SUPPORTING STATEMENT
FOR
MEDICAL DEVICES: CURRENT GOOD MANUFACTURING PRACTICE (CGMP), QUALITY SYSTEM (Q/S) REGULATION
21 CFR PART 820
OMB No. 0910-0073

A. JUSTIFICATION

The Food and Drug Administration (FDA) is requesting extension of approval for information collection requirements in 21 CFR Part 820. 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.

2. Purpose and Use of the Information

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. FDA review of Medical Device Reports (MDRs) for 1991 showed that some 59 deaths and 929 serious injuries were attributed to design-related device failures. Manufacturer compliance with CGMP/QS requirements should decrease such failures and save manufacturers millions of dollars by avoiding recalls caused by inadequate design. Since the last approval of this information collection, there has been some decrease noted of the number of firms with design-related recalls. However, this regulation is still in its infancy and many firms have yet to design new products that incorporate design control requirements. Over the next two years, we will begin to receive information pertaining to whether recalls are design related and better evaluate the effectiveness of the quality system regulation.

"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

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

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 (DSMA) within FDA's Center for Devices and Radiological Health (CDRH). DSMA 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. DSMA participates in and conducts conferences, workshops; and seminars on the application and interpretation of relevant regulations. DSMA also consults with small firms; and develops and disseminates CGMP educational materials, thereby reducing small business expenditures to achieve compliance. DSMA 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 DSMA 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. 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.

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

Notice was published in the **Federal Register** on July 9, 2007 (72 FR 37235) soliciting public comments on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d) No comments were received.

FDA staff met with or discussed CGMP/QS requirements on numerous occasions over the last 3 years. 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 Agency Medical Device GMP/QS expert has 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 Respondent

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. Estimate of Hour Burden Including Annualized Hourly Costs

The CGMP/QS regulation applies to some 9,937 respondents. These recordkeepers consist of 9,871 original respondents and an estimated 66 hospitals which re-manufacture or re-use single use medical devices. They include manufacturers, subject to all requirements and contract manufacturers, specification developers, repackers/relabelers and contract sterilizers, subject only to requirements applicable to their activities. Hospital re-manufacturers of single use medical devices (SUD's) are now defined to be manufacturers

under guidelines issued by the Center for Devices and Radiological Health's (CDRH) Office of Surveillance and Biometrics (OSB). Respondents to this collection have no reporting activities, but must make required records available for review or copying during FDA inspection. The regulation contains additional recordkeeping requirements in such areas as design control, purchasing, installation, and information relating to the re-manufacture of single use medical devices. The estimates for burden are derived from those incremental tasks that were determined when the new CGMP/QS regulation became final as well as those carry-over requirements.

FDA estimates respondents will have a total annual recordkeeping burden of approximately 3,072,337 hours This figure also consists of approximately 143,052 hours spent on a start-up basis by 650 new firms. Table 1 below identifies burden estimates per sections of the regulation.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN1

CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Hours	Hours Per Recordkeeper	Operating and Maintenance Costs	Total Hours
820.20(a)	8,963	1	8,963	6.58		58,977
820.20(b)	8,963	1	8,963	4.43		39,706
820.20(c)	8,963	1	8,963	6.17		55,302
820.20(d)	8,963	1	8,963	9.89		88,644
820.20(e)	8,963	1	8,963	9.89		88,644
820.22	8,963	1	8,963	32.72		293,269
820.25(b)	8,963	1	8,963	12.68		113,651
820.30(a)(1)	8,963	1	8,963	1.75		15,685
820.30(b)	8,963	1	8,963	5.95		53,330
820.30(c)	8,963	1	8,963	1.75		15,685
820.30(d)	8,963	1	8,963	1.75		15,685
820.30(e)	8,963	1	8,963	23.39		209,645
820.30(f)	8,963	1	8,963	37.42		335,395
820.30(g)	8,963	1	8,963	37.42		335,395
820.30(h)	8,963	1	8,963	3.34		29,936
820.30(i)	8,963	1	8,963	17.26		154,701
820.30(j)	8,963	1	8,963	2.64		23,662
820.40	8,963	1	8,963	8.91		79,860

820.40(a)-(b)	8,963	1	8,963	2.04		18,285
820.50(a)(1)-(3)	8,963	1	8,963	21.90	1,300,805	196,290
820.50(b)	8,963	1	8,963	6.02		53,957
820.6	8,963	1	8,963	0.32		2,868
820.65	8,963	1	8,963	0.67		6,005
820.70(a)1)- (5)	8,963	1	8,963	1.85		16,582
820.70(b)-(c)	8,963	1	8,963	1.85		16,582
820.70(d)	8,963	1	8,963	2.87		25,724
820.70(e)	8,963	1	8,963	1.85		16,582
820.70(g)(1) - (g)(3)	8,963	1	8,963	1.43		12,817
820.70(h)	8,963	1	8,963	1.85		16,582
820.70(i)	8,963	1	8,963	7.50		67,223
820.72(a)	8,963	1	8,963	4.92		44,098
820.72(b)(1) - (b)(2)	8,963	1	8,963	1.43		12,817
820.75(a)	8,963	1	8,963	2.69		24,110
820.75(b)	8,963	1	8,963	1.02		9,142
820.75(c)	8,963	1	8,963	1.11		9,949
820.80(a)-(e)	8,963	1	8,963	4.80		43,022
820.86	8,963	1	8,963	0.79		7,081
820.90(a)	8,963	1	8,963	4.95		44,367
820.90(b)(1) - (b)(2)	8,963	1	8,963	4.95		44,367
820.100 (a)(1) - (a)(7)	8,963	1	8,963	12.48		111,858
820.100(b)	8,963	1	8,963	1.28		11,473
820.120(b)	8,963	1	8,963	0.45		4,033
820.120(d)	8,963	1	8,963	0.45		4,033
820.130	8,963	1	8,963	0.45		4,033
820.140	8,963	1	8,963	6.34		56,825
820.150(a)-(b)	8,963	1	8,963	5.67		50,820
820.160(a)-	8,963	1	8,963	0.67		6,005

