MEDICAL DEVICES: CURRENT GOOD MANUFACTURING PRACTICE (CGMP), QUALITY SYSTEM (Q/S) REGULATION
0910-0073
SUPPORTING STATEMENT

A. JUSTIFICATION

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 (CGMP) are set forth in this Quality System (QS) regulation. The authority for this regulation is covered under the Federal Food, Drug, and Cosmetic Act (the Act), 21 U. S. C. sections 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383.

1. Circumstances Making the Collection of Information Necessary

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 non-conforming 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 SMDA Sec. 15 which added sect. 803 to the Federal Food, Drug and Cosmetic Act (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:

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.

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.

21 CFR 820.20(c) – Recordkeeping

Quality systems shall be reviewed for suitability and effectiveness at defined intervals; and dates and results, documented.

21 CFR 820.20(d) – Recordkeeping

A quality plan defining quality practices, resources, and activities, shall be established and maintained.

21 CFR 820.20(e) – Recordkeeping

Manufacturers shall establish and maintain quality system procedures, instructions; and outline appropriate documentation.

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.

21 CFR 820.25(b) – Recordkeeping

Manufacturers shall establish and maintain procedures identifying training needs, and document training.

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.

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.

21 CFR 820.30(c) – Recordkeeping

Procedures identifying design input requirements shall be established and maintained; and requirements, approval dates and persons, documented.

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.

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).

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.

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.

21 CFR 820.30(h) – Recordkeeping

Procedures shall be established and maintained ensuring the device design is correctly translated into production specifications.

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.

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.

21 CFR 820.40 – Recordkeeping

Manufacturers shall establish and maintain procedures controlling approval and distribution of required documents and document changes.

21 CFR 820.40(a) – Recordkeeping

Before issuance, all documentation shall be reviewed and approved by designated personnel; and, approval dates and signatures, documented.

21 CFR 820.40(b) – Recordkeeping

Manufacturers shall maintain a record of approved changes, including descriptions, affected documents, approval dates, and signatures.

21 CFR 820.50 and (a)(1-3) – 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.

21 CFR 820.50(b) – Recordkeeping

Purchasing documents identifying specified requirements for products and services, shall be established, reviewed and approved.

21 CFR 820.60 – Recordkeeping

Procedures shall be established and maintained for identifying product during receipt, production, distribution and installation.

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.

21 CFR 820.70(a) (1-5) – Recordkeeping

Manufacturers shall establish and maintain process control procedures, including instructions, SOPs, production methods, monitoring measures for parameters, reference standards, approvals, and workmanship criteria.

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.

21 CFR 820.70(c) – Recordkeeping

Manufacturers shall establish and maintain procedures to control environmental conditions and document results of systems inspections.

21 CFR 820.70(d) – Recordkeeping

Requirements shall be established and maintained for personnel's health, cleanliness, practices and clothing adversely affecting product quality.

21 CFR 820.70(e) – Recordkeeping

Each manufacturer shall establish and maintain procedures to prevent equipment and product contamination by adverse substances.

21 CFR 820.70(g)(1) – Recordkeeping

Schedules shall be established and maintained for equipment adjustment, cleaning and maintenance; and maintenance, documented.

21 CFR 820.70(g)(2) – Recordkeeping

Results of periodic maintenance inspections, dates, and inspectors shall be documented.

21 CFR 820.70(g)(3) – Recordkeeping

Limitations or tolerances shall be posted on or near equipment and be available to adjusters.

21 CFR 820.70(h) – Recordkeeping

Manufacturers shall establish and maintain procedures for using and removing adverse manufacturing materials.

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.

21 CFR 820.72(a) – Recordkeeping

Procedures shall be established/maintained for equipment calibration, inspection, checks, handling, storage and for documenting these activities.

21 CFR 820.72(b) – Recordkeeping

Established calibration procedures shall provide for directions, accuracy/precision limits, and remedial actions; and such actions, documented.

21 CFR 820.72(b)(1) – Recordkeeping

Absent national or international calibration standards, manufacturers shall establish and maintain in-house standards.

21 CFR 820.72(b)(2) – Recordkeeping

Records shall identify calibrated equipment, dates, calibrators and next calibration.

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.

21 CFR 820.75(b) – Recordkeeping

Procedures shall be established and maintained for keeping validated process parameters within specified parameters.

