying the device, complainant, and relationship of the device to the incident; (3) complaint records that are reasonably accessible to the manufacturing site or at prescribed sites; (4) procedures for performing and verifying that device servicing requirements are met and that service reports involving complaints are processed as complaints; and (5) service reports that record the device, service activity, and test and inspection data.

Section 820.250 requires the establishment and maintenance of procedures to identify valid statistical techniques necessary to verify process and product acceptability; and sampling plans, when used, which are written and based on valid statistical rationale; and procedures for ensuring adequate sampling methods.

The CGMP/QS regulation added design and purchasing controls, modified previous critical device requirements, revised previous validation and other requirements, and harmonized device CGMP requirements with QS specifications in the international standard ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.'' The rule does not apply to manufacturers of components or parts of finished devices, or to manufacturers of human blood and blood components subject to 21 CFR part 606. With respect to devices classified in class I, design control requirements apply only to class I devices listed in § 820.30(a)(2) of the regulation. The rule imposes burden upon: (1) Finished device manufacturer firms, which are subject to all recordkeeping requirements; (2) finished device contract manufacturers, specification developers; and (3) re-packer, re-labelers, and contract sterilizer firms, which are subject only to requirements applicable to their activities. In addition, remanufacturers of hospital single-use devices (SUDs) are now to be considered to have the same requirements as manufacturers in regard to the regulation. The establishment, maintenance, and/or documentation of procedures, records, and data required by the regulation assists FDA in determining whether firms are in compliance with CGMP requirements, which are intended to ensure that devices meet their design, production, labeling, installation, and servicing specifications and, thus are safe, effective, and suitable for their intended purpose. In particular, compliance with CGMP design control requirements should decrease the number of design-related device failures that have resulted in deaths and serious injuries.

The CGMP/QS regulation applies to approximately 25,986 respondents. A query of the Agency's registration and listing database shows that approximately 15,113 domestic and 10,873 foreign establishments are respondents to this information collection.[1] These recordkeepers consist of manufacturers, subject to all requirements and contract manufacturers, specification developers, re-packers, re-labelers, and contract sterilizers, subject only to requirements applicable to their activities. Hospital remanufacturers of SUDs are now defined to be manufacturers under guidance issued by FDA's Center for Devices and Radiological Health, Office of Surveillance and Biometrics. Respondents to this collection have no reporting activities, but must make required records available for review or copying during FDA inspection. Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to Quality Policy (§ 820.20(a)), Document Control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to subpart C, Design Controls. The PRA burden placed on the 25,986 establishments is an average burden.

In the **Federal Register** of July 31, 2013 (78 FR 46347), FDA published a 60-day notice requesting public comment on the proposed collection of information to which one comment was received.

The comment agreed that the information has practical utility but requested clarification regarding whether records gathered in electronic format will be made available outside of FDA.

Disclosure of QS records is governed by the Freedom of Information Act (5 U.S.C. 552) and FDA's Public Information regulation at part 20 (21 CFR part 20). Section 820.180(a) of the CGMP/QS regulation provides that records deemed confidential by manufacturers may be marked to aid FDA in determining what information may be disclosed under part 20. This applies to both paper and electronic QS records.

Another part of the comment expressed a belief that ''the burden on industry of complying with FDA requests for information during an inspection is based on data FDA maintains on actual inspections; the estimates are averages'' and that ''it is unclear how FDA arrived at these estimates since they seem high when spread out across all registered device manufacturers.''

The comment assumes that the burden estimate includes only the burden of responding to information requests during an inspection. However,

[1] Based on fiscal year 2012 data.

the estimates also include the burden of collecting, maintaining, and retaining the records. The comment's suggestion of 3.5 hours per year for ''responding to information requests during an inspection'' does not appear to include the burden of collecting, maintaining, and retaining the records and is based on the experience of only one segment of industry. Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to Quality Policy (§ 820.20(a)), Document Control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to subpart C, Design Controls. The estimated burden is, therefore, an average burden.

As a basis for its burden estimates, the Agency relied in part on certain information found in a study originally developed under FDA contract by Eastern Research Group, Inc., when the CGMP/QS regulation became final. The study was submitted to OMB as part of the original PRA approval and is part of the Federal docket. The Agency performs ongoing reviews of the information collection burden as required under the PRA for purposes of evaluating burden associated with its information collection requests and has done so for the purpose of extending the recordkeeping requirements associated with the CGMP/QS regulations. The commenter believes that the estimates the Agency provides are too high. However, the commenter does not offer an alternative methodology for estimating that the Agency may review. For these reasons we have not changed the hourly burden estimate.

