Medical Devices Current Good Manufacturing Practice Quality System Regulation

0910-0073

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting extension of approval for information collection requirements in 21 CFR Part 820. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=afcb5c61a16e62e65ebb7539ad68aeea&tpl=/ecfrbrowse/Title21/21cfr820_main_02.tpl

Current Good Manufacturing Practices (CGMPs) are set forth in the Quality System (QS) regulation. The authority for this regulation is covered under the Federal Food, Drug, and Cosmetic Act (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 international quality standards, ISO 9001, "Quality Systems Model for Quality Assurance in Design/ Development, Production, Installation, and Servicing." See American National Standard ANSI/ASQC Q 9001-1994, which corresponds to ISO 9001:1994. Harmonization is fostered by the Safe Medical Devices Act of 1990 (SMDA) section 15, which added section 803 to the FD&C Act to encourage FDA to establish an Office of International Relations to work with foreign countries towards mutual recognition of CGMP requirements.

Below is a description of information collection requirements in the CGMP/QS regulation:

Quality policy—21 CFR 820.20(a)—*Recordkeeping*
Executive management shall establish (i.e. define, document, implement) the quality policy and maintain it at all organizational levels.

Organization—21 CFR 820.20(b)—*Recordkeeping*
Manufacturers shall establish and maintain organizational structure adequate to design and produce devices, and establish responsibilities and resources appropriate to manage, perform, and assess activities affecting quality.

Management review—21 CFR 820.20(c)—*Recordkeeping*
Quality systems shall be reviewed for suitability and effectiveness at defined intervals; and dates and results, documented.

Quality planning—21 CFR 820.20(d)—*Recordkeeping*
A quality plan defining quality practices, resources, and activities, shall be established and maintained.

Quality system procedures—21 CFR 820.20(e)—*Recordkeeping*
Manufacturers shall establish and maintain quality system procedures, instructions; and outline appropriate documentation.

Quality audit—21 CFR 820.22—*Recordkeeping*
Quality system audits/reaudits shall be done per established procedures; and results and dates, documented in reports reviewed by management.

Training—21 CFR 820.25(b)—*Recordkeeping*
Manufacturers shall establish and maintain procedures identifying training needs, and document training.

Design procedures—21 CFR 820.30(a)(1)—*Recordkeeping*
Manufacturers of Class III, II and certain Class I devices shall establish and maintain procedures for the design of devices.

Design and development planning—21 CFR 820.30(b)—*Recordkeeping*
A plan describing design and development activities shall be established, maintained, reviewed, updated and approved as device design evolves.

Design input—21 CFR 820.30(c)—*Recordkeeping*
Procedures identifying design input requirements shall be established and maintained; and requirements, approval dates and persons, documented.

Design output—21 CFR 820.30(d)—*Recordkeeping*
Procedures defining design output and acceptance criteria shall be established and maintained; and approvals of design output records, documented.

Design review—21 CFR 820.30(e)—*Recordkeeping*
Procedures shall be established and maintained for systematic design review; and results, documented in the design history file (DHF).

Design verification—21 CFR 820.30(f)—*Recordkeeping*
Procedures shall be established and maintained for verifying device design; and, results, dates, methods and persons used, documented in the DHF.

Design validation—21 CFR 820.30(g)—*Recordkeeping*
Procedures shall be established and maintained for validating design; and results, dates, methods and persons, documented in the DHF.

Design transfer—21 CFR 820.30(h)—*Recordkeeping*
Procedures shall be established and maintained ensuring the device design is correctly translated into production specifications.

Design changes—21 CFR 820.30(i)—*Recordkeeping*
Procedures shall be established and maintained to identify, document, verify or validate, review and approve design changes, before implementation.

Design history file—21 CFR 820.30(j)—*Recordkeeping*
A DHF shall be established/maintained for each device, referencing records showing the device was developed per the design plan/requirements.

Document controls—21 CFR 820.40—*Recordkeeping*
Manufacturers shall establish and maintain procedures controlling approval and distribution of required documents and document changes.

Documentation approval and distribution—21 CFR 820.40(a)—*Recordkeeping*
Before issuance, all documentation shall be reviewed and approved by designated personnel; and, approval dates and signatures, documented.

Document changes—21 CFR 820.40(b)—*Recordkeeping*
Manufacturers shall maintain a record of approved changes, including descriptions, affected documents, approval dates, and signatures.

