

Dated: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0825]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for premarket approval of medical devices.

**DATES:** Submit either electronic or written comments on the collection of information by September 23, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [daniel.gittleson@fda.hhs.gov](mailto:daniel.gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Premarket Approval of Medical Devices—21 CFR Part 814 and Federal Food, Drug, and Cosmetic Act Sections 513, 515, and 520 (OMB Control Number 0910-0231)—Extension

Under section 515 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(e)) 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. 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) 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 (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 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 Re-Submitted 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)—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. A majority of the submitted PMAs require associated post-approval 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**

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 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, or
- Availability is in the best interest of the patients.

#### **Agreement Meeting—Section 520(g)(7) of the FD&C Act**

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**

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.

PMA's have been required since 1976, and there are 556 active PMA's that could be subject to these requirements, based on actual FDA data, and approximately 25 new PMA's are approved every year. The aggregate burden for the estimated 600 PMA holders of approved original PMA's 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 (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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 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 PMA's (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            |
| <b>Total</b> .....   |                       |                                    |                        |                             | <b>148,190</b> |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 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      |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 16, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2013–N–0804]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an

opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on medical device premarket notification.

**DATES:** Submit either electronic or written comments on the collection of information by September 23, 2013.