(b)						
820.170(a)-(b)	8,963	1	8,963	1.50		13,445
820.180 (b-c)	8,963	1	8,963	1.50		13,445
820.181(a)-(e)	8,963	1	8,963	1.21		10,845
820.184(a)-(f)	8,963	1	8,963	1.41		12,638
820.186	8,963	1	8,963	0.40		3,585
820.198(a)-(c)	8,963	1	8,963	4.94		44,277
820.200(a) and (d)	8,963	1	8,963	2.61		23,393
820.25	8,963	1	8,963	0.67		6,005
Totals						3,072,337

Explanation of Recordkeeping Burden Estimate.

Burden (labor) hour and cost estimates were originally developed under FDA contract by Eastern Research Group, Inc. (ERG) in 1996 when the CGMP/QS regulation became final. These figures are still accurate. Additional factors considered in deriving estimates included:

- Establishment type: Query has been made of CDRH's registration/listing data bank and count was 8,963 domestic firms subject to CGMPs. In addition, hospitals which re-use or re-manufacture devices are now considered manufacturers under new FDA guidance. During the last report it was estimated that out of the 6,000 hospitals in the U.S., 1/3 of them (or 2,000 hospitals) will re-use or re-manufacture single use medical devices. After investigations of many hospitals and the changes in enforcements of FDA' requirements for hospitals, the numbers of re-use or re-manufactures of single use medical devices have decrease from the estimated 66 to an estimated 18 hospitals. 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. Currently, there are 8,963 firms subject to the CGMPs; an increase from the last renewal of 8,254.

- Potentially affected establishments: 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 type of firm subject to each requirement was identified by the ERG.

- FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992, under OMB Paperwork Reduction Act submission No. 0910-0073. It was approved by OMB on 7/16/92 and expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became final rule. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 8,963 respondents), which compensates for differences in methodology.

- FDA estimates that some 650 "new" establishments (marketing devices for the first time) will expend some 143,052 "development" hours on a one-time start-up basis to develop records and procedures for the CGMP/QS regulation.

- FDA estimates that annual labor hours are apportioned as follows: 40% - to requirements dealing with manufacturing specifications, process controls and the DHR; 20% - to requirements dealing with components and acceptance activities; 25% - to requirements dealing with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and, 15 % - to quality audit, traceability, handling, distribution, statistical, and other requirements.

Estimate of Burden Hour Cost to Respondents

FDA estimates the total annualized burden hour cost at $51 million. Total Burden Hours of 3,072,337 x $16.60 per hour. (I used a 3% increase each year over the last 3 years)

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

This does not include any capital, operating, maintenance or salary costs. Based on data developed by ERG, respondents will incur about $1.2 million in annual additional supplier auditing requirements, 21 CFR 820.50(a).

factors	small firms	medium firms	large firms	very large firms
- travel cost per visit....	$550	$550	$550	$550
- visits per year....	x 0.5	x 1.0	x 2.0	x 4.0
- no. of affected firms.... (mfrs. and contract mfrs)	x 4,678	x 1,993	x 613	x 383
- noncompliance rate	x 0.50	x 0.40	x 0.20	x 0.10
- Totals ($1,300,805)	$643,225	$438,460	$134,860	$84,260

No capital, start-up or maintenance costs are incurred by respondents to comply with the GMP/QS regulation.

14. Annualized Cost to the Federal Government

The estimate annualized cost to FDA is $9,310,000.

Staff Years	Average Annual Salary	Total
190	$49,000	$9,310

Based on past experience, it is anticipated that it will take a total of 190 staff years to properly maintain and enforce the CGMP/QS final regulation. The $49,000 annual salary is taking into consideration the grade levels of headquarters personnel, field investigators and lab technicians.

15. Explanation for Program Changes or Adjustments

Noted changes have evolved since the last approval was granted. Adjustments have been made to the burden hours, operational and maintenance costs and total number of respondents. These changes are based on the following factors:

- It is believed that the estimated numbers for hospitals, which re-use or re-manufactures single use medical devices, has decrease because of a series of FDA investigations and the enforcement requirements of FDA. As a result it is estimated that 18 hospitals re-use or re-manufacturer single use medical devices.

- The number of respondents has increased 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.

- The hourly burden costs have increased due to normal inflation rates.

- The annual salary rate for government employees has increased due to the normal cost of living increases.

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

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions. There are no exceptions to the certification statement identified in Item 19 of the OMB Form 83-I.