

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		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.

**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 Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [daniel.gittleston@fda.hhs.gov](mailto:daniel.gittleston@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 Notification—21 CFR Part 807, Subpart E (OMB Control Number 0910-0120)—Extension**

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) requires a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol, Humanitarian Device Exemption (HDE), Petition for Evaluation of Automatic Class III Designation (de novo), or be reclassified into class I or class II before being marketed. FDA makes the final decision of whether a device is substantially equivalent or not equivalent.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is: (1) Introducing a device to the market for the first time; (2) introducing a device into commercial distribution for the first time by a person who is required to register; and (3) introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Form FDA 3514, a summary cover sheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, and HDEs. Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement). If the

510(k) submitter includes a 510(k) statement in the 510(k) submission, § 807.93 requires that the official correspondent of the firm make available within 30 days of a request all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any person within 30 days of a request if the device described in the 510(k) submission is determined to be substantially equivalent. The information provided will be a duplicate of the 510(k) submission including any safety and effectiveness information, but excluding all patient identifiers and trade secret and commercial confidential information.

Section 204 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105-115) amended section 514 of the FD&C Act (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. Form FDA 3654, the 510(k) Standards Data Form, standardizes the format for submitting information on consensus standards that a 510(k) submitter chooses to use as a portion of their premarket notification submission (Form FDA 3654 is not for declarations of conformance to a recognized standard). FDA believes that use of this form will simplify the 510(k) preparation and review process for 510(k).

Under § 807.90, submitters may request information on their 510(k) review status 90 days after the initial login date of the 510(k). Thereafter, the submitter may request status reports every 30 days following the initial status request. To obtain a 510(k) status report, the submitter should complete the status request form, Form FDA 3541, and fax it to the Center for Devices and Radiological Health office identified on the form.

The most likely respondents to this information collection will be specification developers and medical device manufacturers.

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

Activity/21 CFR part/section/form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
510(k) submission (807 subpart E) .....	3,900	1	3,900	79	308,100
Summary cover sheet (807.87) and FDA 3514	1,956	1	1,956	0.5 (30 minutes)	978
Status request (807.90(a)(3)) and FDA 3541 ..	218	1	218	0.25 (15 minutes)	55
Standards (807.87(d) and (f)); FDA 3654 .....	2,700	1	2,700	10	27,000
510(k) summary and statement (807.92 and 807.93) .....	225	10	2,250	10	22,500
<b>Total</b> .....					<b>358,633</b>

<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-0001]

**Food Advisory Committee; Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Food Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 23 and 24, 2013, from 8:30 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Karen Strambler, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740,

[FoodAdvisoryCommittee@fda.hhs.gov](mailto:FoodAdvisoryCommittee@fda.hhs.gov), 240-402-2589 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On September 23 and 24, 2013, the Food Advisory Committee will meet to discuss detection signals for noteworthy chemical hazards in foods, dietary supplements, and cosmetics and consider possible sources of information, data on chemical hazards, and how CFSAN might recognize and best take advantage of those data.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 16, 2013. Oral presentations from the public will be scheduled between approximately 11

a.m. to 12 p.m. on September 24, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 26, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 9, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Strambler at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 17, 2013.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
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