the specific symbols used in labels or labeling for the IVDs manufactured.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Glossary	689	1	689	4	2,756

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

Dated: November 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29104 Filed 12–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2544]

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

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.

DATES: Fax written comments on the collection of information by January 4, 2017.

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, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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 Device: Current Good Manufacturing Practice Quality System Regulations— 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, and 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 are now 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 24,738 respondents. A query of the Agency's registration and listing database shows that approximately 13,294 domestic and 11,444 foreign establishments are respondents to this information collection.[1] 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 Paperwork Reduction Act burden placed on the 24,738 establishments is an average burden.

In the **Federal Register** of September 8, 2016 (81 FR 62144), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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)	24,738	1	24,738	7	173,166
Organization—820.20(b)	24,738	1	24,738	4	98,952
Management review—820.20(c)	24,738	1	24,738	6	148,428
Quality planning—820.20(d)	24,738	1	24,738	10	247,380
Quality system procedures—820.20(e)	24,738	1	24,738	10	247,380
Quality audit—820.22	24,738	1	24,738	33	816,354
Training—820.25(b)	24,738	1	24,738	13	321,594
Design procedures—820.30(a)(1)	24,738	1	24,738	2	49,476
Design and development planning—820.30(b)	24,738	1	24,738	6	148,428
Design input—820.30(c)	24,738	1	24,738	2	49,476
Design output—820.30(d)	24,738	1	24,738	2	49,476
Design review—820.30(e)	24,738	1	24,738	23	568,974
Design verification—820.30(f)	24,738	1	24,738	37	915,306
Design validation—820.30(g)	24,738	1	24,738	37	915,306
Design transfer—820.30(h)	24,738	1	24,738	3	74,214
Design changes—820.30(i)	24,738	1	24,738	17	420,546
Design history file—820.30(j)	24,738	1	24,738	3	74,214
Document controls—820.40	24,738	1	24,738	9	222,642
Documentation approval and distribution and document changes—820.40(a) and (b)	24,738	1	24,738	2	49,476
Purchasing controls—820.50(a)	24,738	1	24,738	22	544,236
Purchasing data—820.50(b)	24,738	1	24,738	6	148,428
Identification—820.60	24,738	1	24,738	1	24,738
Traceability—820.65	24,738	1	24,738	1	24,738
Production and process controls—820.70(a)	24,738	1	24,738	2	49,476
Production and process changes and environmental control—820.70(b) and (c)	24,738	1	24,738	2	49,476
Personnel—820.70(d)	24,738	1	24,738	3	74,214
Contamination control—820.70(e)	24,738	1	24,738	2	49,476
Equipment maintenance schedule, inspection, and adjustment—820.70(g)(1)–(g)(3)	24,738	1	24,738	1	24,738
Manufacturing material—820.70(h)	24,738	1	24,738	2	49,476
Automated processes—820.70(i)	24,738	1	24,738	8	197,904
Control of inspection, measuring, and test equipment—820.72(a)	24,738	1	24,738	5	123,690
Calibration procedures, standards, and records—820.72(b)(1)–(b)(2)	24,738	1	24,738	1	24,738
Process validation—820.75(a)	24,738	1	24,738	3	74,214
Validated process parameters, monitoring, control methods, and data—820.75(b)	24,738	1	24,738	1	24,738
Revalidation—820.75(c)	24,738	1	24,738	1	24,738

[1] Based on fiscal year 2015 data.

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
Acceptance activities—820.80(a)–(e)	24,738	1	24,738	5	123,690
Acceptance status—820.86	24,738	1	24,738	1	24,738
Control of nonconforming product—820.90(a)	24,738	1	24,738	5	123,690
Nonconforming product review/disposition procedures and rework procedures—820.90(b)(1)–(b)(2)	24,738	1	24,738	5	123,690
Procedures for corrective/preventive actions—820.100(a)(1)–(a)(7)	24,738	1	24,738	12	296,856
Corrective/preventive activities—820.100(b)	24,738	1	24,738	1	24,738
Labeling procedures—820.120(b)	24,738	1	24,738	1	24,738
Labeling documentation—820.120(d)	24,738	1	24,738	1	24,738
Device packaging—820.130	24,738	1	24,738	1	24,738
Handling—820.140	24,738	1	24,738	6	148,428
Storage—820.150(a) and (b)	24,738	1	24,738	6	148,428
Distribution procedures and records—820.160(a) and (b)	24,738	1	24,738	1	24,738
Installation—820.170	24,738	1	24,738	2	49,476
Record retention period—820.180(b) and (c)	24,738	1	24,738	2	49,476
Device master record—820.181	24,738	1	24,738	1	24,738
Device history record—820.184	24,738	1	24,738	1	24,738
Quality system record—820.186	24,738	1	24,738	1	24,738
Complaint files—820.198(a), (c), and (g)	24,738	1	24,738	5	123,690
Servicing procedures and reports—820.200(a) and (d)	24,738	1	24,738	3	74,214
Statistical techniques procedures and sampling plans—820.250	24,738	1	24,738	1	24,738
Total					8,608,824

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

Dated: November 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29028 Filed 12–2–16; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0117]

Agency Information Collection Activities; Proposed Collection; Comment Request; Providing Information About Pediatric Uses of Medical Devices

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, 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 regarding ''Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act.''

DATES: Submit either electronic or written comments on the collection of information by February 3, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2013–D–0117 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Providing Information About Pediatric Uses of Medical Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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