Purchasing controls—21 CFR 820.50(a)—*Recordkeeping*
Manufacturers shall establish/maintain procedures for product quality requirements to be met by suppliers, contractors; record evaluations; define controls based on these evaluations; and, maintain a record of acceptable suppliers.

Purchasing data—21 CFR 820.50(b)—*Recordkeeping*
Purchasing documents identifying specified requirements for products and services, shall be established, reviewed and approved.

Identification—21 CFR 820.60—*Recordkeeping*
Procedures shall be established and maintained for identifying product during receipt, production, distribution and installation.

Traceability—21 CFR 820.65—*Recordkeeping*
Procedures shall be established and maintained to identify, by control number, lots of life supporting or sustaining implants and their components.

Production and process controls—21 CFR 820.70(a)—*Recordkeeping*
Manufacturers shall establish and maintain process control procedures, including instructions, SOPs, production methods, monitoring measures for parameters, reference standards, approvals, and workmanship criteria.

Production and process changes—21 CFR 820.70(b)—*Recordkeeping*
Procedures shall be established and maintained for changes in a specification, method, process, or procedure, including verification or validation.

Environmental control—21 CFR 820.70(c)—*Recordkeeping*
Manufacturers shall establish and maintain procedures to control environmental conditions and document results of systems inspections.

Personnel—21 CFR 820.70(d)—*Recordkeeping*
Requirements shall be established and maintained for personnel's health, cleanliness, practices and clothing adversely affecting product quality.

Contamination control—21 CFR 820.70(e)—*Recordkeeping*
Each manufacturer shall establish and maintain procedures to prevent equipment and product contamination by adverse substances.

Equipment maintenance schedule—21 CFR 820.70(g)(1)—*Recordkeeping*
Schedules shall be established and maintained for equipment adjustment, cleaning and maintenance; and maintenance, documented.

Equipment maintenance inspection—21 CFR 820.70(g)(2)—*Recordkeeping*
Results of periodic maintenance inspections, dates, and inspectors shall be documented.

Adjustment—21 CFR 820.70(g)(3)—*Recordkeeping*
Limitations or tolerances shall be posted on or near equipment and be available to adjusters.

Manufacturing material—21 CFR 820.70(h)—*Recordkeeping*
Manufacturers shall establish and maintain procedures for using and removing adverse manufacturing materials.

Automated processes—21 CFR 820.70(i)—*Recordkeeping*
A protocol shall be established to validate software/changes for computers and automatic data processing; and validation results, documented.

Control of inspection, measuring, and test equipment—21 CFR 820.72(a)—*Recordkeeping*
Procedures shall be established/maintained for equipment calibration, inspection, checks, handling, storage and for documenting these activities.

Calibration procedures—21 CFR 820.72(b)—*Recordkeeping*
Established calibration procedures shall provide for directions, accuracy/precision limits, and remedial actions; and such actions, documented.

Calibration standards—21 CFR 820.72(b)(1)—*Recordkeeping*
Absent national or international calibration standards, manufacturers shall establish and maintain in-house standards.

Calibration records—21 CFR 820.72(b)(2)—*Recordkeeping*
Records shall identify calibrated equipment, dates, calibrators and next calibration.

Process validation—21 CFR 820.75(a)—*Recordkeeping*
Validation procedures shall be established and maintained for processes whose results are not verifiable by inspection and test; and validation results, dates, approving signatures and equipment, documented.

Validated process parameters—21 CFR 820.75(b)—*Recordkeeping*
Procedures shall be established and maintained for keeping validated process parameters within specified parameters.

Validated process monitoring, control methods, and data—21 CFR 820.75(b)(2)—*Recordkeeping*
Monitoring, control methods, and data for validated processes shall be documented.

Revalidation—21 CFR 820.75(c)—*Recordkeeping*
Results of revalidation activities for product changes or process deviations shall be documented.

Acceptance activities procedures—21 CFR 820.80(a)—*Recordkeeping*
Manufacturers shall establish and maintain procedures for acceptance activities, including inspections, tests or other assessments.

Receiving acceptance activities—21 CFR 820.80(b)—*Recordkeeping*
Procedures shall be established/maintained for incoming acceptance by inspection/test/other verification; and acceptance/rejection, documented.

