SUPPORTING STATEMENT
FOR
PREMARKET APPROVAL OF MEDICAL DEVICES
21 CFR PART 814
OMB No. 0910-0231

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of approval of the information collection requirements under 21 CFR Part 814. The Medical Device Amendments of 1976 require all medical devices to be classified into one of three regulatory categories. Class I devices are subject to only general regulatory controls which are applicable to all products. Class II devices require special controls to ensure their safety and effectiveness. Class III devices, such as implanted, life sustaining devices or devices which otherwise present a potentially unreasonable risk of illness or injury, or for which is of substantial importance in preventing impairment of human health require premarket approval (PMA).

Under section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(e)) (Attachment B), all devices placed into class III by FDA are subject to premarket approval requirements. Premarket approval is the process of scientific and regulatory review to ensure the safety and effectiveness of class III devices. An approved PMA is, in effect, a private license granted to the applicant for marketing a particular medical device. A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) (Attachment C)of the FD&C Act and cannot be marketed. Premarket approval requirements apply differently to preamendments devices, postamendments devices, and transitional class III devices.

Manufacturers of class III preamendments devices, devices that were in commercial distribution before May 28, 1976, are not required to submit a PMA until 30 months

after the promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after promulgation of a final rule for submission of a PMA.

A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments devices determined by FDA to be substantially equivalent to preamendments class III devices are subject to the same requirements as the preamendments devices. FDA determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with section 510(k) of the FD&C Act. The information collection burdens for these devices are calculated under OMB control number 0910-0120. Postamendments devices determined by FDA to be not substantially equivalent to either preamendments devices or postamendments devices classified into class I or II are "new" devices and fall automatically into class III. Before such devices can be marketed, they must have an approved premarket approval application or be must reclassified into class I or class II.

The Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105-115) http://www.fda.gov/cder/guidance/105-115.htm, was enacted on November 21, 1997 to implement revisions to the Federal Food, Drug, and Cosmetic Act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Several provisions of this act affect the PMA process, and are further discussed throughout this supporting statement.

FDAMA added section 515(d)(6) to the act (21 U.S.C. 360e(d)(6))) which provided that PMA supplements were required for all device changes that affect safety and effectiveness unless such changes are modifications to manufacturing procedures or method of manufacture. That type of manufacturing change will require a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

The implementing regulations, contained in 21 CFR Part 814, further specify the contents of a PMA for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA and supplements to PMA's. The regulation's purpose is to establish an efficient and thorough procedure for FDA's review of PMA's and supplements to PMA's for class III (premarket approval) medical devices. The regulations facilitate the approval of PMA's and supplements to PMA's for devices that have been shown to be safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the disapproval of PMA's and supplements to PMA's for devices that have not been show to be safe and effective and that do not otherwise meet the statutory criteria for approval.

Reporting Requirements:

21 CFR 814.15 (b)

States that FDA will accept studies submitted in support of a PMA which have been conducted outside the United States and begun on or after November 19, 1986, if the data are valid and the investigator has conducted the studies in conformance with the "Declaration of Helsinki" or the laws and regulations of the country in which the research is conducted, whichever accords greater protection to the human subjects. If the standards of the country are used, the applicant shall state in detail any differences between those standards and the "Declaration of Helsinki" and explain why they offer greater protection to the human subjects.

21 CFR 814.20

Specifies the information required in a PMA and update reports such as the applicant's name and address, a description of the device, its labeling, its indications for use, and summary of clinical and non-clinical studies.

21 CFR 814.37(a-c) and (e)

This specifies the procedures for amending an incomplete PMA or resubmitting a withdrawn PMA.

21 CFR 814.39(a) (c), (d) and (f) – Reporting

PMA supplements are required for all changes that affect safety and effectiveness unless such changes involve modifications to manufacturing procedures or method of manufacture. Changes to manufacturing procedures or methods which affect safety and effectiveness may require only a written notice to FDA, which describes the changes in detail and summarize the information that supports the change. The devices subject to manufacturing changes can be distributed 30 days after a notification report is submitted to FDA unless the agency notifies the submitter that the notice is not adequate.

If the FDA deems the notice to be inadequate, FDA may request further information and require a 135-day PMA supplement.

FDA may require a sponsor to submit new clinical data to demonstrate safety and effectiveness to support incremental changes.

21 CFR 814.82(a)(9)

Requires continued postapproval evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use.