The comment also suggests that FDA did not make clear what was meant by the ''quality, utility, and clarity of the collected information'' in the 60-day notice requesting public comment on the information collection. ''Quality, utility, and clarity'' have the same meaning as in OMB's regulations at 5 CFR 1320.8(d)(1)(iii).

Another part of the comment addressed concerns about the use of electronic means to fulfill the information collection requirements. The comment seems to assume that it would take additional time to provide electronic records at the request of an inspector because records that are not kept in electronic format would need to be scanned in order to fulfill the inspector's request. The comment also requests that FDA ''publish procedures for the use of any electronic submissions which may be contemplated'' to help the commenter allay concerns about misuse of photographs and electronic submissions.

At this time, fulfillment of the information collection via electronic means is optional. We estimate that approximately 75 percent of respondents currently use some form of electronic recordkeeping to fulfill the information collection. Firms may use appropriate technology in accordance with FDA's ''Electronic Records; Electronic Signatures'' final rule (62 FR 13430; March 20, 1997) to comply with the CGMP/QS recordkeeping requirements. However, respondents may make the records available in paper format. There is no additional requirement that respondents convert existing paper records to an electronic format.

The comment also requests an explanation regarding the citation of the standard ''ISO 9001'' in the 60-day notice for public comment, rather than ''ISO 13485.''

In the notice, we included background information regarding the Quality System Regulation (part 820). We referenced ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing'' because at the time the Quality System Regulation was issued and the preamble was written, ISO 9001 was the current standard.

Additionally, the comment requests clarification regarding the Agency's contemplation of new submissions of information and includes suggestions related to such new submissions.

At this time, there is no new requirement for submission of information under the QS regulations. Any future new requirements for information collection will be made available for public comment as required by 5 CFR part 1320.

The Center for Devices and Radiological Health is proactive in ensuring that the medical device industry and other affected individuals are made aware of ongoing issues relating to the CGMP/QS regulations. FDA's Medical Device GMP/QS experts have participated in numerous conferences and seminars relating to the CGMP/QS regulatory requirements. During these sessions, our GMP/QS experts share information through speeches and panel discussions that provide a forum for open discussion. During these discussions guidance and direction is often given to the audience to help them understand their regulatory responsibilities under the GMP/QS regulation. In addition, issues are sometimes identified by the audience that provides the Agency areas that we may need to clarify to affected individuals.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Quality policy—820.20(a)	25,986	1	25,986	7	181,902
Organization—820.20(b)	25,986	1	25,986	4	103,944
Management review—820.20(c)	25,986	1	25,986	6	155,916
Quality planning—820.20(d)	25,986	1	25,986	10	259,860
Quality system procedures—820.20(e)	25,986	1	25,986	10	259,860
Quality audit—820.22	25,986	1	25,986	33	857,538
Training—820.25(b)	25,986	1	25,986	13	337,818
Design procedures—820.30(a)(1)	25,986	1	25,986	2	51,972
Design and development planning—820.30(b)	25,986	1	25,986	6	155,916
Design input—820.30(c)	25,986	1	25,986	2	51,972
Design output—820.30(d)	25,986	1	25,986	2	51,972
Design review—820.30(e)	25,986	1	25,986	23	597,678
Design verification—820.30(f)	25,986	1	25,986	37	961,482
Design validation—820.30(g)	25,986	1	25,986	37	961,482
Design transfer—820.30(h)	25,986	1	25,986	3	77,958
Design changes—820.30(i)	25,986	1	25,986	17	441,762

