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 in 21 CFR Part 814 (Attachment A).

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.

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) 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 Information Collection 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) (Attachment C) 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.

21 CFR 814.15(a), (b), and (c) -Reporting

This section requires applicants conducting research outside the United States in support of a premarket approval application (PMA) to conduct such research in conformance with the "Declaration of Helsinki" or the laws and regulations of the country where the research is conducted, whichever affords greater protection to the research subjects. Applicants using foreign standards must detail any differences between those standards and the Declaration of Helsinki and explain why the standards offer greater protection to human subjects. For research conducted outside the United States that was started before November 19, 1986, FDA must be satisfied that the data is scientifically valid and that the rights, safety, and welfare of the subjects have not been violated.

21 CFR 814.20(b) – Reporting

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(c) and (e) – Reporting

This specifies the procedures for amending an incomplete PMA or resubmitting a withdrawn PMA.

21 CFR 814.39(a) 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 written notice must also state that the changes were made in accordance with the Quality Systems Regulations (GMPs). 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. The initial 30 day notification review period will be deducted from the 135 day supplement review period if the original notification meets the appropriate content requirements for a PMA supplement.

An example of changes which may potentially qualify for a 30-day notice are those designed to reduce manufacturing and/or labor cost, reduce manufacturing time, reduce waste, or compensate for a change in suppliers of raw material or components.

PMA supplements for incremental changes in design affecting safety and effectiveness can be approved based on non-clinical data that demonstrate the change creates the intended additional capacity, function, or performance of the device. They also contain clinical data included in the original PMA application or any supplement to that application that provides reasonable assurance of safety and effectiveness.

However, if needed, FDA may require a sponsor to submit new clinical data to demonstrate safety and effectiveness.

21 CFR 814.82(a)(2) – Reporting

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

21 CFR 814.82(a)(3) & (4) - Disclosure

This section requires labeling of a device and warnings, hazards, or precautions in the advertising of any restricted device, important to the device's safe and effective use.

Also, inclusion of identification codes on the device or its labeling or identification cards (if implant).

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

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.

21 CFR 814.82(a)(7) – Reporting

This requires submission to FDA of periodic postapproval reports as required by 814.84 below.

21 CFR 814.84(a)(b) – Reporting

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.

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 205 – Scope of Review/Collaborative Determinations of Device Data Requirements -

This section is now included as part of 21 CFR Part 814.39, as explained in the Federal Register on April 27, 1998 (63 FR 20530).

Section 207 - Risk Based Classification of Postamendment Class III Devices -- Statutory Burden

An applicant, who submits a Premarket Notification Submission [510(k)] and receives a Not Substantially Equivalent (NSE) determination, placing the device into a Class III category, can request FDA to classify the product into Class I or II.

The request must be in writing and sent within 30 days from the receipt of the NSE determination. In addition, the request must include a description of the device, reasons for the recommended classification (into Class I or II), and information to support the recommendation. Within 60 days from the date the written request is submitted to FDA, the Agency must classify the device by written order.

If FDA classifies the device into Class I or II, this device can be used as a predicate device for other 510(k)s. However, if FDA determines that the device will remain in Class III, the device cannot be distributed until the applicant has obtained an approved Premarket Approval (PMA) application or an approved Product Development Protocol (PDP).

Within 30 days of notifying the applicant of the determination that the device has been classified into Class I or Class II, FDA will announce the final classification in the Federal Register.

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 information collection requirements are either specifically called for in the Act or were developed to aid the Agency in performing its obligations under the Act. The requirements are placed upon manufacturers of medical devices. 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. FDA only relies upon valid scientific evidence to determine whether there is reasonable assurance that devices are safe and effective.

Manufacturers who believe that changes they intend to make qualify for this review must submit a 30-day notice to FDA. They must describe in detail the change the manufacturer intends to make, 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 FDA receives the notice, unless FDA notifies the applicant within that 30-day period that the notice is not adequate. If the notice is not adequate, FDA will inform the applicant in writing that a 135-day supplement is needed and will describe what further action or information is required for FDA to approve the change. The time FDA uses to review the 30-day notice will be deducted from the 135-day supplement review period if the notice contains the appropriate information that is required for review of PMA supplements. The provisions for a 30-day notice and 135-day PMA supplement are incorporated into FDA's regulations at Section 21 CFR 814.39.

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.