21 CFR 814.84(b)

Requires the holder of an approved PMA to submit periodic reports of new information related to the device (or related device) or changes in the device (or related device) that could affect its safety or effectiveness.

Recordkeeping Requirements:

21 CFR 814.82(a)(5) & (6)

This requires maintenance of records that will enable the applicant to submit to FDA information needed to trace patients if necessary. It also requires maintenance of records for specified periods of time and organization and indexing into identifiable files to ensure the device's safety and effectiveness, to support continued approval of the device.

FDAMA Statutory Provisions

Section 201 - Data from Previous Investigations--Statutory burden

This section allows the submission of data from investigations of earlier versions of a device, in support of safety and effectiveness. Such data is only valid if modifications to earlier versions of the investigational device, whether made during or after the investigation, do not constitute a significant change that would invalidate the relevance of the data. In addition, this section allows for the submission of data or information relating to an approved device that are relevant to the design and intended use of a device for which an application is pending, provided the data are available for use under the FFD&C Act. (i.e. available by right of reference or in the public domain).

Section 202 - Special Review for Certain Devices -- Statutory burden

FDA will provide special review, which can include expedited processing of a Premarket Approval (PMA) application, for certain devices intended to treat or diagnose life threatening or irreversibly debilitating diseases or conditions. To receive special review, the devices must meet one of the following criteria:

1) The device represents a breakthrough technology;
2) There are no approved alternatives;
3) The use of the device offers significant advantages over existing approved alternatives; or
4) Availability is in the best interest of the patients.

Section 205 - Meeting on Evidence of Effectiveness for PMA's -- Statutory burden

Sponsors planning to submit a Premarket Approval Application (PMA) may submit a written request to FDA for a meeting to determine the type of information (valid scientific evidence) necessary to support the effectiveness of their device.

Section 208 - Classification Panels -- Statutory Burden

• Review by the Panel

PMA applicants shall have:

the same access as FDA to data and information submitted by FDA to a classification panel, except data not available for public disclosure;

the opportunity to submit information based on the PMA, through FDA, to the panel; and

the same opportunity as FDA to participate in panel meetings.

Section 209 - For PMA Collaborative Review Process -- Statutory Burden

FDA must, upon the written request of the applicant, meet with that party within 100 days of receipt of the filed PMA application to discuss the review status of the application. With the concurrence of the applicant, a different schedule may be established.

Prior to this meeting, FDA must inform the applicant in writing of any identified deficiencies and what information is required to correct those deficiencies. FDA must also promptly notify the applicant if FDA identifies additional deficiencies or of any additional information required to complete Agency review.

2. Purpose and Use of the Information

The data reported to FDA and the records that are maintained by the manufacturers allow FDA and industry to make decisions and take actions to protect the public health from defective medical devices.

The PMA regulation establishes procedures that FDA utilizes in approving, denying, or withdrawing approval of any PMA. It provides specific, clear, and flexible instructions to applicants so those respondents know what information is required in a PMA. PMA supplements are also used by FDA to determine any additional action the agency must take to protect the public health.

3. Use of Information Technology and Burden Reduction

FDA believes that the PMA regulation is flexible enough to allow for improved technology for data collection and is investigating several improved information

technologies and methods to reduce the burden placed on manufacturers of devices, such as electronic transfer and optical storage of documents.

In the Federal Register of March 20, 1997 (62 FR 13430), FDA issued a final regulation that will allow, under certain circumstances, the agency to accept electronic signatures and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These proposed regulations would apply to records, when submitted in electronic form, which are required in Title 21 of the Code of Federal Regulations (CFR). Petitioners may make use of electronic recordkeeping and reporting in accordance with this regulation.

FDA is also using information technology to assist in the reduction of 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 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.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only authorized Agency to regulate the manufacturer and distribution of medical devices. The information collected cannot be obtained from any other source other than the manufacturer, therefore this effort is not duplicated anywhere else.

No similar data are available to or collected by FDA because each PMA is product and manufacturer specific. Most information in a PMA is unique and is presented

to support claims of safety and effectiveness for that particular purpose.

5. Impact on Small Business or Other Small Entities

This information collection will have a minimal impact on a substantial number of small entities. The efforts described below help to assure that the burden on all manufacturers, including small manufacturers, are minimized.