21 CFR 820.75(b)(2) – Recordkeeping

Monitoring, control methods, and data for validated processes shall be documented.

21 CFR 820.75(c) – Recordkeeping

Results of revalidation activities for product changes or process deviations shall be documented.

21 CFR 820.80(a) – Recordkeeping

Manufacturers shall establish and maintain procedures for acceptance activities, including

inspections, tests or other assessments.

21 CFR 820.80(b) – Recordkeeping

Procedures shall be established/maintained for incoming acceptance by inspection/test/other verification; and acceptance/rejection, documented.

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.

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.

21 CFR 820.80(e) – Recordkeeping

Acceptance dates, results, performance signatures and equipment shall be recorded in the device history record (DHR).

21 CFR 820.86 – Recordkeeping

Product acceptance status shall be identified during receipt, manufacture, packaging, labeling, installation and servicing.

21 CFR 820.90(a) – Recordkeeping

Manufacturers shall establish and maintain procedures for identification, documentation, evaluation, and disposition of nonconforming product.

21 CFR 820.90(b)(1) – Recordkeeping

Manufacturers shall establish/maintain procedures for review/disposition of nonconforming product; and dispositions/concessions, documented.

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.

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.

21 CFR 820.100(b) – Recordkeeping

All corrective/preventive activities shall be documented.

21 CFR 820.120 – Recordkeeping

Manufacturers shall establish/maintain procedures to control labeling storage/application; and examination/release for storage and use, documented.

21 CFR 820.120(b), (d) – Recordkeeping

Labels/labeling used shall be documented in DHR.

21 CFR 820.130 – Recordkeeping

Manufacturers shall ensure device packaging and shipping containers are designed to protect devices from alteration or damage.

21 CFR 820.140 – Recordkeeping

Handling procedures shall be established and maintained to prevent product mix-ups, and adverse effects.

21 CFR 820.150(a), (b) – Recordkeeping

Manufacturers shall establish/maintain procedures for controlling product storage areas/stock rooms and for authorizing receipt/dispatch.

21 CFR 820.160(a) – Recordkeeping

Manufacturers shall establish/maintain distribution control procedures so released devices-distributed, errors- resolved, expired product- not distributed.

21 CFR 820.160(b) – Recordkeeping

Distribution records shall be maintained, identifying consignees, products, quantities, dates, and control numbers shipped.

21 CFR 820.170(a), (b) – Recordkeeping

For installed devices, manufacturers shall establish instructions, inspection/test procedures, make them available, and record results.

21 CFR 820.180 and (b), (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.

21 CFR 820.181(a)-(e) – Recordkeeping

Manufacturers shall maintain DMRs that contain reference: device/process specifications, quality assurance procedures/specifications, packaging /labeling specifications, and installation/maintenance/servicing procedures.

21 CFR 820.184(a)-(f) – 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.

21 CFR 820.186 – Recordkeeping

Manufacturers shall maintain a quality system record (QSR) that contains/references/documents procedures/activities not specific to particular devices.

21 CFR 820.198(a), (c), (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.

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.

21 CFR 820.200(d) – Recordkeeping

Service reports shall record the device, date, service, service done, and test and inspection data.

21 CFR 820.250(a) – Recordkeeping

As appropriate, manufacturers shall establish and maintain procedures to identify valid statistical techniques to access process/product acceptability.

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.

CGMP/QS information collections will 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 US

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 Information Technology and Burden Reduction

FDA estimates that approximately 50% 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 collection's may use computer word processing, electronic form, spreadsheet, and database software to collect and format information for submission to FDA. FDA has reduced the burden of responding to regulatory statute through the use of these electronic applications, the Fax-On-Demand fax-back system, the Electronic Docket, and the Internet.

In addition, FDA is currently receiving manufacturer's application by computer word processing, electronic form and CD-ROM to assist in reducing manufacturer's application submission burdens. However, in the event that FDA requests an applicant to deliver copies of their application to FDA, electronic storage allows for the fastest transmission of those records to FDA.

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 not other sources. FDA is the only regulatory Federal agency responsible for collecting such information.