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity/21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Design history file—820.30(j)	25,986	1	25,986	3	77,958
Document controls—820.40	25,986	1	25,986	9	233,874
Documentation approval and distribution and document changes—820.40(a) and (b)	25,986	1	25,986	2	51,972
Purchasing controls—820.50(a)	25,986	1	25,986	22	571,692
Purchasing data—820.50(b)	25,986	1	25,986	6	155,916
Identification—820.60	25,986	1	25,986	1	25,986
Traceability—820.65	25,986	1	25,986	1	25,986
Production and process controls—820.70(a)	25,986	1	25,986	2	51,972
Production and process changes and environmental control—820.70(b) and (c)	25,986	1	25,986	2	51,972
Personnel—820.70(d)	25,986	1	25,986	3	77,958
Contamination control—820.70(e)	25,986	1	25,986	2	51,972
Equipment maintenance schedule, inspection, and adjustment—820.70(g)(1) to (g)(3)	25,986	1	25,986	1	25,986
Manufacturing material—820.70(h)	25,986	1	25,986	2	51,972
Automated processes—820.70(i)	25,986	1	25,986	8	207,888
Control of inspection, measuring, and test equipment—820.72(a)	25,986	1	25,986	5	129,930
Calibration procedures, standards, and records—820.72(b)(1) to (b)(2)	25,986	1	25,986	1	25,986
Process validation—820.75(a)	25,986	1	25,986	3	77,958
Validated process parameters, monitoring, control methods, and data—820.75(b)	25,986	1	25,986	1	25,986
Revalidation—820.75(c)	25,986	1	25,986	1	25,986
Acceptance activities—820.80(a) to (e)	25,986	1	25,986	5	129,930
Acceptance status—820.86	25,986	1	25,986	1	25,986
Control of nonconforming product—820.90(a)	25,986	1	25,986	5	129,930
Nonconforming product review/disposition procedures and rework procedures—820.90(b)(1) to (b)(2)	25,986	1	25,986	5	129,930
Procedures for corrective/preventive actions—820.100(a)(1) to (a)(7)	25,986	1	25,986	12	311,832
Corrective/preventive activities—820.100(b)	25,986	1	25,986	1	25,986
Labeling procedures—820.120(b)	25,986	1	25,986	1	25,986
Labeling documentation—820.120(d)	25,986	1	25,986	1	25,986
Device packaging—820.130	25,986	1	25,986	1	25,986
Handling—820.140	25,986	1	25,986	6	155,916
Storage—820.150(a) and (b)	25,986	1	25,986	6	155,916
Distribution procedures and records—820.160(a) and (b)	25,986	1	25,986	1	25,986
Installation—820.170	25,986	1	25,986	2	51,972
Record retention period—820.180(b) and (c)	25,986	1	25,986	2	51,972
Device master record—820.181	25,986	1	25,986	1	25,986
Device history record—820.184	25,986	1	25,986	1	25,986
Quality system record—820.186	25,986	1	25,986	1	25,986
Complaint files—820.198(a), (c), and (g)	25,986	1	25,986	5	129,930
Servicing procedures and reports—820.200(a) and (d)	25,986	1	25,986	3	77,958
Statistical techniques procedures and sampling plans—820.250	25,986	1	25,986	1	25,986
Total					9,043,128

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–29394 Filed 12–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1478]

Agency Information Collection Activities; Proposed Collection; Comment Request; Providing Waiver-Related Materials in Accordance With Draft Guidance for Industry on Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the submission of periodic safety reports as described in the guidance entitled ''Periodic Benefit-Risk Evaluation Report (PBRER) (E2C(R2)).'' The guidance was prepared under the auspices of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, and describes the format, content, and timing of a PBRER for an approved drug or biologic. This notice also solicits comments on the information collection associated with the submission of waiver-related materials as described in the draft guidance entitled ''Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format.'' The draft guidance is intended to inform applicants of the conditions under which FDA will exercise its waiver authority to permit applicants to submit an ICH E2C(R2) PBRER in place of the ICH E2C(R1) Periodic Safety Update Report (PSUR), U.S. periodic adverse drug experience report (PADER), or U.S. periodic adverse experience report (PAER), to satisfy the periodic safety reporting requirements in FDA regulations.

DATES: Submit either electronic or written comments on the collection of information by February 10, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration,1350 Piccard Dr.,PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reporting in Accordance With International Conference on Harmonisation—Periodic Benefit-Risk Evaluation Report (E2C(R2)) Guidance

I. Background

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. In January 2012, the ICH Steering Committee agreed that the ''E2C(R2) Periodic Benefit-Risk Evaluation Report'' draft guidance (the draft PBRER guidance) should be made available for public comment. The PBRER is intended to provide a common standard for periodic reporting on approved drugs or biologics among the ICH regions. The harmonized PBRER is intended to promote a consistent approach to periodic postmarket safety reporting among the ICH regions and to enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

The draft PBRER guidance revises an earlier version of this guidance issued in 1997 with an addendum issued in 2004. In the **Federal Register** of April 11, 2012 (77 FR 21782), FDA announced the availability of the draft PBRER guidance for public comment. FDA presented the comments received as part of the considerations by the E2C(R2) Expert Working Group for revisions of the guidance. A final version of the guidance was subsequently endorsed by the ICH on November 15, 2012, and published as the ICH harmonized tripartite guideline ''Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)'' (the PBRER guidance), available at *http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.* FDA anticipates issuing final guidance on this topic that is consistent with the final ICH document, published November 2012, and thus is seeking PRA approval for information collections consistent with that document.

The April 11, 2012, **Federal Register** notice stated that the draft PBRER guidance includes information collection provisions that are subject to review by OMB under the PRA, and that before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in the guidance that are