The Program Operations Staff (POS) in the Office of Device Evaluation (ODE), FDA, routinely participates in conferences and device submission workshops designed to educate the medical device industry on how to prepare a PMA submission such that it can be filed and reviewed in an expeditious manner. POS also annually meets with organizations such as Advanced Medical Technology Association (Advamed), Medical Device Manufacturers Association (MDMA), or Regulatory Affairs Professional Society (RAPS) to discuss concerns regarding the PMA review process. FDA answers any questions that these organizations may have and provides them with information to improve their submissions. In addition, ODE also issues many device specific guidance documents and general guidance documents to assist the industry in improving the quality of their submissions.

FDA also maintains a fax on demand system (FACTS) which provides firms with information pertaining to medical devices and radiological health. FDA, as required by the 1976 Amendments to the Act, has established the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) to provide technical and non-technical assistance to small firms (and firms of any size) expressly to aid them in complying with requirements of the Act.

FDA also aids small business in dealing with the requirements of the regulations by providing guidance and information through the DSMICA, and through the scientific and administrative staff, and through the CDRH website at http://www.fda.gov/cdrh .

DSMICA participates in and presents conferences, workshops, and seminars on the application and interpretation of relevant regulations, consults with individual firms/sponsors, and develops and disseminates educational materials. Staff is available to respond to questions and a toll free telephone number was established to facilitate this communication link.

6. Consequences of Collecting the Information Less Frequently

Manufacturers determine when a product will be submitted for premarket approval. Notices and supplements are required only when an affected person or entity determines that a change in their device is necessary. FDA determines subsequent reporting requirements and their frequency based on the necessity for manufacturers to provide reasonable assurance of their device's continued safety and effectiveness.

If this information were not collected, FDA could not ensure that the devices were safe and effective.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5(d)(2).

Requirements under Section 5 CFR Part 1320.5(d)(2) are met with the exception regarding the number of copies of information submitted. 5 CFR 1320.5 requires that not more than one original and two copies be submitted.

FDA, however, requires under 21 CFR 814.20(b)(2) that each respondent must submit 6 copies of a PMA and 3 copies of a PMA supplement for review. FDA maintains the original PMA and PMA supplement in the PMA Document Mail Center in its Center for Devices and Radiological Health (CDRH). Additional copies of PMA's and PMA supplements are used for concurrent review by CDRH personnel such as the ODE Division, statisticians, GMP manufacturing inspection staff, and Bioresearch Monitoring. The final copy of a PMA or PMA supplement is

retained for team review by other statisticians, physicians, and scientists.

Few manufacturers have objected to the request for additional PMA and PMA supplement copies (or more if needed) because the review process has been substantially expedited to their advantage. If FDA were required to construct review copies for concurrent review by FDA personnel or advisory committee review, substantial delays would be anticipated due to lack of computer equipment and personnel to perform the copying and collation of the documents.

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

Notice has been published in the Federal Register on June 28, 2007 (72 FR 35494) soliciting comments on this information collection prior to its submission to the Office of Management and Budget (OMB). No comments were received.

POS annually meets with Advamed, MDMA, RAPS and others to discuss concerns regarding the PMA review process. FDA answers these organization's questions and provides them with information on improvement of their submissions. ODE also issues many device specific and general guidance documents, which assist industry in the improvement of the quality of their submissions, and communicates with affected persons regularly through these organizations and the Food and Drug Law Institute, an educational organization consisting primarily of attorneys practicing in the Food and Drug law area. Problems raised in these discussions have been addressed by the built-in flexibility provided by the PMA regulation.

The following groups were consulted in the past regarding this information collection.

Advance Medical Technology Association (AdvaMed)

Washington, DC
202-783-8700

W. L. Gore & Associates, Inc.
Elkton, MD 21921
Medical Products Division
410-392-7600

Hale & Dorr, LLP
Washington, DC
202-663-6000

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondent

Confidentiality of data and disclosure regarding the existence of a PMA are governed by 21 CFR 814.9, the Freedom of Information Act (FOIA) (5 U.S.C. 552), and sections 301(j) and 520(c) and (h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 331(j), 360(c) and (h)). Under FOIA, the public has broad access to government documents.

However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b) (1-9). One such provision, 5 U.S.C. 552(b) (4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure.

Section 520(c) of the Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4). Part 20 of FDA's regulations, 21

CFR Part 20, sets forth FDA's general policy concerning public availability of FDA records. Under section 520(h) of the Act, FDA is required to make publicly available a detailed summary of the safety and effectiveness information contained in a PMA that is the basis for an order approving, denying approval of, or withdrawing approval of a PMA.