5. Impact on Small Business 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 Small Manufacturers Assistance (DSMICA) within FDA's Center for Devices and Radiological Health (CDRH). DSMICA was established, as required by the 1976 Amendments to the act, to provide technical and other non-financial assistance to small firms, expressly to aid them in complying with the requirements of the act. DSMICA participates in and conducts conferences, workshops; and seminars on the application and interpretation of relevant regulations. DSMICA also consults with small firms; and develops and disseminates CGMP educational materials, thereby reducing small business expenditures to achieve compliance. DSMICA staff is available to respond to questions via a toll-free telephone number, and provides additional information to firms on its website, located at http:\\www.fda.gov (once on the site, click on the Center for Devices and Radiological Health (CDRH) link, and choose the DSMICA link).

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.

Sect. 510(h) of the 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.

There are no legal obstacles to reduce the burden.

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 since 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 Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of June 24, 2010 (75 FR 36092). FDA received two comments, however only one was regarding the information collection. One part of the comment questioned a technical reference found within the 60-day notice, stating not that the reference was incorrect, but that it may be somewhat misleading since the reference is updated on a regular basis and this was not communicated in the notice. While the commenter is correct that ISO 9001 is on version 2008 and ISO/DIS 13485 is on version 2003, the standard ISO 9001 and ISO/DIS 13485 are referenced because they are the standard regardless of version.

Another part of the comment maintains that the term “collect” is misleading as it pertains to recordkeeping requirements because relevant documents are only submitted if requested; however, the comment agrees that the information collection is necessary. Under the PRA regulations, records retention is considered “information collection”, as defined by the PRA 5 CFR 1320.3

A third part of the comment stated that it was not clear to whom the regulations applied based on the statement, “[e]xcept for manufacturers, not every type of firm is subject to every CGMP/QS requirement.” FDA believes the scope of the regulations found at 21 CFR 820.1 makes it clear to whom the requirements are applicable.

The commenter questioned the validity and availability of a study that was conducted by the Eastern Research Group (ERG) in 1996, claiming that without benefit of the study itself, comments regarding burden estimates were too difficult to make. As a basis for its burden estimates, the agency relied in part on certain pieces of information found in the 1996 study and recommends that FDA make this document part of the docket. The study

was submitted to OMB as part of the original PRA approval and is part of the federal docket.

The commenter sates that FDA assumes that the burden for each firm is the same, *i.e.,* each of the 8,924 firms has exactly the same burden. The flexibility of the system suggests that the "one size fits all" approach in the Federal Register is not appropriate. The PRA burden placed on the 8,924 firm is an average burden on respondents.

The commenter believes that the estimates the agency provides are too low, but does not offer an alternative methodology for estimating that the agency may review. The comment goes on to suggest, however, that a new analysis similar to the 1996 study be conducted and serve as the basis for future burden estimates because our estimates have not changed in several years. While FDA agrees that additional analysis is always helpful in determining burden, the agency does perform ongoing reviews of the burden associated with PRA burden as required under the PRA for purposes of evaluating burden associated with its information collection requests, and has done so for purposes of renewing these CGMP/QS regulations.

Finally, the commenter suggests that the agency's regulation regarding electronic signatures found at 21 CFR part 11 is overly cumbersome to many firms. 21 CFR part 11 is a separate regulation from 21 CFR part 820 and is only mentioned for reference purposes in the preamble. The record keeping for Part 11 is not within the scope of this paperwork analysis.

Also, CDRH is proactive in ensuring that the medical device industry and other affected individuals are made aware of on-going issues relating to the CGMP/QS regulations. The 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.

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, 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.

Information required by the CGMP/QS regulation doesn't include questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs or matters considered private.

12. Estimates of Annualized burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
820.20(a)	8,924	1	8,924	7	62,468
820.20(b)	8,924	1	8,924	4	35,696
820.20(c)	8,924	1	8,924	6	53,544
820.20(d)	8,924	1	8,924	10	89,240
820.20(e)	8,924	1	8,924	10	89,240
820.22	8,924	1	8,924	33	294,492
820.25(b)	8,924	1	8,924	13	116,012
820.30(a)(1)	8,924	1	8,924	2	17,848
820.30(b)	8,924	1	8,924	6	53,544
820.30(c)	8,924	1	8,924	2	17,848
820.30(d)	8,924	1	8,924	2	17,848
820.30(e)	8,924	1	8,924	23	205,252
820.30(f)	8,924	1	8,924	37	330,188
820.30(g)	8,924	1	8,924	37	330,188
820.30(h)	8,924	1	8,924	3	26,772
820.30(i)	8,924	1	8,924	17	151,708
820.30(j)	8,924	1	8,924	3	26,772

CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
820.40	8,924	1	8,924	9	80,316
820.40(a)-(b)	8,924	1	8,924	2	17,848
820.50(a)(1)-(3)	8,924	1	8,924	22	196,328
820.50(b)	8,924	1	8,924	6	53,544
820.6	8,924	1	8,924	1	8,924
820.65	8,924	1	8,924	1	8,924
820.70(a)1)- (5)	8,924	1	8,924	2	17,848
820.70(b)-(c)	8,924	1	8,924	2	17,848
820.70(d)	8,924	1	8,924	3	26,772
820.70(e)	8,924	1	8,924	2	17,848
820.70(g)(1) - (g)(3)	8,924	1	8,924	1	8,924
820.70(h)	8,924	1	8,924	2	17,848
820.70(i)	8,924	1	8,924	8	71,392
820.72(a)	8,924	1	8,924	5	44,620
820.72(b)(1) - (b)(2)	8,924	1	8,924	1	8,924
820.75(a)	8,924	1	8,924	3	26,772
820.75(b)	8,924	1	8,924	1	8,924
820.75(c)	8,924	1	8,924	1	8,924
820.80(a)-(e)	8,924	1	8,924	5	44,620
820.86	8,924	1	8,924	1	8,924
820.90(a)	8,924	1	8,924	5	44,620
820.90(b)(1) - (b)(2)	8,924	1	8,924	5	44,620
820.100 (a)(1) - (a)(7)	8,924	1	8,924	12	107,088
820.100(b)	8,924	1	8,924	1	8,924
820.120(b)	8,924	1	8,924	1	8,924
820.120(d)	8,924	1	8,924	1	8,924
820.130	8,924	1	8,924	1	8,924

CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
820.140	8,924	1	8,924	6	53,544
820.150(a)-(b)	8,924	1	8,924	6	53,544
820.160(a)-(b)	8,924	1	8,924	1	8,924
820.170(a)-(b)	8,924	1	8,924	2	17,848
820.180 (b-c)	8,924	1	8,924	2	17,848
820.181(a)-(e)	8,924	1	8,924	1	8,924
820.184(a)-(f)	8,924	1	8,924	1	8,924
820.186	8,924	1	8,924	1	8,924
820.198(a)-(c)	8,924	1	8,924	5	44,620
820.200(a) and (d)	8,924	1	8,924	3	26,772
820.25	8,924	1	8,924	1	8,924
Totals					3,105,552

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

These CGMP/QS regulations apply to approximately 8,924 respondents. A query of the Agency's registration and listing databank shows that 8,190 domestic firms are subject to the regulations. The data also showed that the number of new domestic firms subject to the regulations is 734. Using the data provided, FDA therefore estimated the average number of firms subject to the CGMP/QS regulations over the three years is 8,924. This figure was used to calculate the total burden. Because the total number of registered firms is not static, the number of respondents will fluctuate from year to year resulting in slight changes to the overall burden.

12b. Annualized Cost Burden Estimate

FDA estimates the total annualized burden hour cost at $53,096,728 million. Total Burden Hours of 3,105,552 x $17.10 per hour. This cost includes manufacturers, subject to all requirements and contract manufacturers.

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

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

14. Annualized Cost to the Federal Government

The estimate annualized cost to FDA is $9,576,000 (190 FTE's x $50,400).

Based on past experience, it is anticipated that it will take a total of 190 FTE's to properly maintain and enforce the CGMP/QS final regulation. The $50,400 annual salary is taking into consideration the grade levels of headquarters personnel, field investigators and lab technicians.

15. Explanation for Program Changes or Adjustments

While there is an increase of 33,215 hours from the last submission, there is a decrease in the total number of respondents by 39. FDA attributes the decrease in the number of respondents to regular fluctuations in firms that register and list with the agency from year to year. With regard to an increase in hours, in its last submission, burden hours were recorded as fractions, whereas the agency has rounded up to the nearest whole number for this submission. Additionally, one time 1.2M capital costs that were associated with the implementation of the regulations are no longer associated with this information collection.

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

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.