In-process acceptance activities—21 CFR 820.80(c)—*Recordkeeping*
Procedures shall be established and maintained to ensure in-process product meets specified requirements and is controlled until inspections, tests or verifications are completed and approvals, documented.

Final acceptance activities—21 CFR 820.80(d)—*Recordkeeping*
Procedures shall be established and maintained so that finished devices meet acceptance criteria and are not distributed until device master record (DMR) activities are completed; data, reviewed; and approvals, documented.

Acceptance records—21 CFR 820.80(e)—*Recordkeeping*
Acceptance dates, results, performance signatures and equipment shall be recorded in the device history record (DHR).

Acceptance status—21 CFR 820.86—*Recordkeeping*
Product acceptance status shall be identified during receipt, manufacture, packaging, labeling, installation and servicing.

Control of nonconforming product—21 CFR 820.90(a)—*Recordkeeping*
Manufacturers shall establish and maintain procedures for identification, documentation, evaluation, and disposition of nonconforming product.

Nonconforming product review/disposition procedures—21 CFR 820.90(b)(1)—*Recordkeeping*
Manufacturers shall establish/maintain procedures for review/disposition of nonconforming product; and dispositions/concessions, documented.

Rework procedures—21 CFR 820.90(b)(2)—*Recordkeeping*
Procedures shall be established/maintained for rework, reevaluation of product/adverse rework effects; and, activities/results, recorded in DHR.

Procedures for corrective/preventive actions—21 CFR 820.100(a)(1-7)—*Recordkeeping*
Procedures and requirements shall be established and maintained for corrective/preventive actions, including: analysis of data from process, work, quality, servicing records; investigation of nonconformance causes; identification of corrections and their effectiveness; recording of changes made; and, appropriate distribution and managerial review of corrective and preventive action information.

Corrective/preventive activities—21 CFR 820.100(b)—*Recordkeeping*
All corrective/preventive activities shall be documented.

Labeling procedures—21 CFR 820.120—*Recordkeeping*
Manufacturers shall establish/maintain procedures to control labeling storage/application; and examination/release for storage and use, documented.

Labeling documentation—21 CFR 820.120(b) and (d)—*Recordkeeping*
Labels/labeling used shall be documented in DHR.

Device packaging—21 CFR 820.130—*Recordkeeping*
Manufacturers shall ensure device packaging and shipping containers are designed to protect devices from alteration or damage.

Handling—21 CFR 820.140—*Recordkeeping*
Handling procedures shall be established and maintained to prevent product mix-ups and adverse effects.

Storage—21 CFR 820.150(a) and (b)—*Recordkeeping*
Manufacturers shall establish/maintain procedures for controlling product storage areas/stock rooms and for authorizing receipt/dispatch.

Distribution procedures—21 CFR 820.160(a)—*Recordkeeping*
Manufacturers shall establish/maintain distribution control procedures so released devices- distributed, errors- resolved, expired product- not distributed.

Distribution records—21 CFR 820.160(b)—*Recordkeeping*
Distribution records shall be maintained, identifying consignees, products, quantities, dates, and control numbers shipped.

Installation—21 CFR 820.170—*Recordkeeping*
For installed devices, manufacturers shall establish instructions, inspection/test procedures, make them available, and record results.

Record retention period—21 CFR 820.180(b) and (c)—*Recordkeeping*
Required records shall be: maintained at manufacturing sites or other sites accessible to manufacturers and FDA; made readily available to FDA; retained for device's life expectancy or 2 years; and, per request, audit reviews certified.

Device master record—21 CFR 820.181—*Recordkeeping*
Manufacturers shall maintain DMRs that contain reference: device/process specifications, quality assurance procedures/specifications, packaging /labeling specifications, and installation/maintenance/servicing procedures.

Device history record—21 CFR 820.184—*Recordkeeping*
For each unit/lot/batch, manufacturers shall maintain DHRs demonstrating manufacture per DMR/regulatory requirements; manufacturing dates; quantities made/distributed; acceptance records; labels/labeling; control numbers.

Quality system record—21 CFR 820.186—*Recordkeeping*
Manufacturers shall maintain a quality system record (QSR) that contains/references/documents procedures/activities not specific to particular devices.

Complaint files—21 CFR 820.198(a), (c), and (g)—*Recordkeeping*
Manufacturers shall maintain complaint files/establish procedures for receiving/reviewing/evaluating complaints, to include: recording why complaints are not investigated, and investigating complaints about devices not meeting specifications or associated with events reportable to FDA under separate regulations; and, when

complaint units are at separate or foreign sites, maintaining the records at the manufacturer's regular U.S. records site, or at the firm's U.S. designated agent.