11. Justification for Sensitive Questions.

The information required in a premarket approval or premarket supplement application does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

Respondents to this information collection are persons filing an application or a supplement with the Secretary of Health and Human Services for approval of a Class III medical Device.

The total estimated reporting and recordkeeping burden for this information collection is 97,690.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/FDAMA Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Responses	Total Hours
814.15(b)	10	1	10	2	20
814.20	48	1	48	668	32,064
814.37(a-c) and (e)	48	1	48	167	8,016
814.39(a)	460	1	460	60	27,600
814.39(d)	70	1	70	6	420
814.39(f)	254	1	254	16	4,064
814.82(a)(9)	34	1	34	135	4,590
814.84(b)	34	1	34	10	340
Section 201 (FDAMA) Agreement Meeting	3	1	3	50	150
Section 202 (FDAMA) ExpeditedReviewRequest	7	1	7	10	70
Section 205 (FDAMA) Effectiveness Meeting	5	1	5	50	250
Section 208 (FDAMA) Classification Panel Meetings	19	1	19	30	570
Section 209 (FDAMA) 100 day meeting	36	1	36	10	360
Totals	1,028	13	1,028	1,214	78,514

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.82(a)(5) and (a)(6)	1,128	1	1,128	17	19,176

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

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year (FY) annual rate of receipt of 48 PMA original applications, 530 PMA supplements, and 254 30-day notices using FY 2002 through 2006 data. The burden data for PMAs is

based on data provided by manufacturers by device type and cost element in an earlier study. The specific burden elements for which FDA has data are as follows:

- Clinical investigations--67 percent of total burden estimate;
- Submission of additional data or information to FDA during a PMA review--12 percent;
- Additional device development cost (e.g., testing)--10 percent; and
- PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data-- 11 percent.

Reporting Burden:

The reporting burden can be broken out by certain sections of the PMA regulation as follows:

§ 814.15--Research Conducted Outside the United States

Approximately 20 percent of the clinical studies submitted in support of a PMA application are conducted outside the United States. Each study should be performed in accordance with the "Declaration of Helsinki" or the laws and regulations of the country in which the study was conducted. If the study was conducted in accordance with the laws of the country, the PMA applicant is required to explain to FDA in detail the differences between the laws of the country and the "Declaration of Helsinki". Based on the number of PMAs received that contained studies from overseas, FDA estimates that the burden estimate necessary to meet this requirement is 20 hours.

§ 814.20 (a) through (c) and (e)--Application

The majority of the 32,064 hourly burden estimate is due in part to this requirement. Included in this requirement are theconduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 48 manufacturers, including hospital re-manufacturers of SUDs, will be affected by these requirements which are based on the actual average of FDA receipt of new PMA applications in FY 2002 through 2006. FDA's

estimate of the hours per response (668) was derived through FDA's experience and consultation with industry and trade associations. In addition, FDA also based its estimate on the results of an earlier study which accounts for the bulk of the hourly burden for this requirement, which is identified by manufacturers.

§ 814.37--PMA Amendments and Re-Submitted PMAs

As part of the review process, FDA often requests PMA applicant to submit additional information regarding the device necessary for FDA to file the PMA or to complete its review and make a final decision. The PMA applicant may, also on their own initiative, submit additional information to FDA during the review process. These amendments contain information ranging from additional test results, re-analysis of the original data set to revised device labeling. Almost all PMAs received by the agency have amendments submitted during the review process. FDA estimates that 8,016 burden hours are necessary to satisfy this requirement.

§ 814.39 (a)--PMA Supplements

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 20 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 27,600 hours of burden are needed to complete the requirements for regular PMA supplements.

§ 814.39(d)--Special PMA Supplements--Changes Being Affected

This type of supplements is intended to enhance the safety of the device or the safe use of the device. The number of PMA supplements received that fit this category averaged 70 per year based on the numbers received from FY 2002 through FY 2006. Because of the minimal data required to be included in this type of supplement, FDA estimates that the burden hours necessary to satisfy this requirement are 420 hours.

§ 814. 39(f)--30-Day Notice

Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under paragraph (a) of this section and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 (21 CFR part 820). The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice, that it is not adequate. FDA estimates the burden to satisfy this requirement is 4,064 hours.