In addition, FDA is committed to meeting the provisions of the Government Paperwork Elimination Act (GPEA) by October, 2003, by setting up a mechanism which would allow for the electronic submission of documents to FDA to assist in respondent burden reduction. In the near future, this collection's information will be used on a pilot basis and stored on an electronic document management system. Success in this pilot project will assist FDA in meeting GPEA goals by 2003.

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

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

The FDA exercises caution and discretion when implementing additional reporting and recordkeeping requirements to industry. While FDA recognizes that submission of this data may be a hardship for small businesses, protection of public health requires periodic submission of product data to FDA. Every business, regardless of its size, should provide reasonable assurance of their device's safety and effectiveness before commercial marketing. In the last several years, on average, 47 percent of the PMAs received by FDA were from large manufacturers who had 500 or more employees; while only 34 percent of the PMAs were received from small manufacturers with fewer than 100 employees.

In regard to PMA supplements, the information process required for the supplements has simplified the procedure by which manufacturers may make changes to existing devices.

The Program Operations Staff (POS) in the Office of Device Evaluation (ODE) routinely participates in conferences and device submission workshops (e.g., Advamed PMA 101) 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 Advamed, MDMA, or 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 Division of Small Manufacturers, International, and Consumer Assistance (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. Additional information about DSMA may be obtained by logging onto the FDA's web site (http://www.fda.gov) and clicking on the Center for Devices and Radiological Health (CDRH) link. DSMICA and Office of Device Evaluation staff is available to answer manufacturer's questions in a timely manner.

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

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.

Requirements under Section 5 CFR Part 1320.5 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. This provision is reasonable and results in efficient and expeditious PMA reviews. . 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 April 5, 2004 (69 FR 17689) soliciting 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) (see Attachment D). No comments were received.

FDA, through its Center for Devices and Radiological Health (CDRH) and primarily through its Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), regularly meets, corresponds, and speaks with the industry on an informal basis through the use of its toll-free number. FDA also communicates informally through the many training sessions it holds throughout the country. ODE's POS staff participates in conferences and device submission workshops on a regular basis. These conferences and workshops are designed to educate the medical device industry on the preparation of a PMA submission which can be filed and reviewed in an timely

manner.

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 guidance documents 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. CDRH has issued general guidance in its "Premarket Approval Manual" (HHS Publication FDA 93-4214) and also in guidance for specific products such as its" Guidance for Class III Contact Lenses."
<http://www.fda.gov/cdrh/manual/pmamanul.pdf>

The following groups were consulted regarding this information collection.

Advance Medical Technology Association (AdvaMed)
Washington, DC
202-434-7228

W. L. Gore & Associates, Inc.
Elkton, MD 21921
Medical Products Division
410-398-6400

Hale & Dorr, LLP
Washington, DC
202-942-8488

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. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include entities meeting the definition of manufacturers such as manufacturers of commercial medical devices in distribution prior to May 28, 1979 (the enactment date of the Medical Device Amendments). Additionally, hospitals which re-use or re-manufacture single use devices (SUD's) are now included in the definition of manufacturers. For the next three years, it is expected that FDA will receive 4 PMA applications from hospitals remanufacturing SUD's. This figure has been included in the tables below.

The total estimated reporting and recordkeeping burden for this information collection is 107,321 hours.

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

Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours

814.15, 814.20, and 814.37	64	1	64	837	53,568
814.39(f)	581	1	581	66	33,346
814.82	45	1	45	135	6,075
814.84	45	1	45	10	450
Section 201 (FDAMA)	10	1	10	10	100
Section 202 (FDAMA)	15	1	15	10	150
Section 205 (FDAMA)	8	1	8	50	400
Section 208 (FDAMA)	26	1	26	30	780
Section 209 (FDAMA)	8	1	8	40	320
Totals					95,189

(Footnote) There are no capital costs or operating and maintenance costs associated with this collection.

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency of Record-keeping	Total Annual Records	Hours per Record-keeper	Total Hours
814.82 (a)(5) & (a)(6)	1,075	1	1,075	17	18,275
Totals					18,275

(Footnote) There are no capital costs or operating and maintenance costs associated with this collection.

FDA estimates that the cost to device manufacturers to comply with the 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 in 1985 by device type and cost element. 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 1985 produced a total cost of $280,000 for a PMA application. These cost estimates are considered to be solely attributable to PMA requirements. FDA does not have more recent data on the cost to manufacturers of collecting, analyzing, and preparing the data needed for a PMA submission. FDA has adjusted the 1985 estimate for inflation (using an average of 7.5 percent per year for the health care sector) and multiplied it by 64 (the average number of PMAs submitted annually) to yield an annual cost attributable to PMAs of $60,928,000 ($280,000 x index of 3.4 x 64).