Servicing procedures—21 CFR 820.200(a)—*Recordkeeping*
Where servicing is required, manufacturers shall establish/ maintain procedures for performing/verifying that servicing requirements are met and service reports (for FDA reportable events) are processed as complaints.

Service reports—21 CFR 820.200(d)—*Recordkeeping*
Service reports shall record the device, date, service, service done, and test and inspection data.

Statistical techniques procedures—21 CFR 820.250(a)—*Recordkeeping*
As appropriate, manufacturers shall establish and maintain procedures to identify valid statistical techniques to access process/product acceptability.

Sampling plans—21 CFR 820.250(b)—*Recordkeeping*
Written sampling plans shall be based on valid statistical rationale; and procedures, established, maintained and reviewed to ensure their adequacy.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The respondents to this information are private sector, for-profit businesses.

CGMP/QS information collections assist FDA inspections of manufacturer compliance with quality system requirements encompassing design, production, installation, and servicing processes. Manufacturers must ensure that medical devices meet design specifications and that design specifications are effectively transferred from research and development to production. Manufacturer compliance with CGMP/QS requirements should decrease such failures and save manufacturers millions of dollars by avoiding recalls caused by inadequate design.

“Harmonized” CGMP/QS requirements have benefited export-oriented manufacturers because they are consistent with the ISO 9000 international quality standards. The least expensive way for U.S. firms to meet the medical device directives of the European Union (EU) and obtain the EU mark to sell their products is to certify that their quality systems comply with the ISO standards. By complying with CGMP/QS requirements U.S. manufacturers will satisfy both domestic and international regulatory requirements.

Not implementing the CGMP/QS regulation would result in the continuation of a significant number of preventable deaths and injuries, and in the loss by manufacturers of substantial savings attributable to reduced recall costs, improved manufacturing efficiency, and improved access to international markets.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that approximately 75% of the respondents will use electronic means to fulfill the agency's requirement or request.

In the Federal Register of March 20, 1997 (62 FR 13430), FDA published a final rule establishing procedures for electronic records, electronic signatures, and electronic submissions. Firms may use appropriate technology in accordance with this rule to comply with the CGMP/QS recordkeeping requirements.

FDA is also using information technology to assist in the reduction of information burden to respondents of information queries. Presently, respondents to FDA information collections may use computer word processing, electronic form, spreadsheet, and database software to collect and format information.

FDA has attempted to maximize current technology to reduce burden for respondents of its data by the methods mentioned above. FDA will continue to pursue methods of applying technology to reduce burden to the respondents of its information collections.

4. Efforts to Identify Duplication and Use of Similar Information

Required information is available from individual manufacturers and no other sources. FDA is the only Federal regulatory agency responsible for collecting such information.

5. Impact on Small Businesses or Other Small Entities

Under the Small Business Administration's definition of a small business, 98% of the manufacturers who keep records are small businesses.

CGMP/QS requirements have a significant impact on a substantial number of small businesses. However, when the CGMP/QS became final rule and exempted the majority of Class I device manufacturers from design controls, FDA estimated a decrease in compliance costs by approximately $6.8 million, 60 percent of which would have been borne by small businesses. By excluding component manufacturers from CGMP/QS requirements, FDA eliminated potential rises in the cost of components purchased by small businesses. By deleting "complete" and "all" from many previous recordkeeping provisions, FDA provides small businesses with greater flexibility in determining the type and quantity of necessary records. By harmonizing requirements with international standards, FDA provides benefits to small firms pursuing exports since they no longer need to expend resources to maintain a quality system for FDA regulated domestic products and another for foreign regulated exports.

Small firms are assisted by the Division of Industry and Consumer Education (DICE) within FDA's Center for Devices and Radiological Health (CDRH). DICE was established, to provide technical and other non-financial assistance to small firms, expressly to aid them in complying with the requirements of the FD&C Act. DICE participates in and conducts conferences, workshops, and seminars on the application and interpretation of relevant regulations. DICE also consults with small firms, and develops

and disseminates CGMP educational materials, thereby reducing small business expenditures to achieve compliance. DICE staff are available to respond to questions via a toll-free telephone number, and they provide additional information to firms on the DICE website, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

6. Consequences of Collecting the Information Less Frequently

   There are no technical or legal obstacles to the collection of information required by this collection. Respondents keep records on a daily basis.