§ 814.82 (a)(9)--Post-Approval Requirements

Post-approval requirements concerns approved PMAs that were not reclassified and require a periodic report. After approval, all PMAs require a submission of an annual report. On average, approximately half of the submitted PMAs (34), require associated post-approval studies, i.e., follow-up of patients used in clinical trials to support the PMA or additional preclinical information, that is labor-intensive to compile and complete; the remaining PMAs require minimal information. Based on experience and consultation with industry, FDA has estimated that preparation of reports and information required by this section requires 4,590 hours.

§ 814.84(b)--Reports

Post-approval requirements described in § 814.82 (a)(7) require submission of an annual report for each approved PMA. FDA estimates that respondents will average about 10 hours in preparing their reports to meet this requirement. This estimate is based on FDA's experience and consultation with industry. Thus, FDA estimates that the periodic reporting burden required by this section will take 340 hours.

Statutory Reporting Burden Estimate (FDAMA)

The total statutory reporting burden under the requirements of sections 201, 202, 205, 208, and 209 of FDAMA is estimated to be 1,400 hours. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was also derived to forecast future expectations with regard to this statutory data.

Recordkeeping:

§ 814.82 (a) (5) and (a)(6) The recordkeeping burden under this section requires the maintenance of records, used to trace patients and the organization and the indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions,70 percent of the PMAs are eventually approved with 75 percent of these having original clinical trial data. Therefore, approximately 34 PMAs a year would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of an active PMA application must maintain these records.

PMAs have been required since 1976, and there are 1,128 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 1,128 holders of approved original PMAs, therefore, is 19,176 hours.

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

Costs Estimates:

The cost estimate requirements for premarket approval of medical devices is approximately $60.9 million per year. The industry-wide cost estimate for PMA's is based on an FDA actual average fiscal year annual rate of receipt of 64 PMA original applications and 581 PMA supplements, using fiscal years 1998 through 2002 data.

The cost data for PMAs is based on data provided by manufacturers by device type and cost element in an earlier study. The specific cost elements for which FDA has data are as follows:

a Clinical investigations: 67% of total cost estimate

b Submitting additional data or information to FDA during a PMA review: 12%

c.Additional device development cost (e.g., testing): 10%

d. PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data: 11%.

A weighted-average calculation in an earlier study produced a total cost o f $280,000 for a PMA application. These cost estimates are considered to be solely

attributable to PMA requirements. FDA has adjusted these estimates for inflation (using an average of 7.5 percent per year for the health care sector) and multiplied it by 48 (the average number of PMAs submitted annually) to yield an annual cost attributable to PMAs of $45,696,000 ($280,000 x index of 3.4 x 48).

The estimated annual recordkeeping cost to the industry is $3,079,412, based on hourly burden presented in the burden charts. This amount is derived from the total burden hours (113,464 hours) multiplied by an average estimated industry cost of $27.14 per hour ($56,668 per staff year of 2080 hours). The average hourly cost includes overhead, technical staff, support staff, etc., and was based on the "United States Department of Labor Bureau of Labor Statistics News" (USDL 04-288, February 26, 2004), which can be access on the web at: http://www.bls.gov/news.release/pdf/ecec.pdf Using the information contained in the BLS News for the Health Care Industry, the FDA estimates that the average cost for respondents to prepare and submit records and reports is approximately $27.14 per hour (the average fully compensated pay per hour for technical Health Care Industry personnel).

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

There are no additional capital costs or operating/maintenance costs associated with this regulation.

14. Annualized Cost to the Federal Government

In September 2005, FDA published the results of a cost analysis report entitled "FY2003 – FY2004 Unit Cost for the Process of Medical Device Review" - http://www.fda.gov/cdrh/mdufma/fy2003-4costsop.html. In that report, it was estimated that each original PMA costs $563,000 and each PMA supplement costs $14,700. Based on this report, FDA estimates the costs for the PMA review process as follows:

	PMA	Cost/PMA	Total
Originals - 48		$563,000	$27,024,000
Supplements – 784		$14,7000	$11,524,800
			$38,548,800

15. Explanation for Program Changes or Adjustments

The burden represented by this collection has decreased by 15,774 (adjustment),because of a recalculation of the burden and a decrease in the hours per response.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the collection of information under these regulations for statistical use unless requested by Congress in accordance with Section 533 of the Act.

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.

B. Collection of Information Employing Statistical Methods.

There are no statistical methods being employed in this collection of information.