TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	10	20	200	14	2,800
312.32(c)(1)(ii) and (c)(1)(iii)—IND Safety Reports [2]	100	6	600	12	7,200
312.32(c)(1)(iv)—IND Safety Reports [3]	10	1	10	12	120
Total					10,120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information. The estimates are for the additional burdens beyond those already approved for current §§ 312.32 and 312.64.

[2] Includes reports based on findings suggesting a significant risk in humans from epidemiological studies, pooled analysis of multiple studies, other clinical studies, or in vitro testing. Reports from animal testing are not included.

[3] Includes reports of clinically important increases in the rate of occurrence of serious, expected suspected adverse reactions.

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25959 Filed 10–30–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0825]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 2, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0231. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Approval of Medical Devices—(OMB Control Number 0910–0231)—Extension

Under section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e) all devices placed into class III by FDA are subject to premarket approval requirements. Premarket approval (PMA) 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 (21 U.S.C. 351(f)) 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 issuance 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 issuance 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 (21 U.S.C. 360(k)). 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) (Pub. L. 105–115) was enacted on November 21, 1997, to implement revisions to the FD&C Act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. FDAMA added section 515(d)(6) to the FD&C Act, 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 part 814 (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 PMAs. The regulations' purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for class III medical devices. The regulations facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the denial of PMAs and supplements to PMAs for devices that have not been

shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year (FY) annual rate of receipt of PMA submissions data FY 2010 through 2012 and our expectations of submissions to come in the next few years. The burden data for PMAs is based on data provided by applicants by device type and cost element in an earlier study.

Reporting Burden: The reporting burden can be broken out by certain sections of the PMA regulations and the FD&C Act as follows:

§ 814.15(b)—Research Conducted Outside the United States

Each foreign 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 50 hours.

§ 814.20—Application

Included in this requirement are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 40 applicants, including hospital re-manufacturers of single use devices, will be affected by these requirements which are based on the actual average of FDA receipt of new PMA applications in FY 2010 through 2012. 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 applicants.

§ 814.37(a) Through (c) and (e)—PMA Amendments and Resubmitted PMAs

As part of the review process, FDA often requests the 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 20,040 burden hours are necessary to satisfy this requirement.

§ 814.39(a)—PMA Supplements

FDA believes that 39,000 burden hours are needed to complete the requirements for the range of PMA supplements (180-day fee-based, 180-day non-fee based, and real-time 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 80 per year based on the numbers received from FY 2010 through FY 2012. 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 480 hours.

§ 814.39(f)—30-Day Notice

Under section 515(d) of the FD&C 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 applicant 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 24,000 hours.

§ 814.82(a)(9)—Postapproval Requirements

Postapproval requirements concerns approved PMAs that were not reclassified and require a periodic report. After approval, all PMAs require a submission of an annual report. A majority of the submitted PMAs require associated postapproval studies, i.e., followup 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 31,050 hours.

§ 814.84(b)—Periodic Reports

Postapproval 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 6,000 hours.

Expedited or Priority Review—Section 515(d)(5) of the FD&C Act

FDA will provide special review, which can include expedited processing of a 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:

- The device represents a breakthrough technology.
- There are no approved alternatives.
- The use of the device offers significant advantages over existing approved alternatives.
- Availability is in the best interest of the patients.

Agreement Meeting—Section 520(g)(7) of the FD&C Act (21 U.S.C. 360j(g)(7))

Applicants planning to submit a PMA may submit a written request to reach agreement with FDA on the key parameters of the investigational plan.

Determination Meeting—Section 513(a)(3)(D) of the FD&C Act (21 U.S.C. 360c(a)(3)(D))

Applicants planning to submit a 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.

Panel of Experts—Section 515(c)(3) of the FD&C Act

An original PMA or panel track PMA supplement is taken to an advisory panel of experts unless FDA determines that the information in the application substantially duplicates information which has previously been reviewed by the panel.

Day 100 Meeting—Section 515(d)(3) of the FD&C Act

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.

Recordkeeping

§ 814.82(a)(5) and (a)(6)—Maintenance of Records

The recordkeeping burden under this section requires the maintenance of records, used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required of all applicants who have an approved PMA.

PMAs have been required since 1976, and there are 556 active PMAs that could be subject to these requirements, based on actual FDA data, and approximately 25 new PMAs are approved every year. The aggregate burden for the estimated 600 PMA holders of approved original PMAs for the next few years is estimated to be 10,200 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 (21 CFR 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.

In the **Federal Register** of July 23, 2013 (78 FR 44128), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR or FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Research conducted outside the United States (814.15(b))	25	1	25	2	50
PMA application (814.20)	40	1	40	668	26,720
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e))	120	1	120	167	20,040
PMA supplements (814.39(a))	650	1	650	60	39,000
Special PMA supplement—changes being affected (814.39(d))	80	1	80	6	480
30-day notice (814.39(f))	1,500	1	1,500	16	24,000
Postapproval requirements (814.82(a)(9))	230	1	230	135	31,050
Periodic reports (814.84(b))	600	1	600	10	6,000
Agreement meeting (520(g)(7))	3	1	3	50	150
Expedited review request (515(d)(5) of the FD&C Act)	5	1	5	10	50
Determination Meeting (513(1)(3)(D) of the FD&C Act)	5	1	5	50	250
Panel meeting (515(c)(3) of the FD&C Act)	10	1	10	30	300
Day 100 meeting (515(d)(3) of the FD&C Act)	10	1	10	10	100
Total					148,190

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of records (814.82(a)(5) and (a)(6))	600	1	600	17	10,200

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

Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25960 Filed 10–30–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Grant Funds

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Deviation: Non-Competitive Expansion Supplement Funds to the Healthcare Systems Bureau (HSB).

SUMMARY: HRSA will be issuing a non-competitive award to the Children's Hospital of Alabama's Regional Poison Control Center. The 11-month award for $126,144 will be made available in the form of a supplement to grant funds to the organization's current grant, H4BHS15500. Effective October 1, 2013, the Regional Poison Control Center will be Alabama's sole poison control center. The center's responsibility to provide poisoning triage and treatment to half the state will be expanded to the entire state. The grant supplement will allow