   Section 510(h) of the FD&C Act requires FDA to inspect registered manufacturers of Class II (special controls) devices and Class III (premarket approval) devices, at least once every 2 years. FDA inspects manufacturers of Class I (general controls) devices as often as feasible. If inspection reviews were conducted less frequently, FDA's effectiveness in increasing the safety of medical devices by monitoring manufacturers' compliance with CGMPs, would be significantly reduced.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   Collections are consistent with 5 CFR 1320.5 except for the requirement in section 820.180(b). This section requires records to be retained for a period equivalent to the design and expected life of the device, but in no case less than 2 years from release for distribution. This is necessary because many devices are labeled for extended periods of use. For example, pacemaker life expectancy depends on battery life, which is usually more than 3 years. Manufacturers must retain records as required above in order to perform failure/problem investigations and FDA must have access to these records to conduct long range investigations protecting public health.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of 09/08/2016 (81 FR 62144). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   There is no payment or gift to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

    CDRH complies with the Freedom of Information Act (5 U.S.C. 552) and FDA's Public Information regulation at 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 21 CFR part 20.

11. Justification for Sensitive Questions

    This information collection does not include questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden

Activity/ 21 CFR Section	No. of Recordkeepers	No. 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

Table 1.--Estimated Annual Recordkeeping Burden

Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
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
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
Totals					8,608,824

All registered establishment types must comply with the CGMP/QS regulations. Upon review of the data and this ICR under the PRA we have also determined that, for accuracy, it is preferable to estimate the number of respondents based on the number of establishments, rather than the number of owner/operators of those establishments. A query of the Agency's registration and listing databank for fiscal year (FY) 2015 shows that 13,294 domestic and 11,444 foreign establishments are subject to the regulations. Therefore, approximately 24,738 respondents must comply with the CGMP/QS regulations. Because the total number of registered establishments is not static, the

number of respondents will fluctuate from year to year resulting in changes to the overall burden.

12b. Annualized Cost Burden Estimate

FDA estimates the annualized cost burden as $127,896.000. We have determined, based on Agency data and expertise, that recordkeeping is performed by several types of worker. We used the occupational categories and updated wage rates from the Bureau of Labor and Statistics data* to determine the cost burden estimate.

*Approximate hourly wage rate is based on the Bureau of Labor and Statistics May 2015 National Occupational Employment and Wage Estimates for life, physical, and social science occupations (http://www.bls.gov/oes/current/oes_nat.htm#19-0000).

Type of Respondent- (% Record Responsibility)	Total Burden Hours*	Hourly Wage Rate	Total Respondent Costs*
General & Operations Managers- 10%	378,491	$57.44	$21,740,523
Compliance Officers-10%	378,491	$33.26	$12,588,610
Computer Occupations-5%	189,246	$41.39	$7,832,892
Statisticians- 5%	189,246	$40.60	$7,683,388
Biomedical Engineers- 20%	756,983	$43.86	$33,201,274
Customer Service Representatives- 10%	378,491	$16.62	$6,290,520
Information and Record Clerks- 15%	567,737	$18.64	$10,582,617
Supervisors of Production Workers- 10%	378,491	$28.81	$10,904,325
Misc. Plant & System Operators- 15%	567,737	$30.07	$17,071,851
Total			$127,896,000
* Numbers have been rounded.			

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, or operating and maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Based on past experience, it is anticipated that 190 full time equivalent (FTE) positions, including headquarters personnel, field investigators, and lab technicians, will be used to properly maintain and enforce the CGMP/QS final regulation. An average full time equivalent (FTE) employee is projected to cost FDA/CDRH $283,487,* which consists of the employee's salary and any overhead which accompanies that employee. The estimated annualized burden to government for this information collection is $53,862,530 per year ($283,487 x 190 FTEs).

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

    We have adjusted the number of respondents based on updated Registration and Listing data for FY2015 (previously 25,986 respondents per IC; updated to 24,738 respondents per IC). This caused a 434,304-hour reduction in the total estimated burden. There are no program changes.
16. Plans for Tabulation and Publication and Project Time Schedule

    The results of this collection of information will not be published.
17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA is not requesting an exemption for display of the OMB expiration date.
18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.