Paperwork Burden Estimate

The estimated total annual reporting and recordkeeping burden for this information collection is 113,464 hours.

REPORTING/DISCLOSURE

The reporting burden can be broken out by certain sections of the PMA regulation.

Section 814.15 - Research Conducted Outside U.S.
Section 814.20 - Applications:
Section 814.37 - PMA Amendments and Resubmitted PMAs:

The majority of the burden - 53,568 burden hours - is due to the above three requirements. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 64 manufacturers (including hospital re-manufacturers of single use devices) will be affected by these requirements based on actual average FDA receipt of new PMA applications in fiscal years 1998 through 2002. FDA's estimate of the hours per response (837) was derived through FDA's experience and consultation with industry and trade associations. Included in these three requirements are the conduct of laboratory and clinical trails as well as the analysis, review, and physical

preparation of the PMA application. In addition, FDA has based its estimate on the results of an earlier study that these requirements account for the bulk of the burden identified by manufacturers.

21 CFR 814.39 - PMA Supplements: 33,346 burden hours

The amendments mandated by FDAMA for Section 814.39 (f), permitting the submission of the 30-day notices in lieu of PMA supplements, has resulted in an approximate ten percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 33,346 hours of burden are needed to complete the requirements for regular PMA supplements.

21 CFR 814.82 - Postapproval Requirements: 6,075 burden hours.

Postapproval requirements concern approved PMAs that were not reclassified and require an annual report. The range of PMAs that fit this category averaged approximately 45 per year (70 percent of the 64 average annual submissions). Most approved PMAs have been subject to some restriction. Approximately half of the average submitted PMAs (32) require associated postapproval information (i.e., clinical trials or additional pre-clinical information) that is labor-intensive to compile and complete, and the other PMAs require minimal information. Based on its experience and on consultation with industry, FDA estimates that preparation of reports and information required by this section require 6,075 hours (135 hours per respondent).

21 CFR 814.84 - Reports: 450 burden hours.

Postapproval requirements described in 21 CFR 814.82 (above) require a periodic report. FDA has determined respondents meeting the criteria of 21 CFR 814.84 will submit reports on an annual basis. As stated previously, the range of PMAs fitting this category average approximately 45 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by this section take 450 hours.

Statutory Burden: The total hours for statutory burden is 1,750.

RECORDKEEPING

The recordkeeping burden in this section involves the maintenance of records to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records would be 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 and 75 percent of those have original clinical trial data. Therefore, approximately 45 PMAs a year (64 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements

apply to all active PMAs, all holders of active PMA applications must maintain these records. PMAs have been required since 1976, and there are 1,075 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 1,075 holders of approved original PMAs, therefore, is 18,275 hours (1,075 approved PMAs with clinical data x 17 hours per PMA).

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 (21 CFR 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 to approval to ensure the device's continuing safety and effectiveness.

The burden estimates were derived by consultation with FDA and industry personnel. FDA's estimates are based on actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals.

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 or operating/maintenance costs associated with this regulation.

14. Annualized Cost to the Federal Government

FDA estimates that approximately 211 staff-years are devoted to the activity annually, at a cost of $22.6 million. The average time modules for the activity are 1.2 staff-years for a PMA review and 0.1 staff-years for a supplemental PMA. The cost estimate includes FDA staff effort and advisory panel costs for those PMA's requiring panel review under the law, as changed by the Safe Medical Devices Act of 1990.

FTEs	Cost/FTE	Total Cost
211	$107,000	$22,577,000

15. Explanation for Program Changes or Adjustments

The burden represented by this collection has increased by 6,143 hours (113,464 – 107,321) since the last time OMB-approved this information collection because this collection includes the additional PMA's expected from Hospital remanufacturers of SUD's, and reflects the trend of increasing PMA applications.

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.

Information submitted which is found susceptible to tabulation for statistical purposes may be tabulated in accordance with program needs, however, there are no statistical methods being employed in this collection of information.

List of Attachments to Supporting Statement

Attachment A - Code of Federal Regulations (21 CFR Part 814)
Attachment B - The Federal Food, Drug, and Cosmetic Act, Section 515 (21 U.S.C. 360(e))
Attachment C - The Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105-115)
Attachment D - Federal Register 60 day Notice Soliciting Comments on "Premarket Approval of Medical Devices –21 CFR 814", [February 8, 2001], 66 FR 9582, Docket No. 01N-0050.