TABLE 1—ESTIMATED HOUR BURDEN AND COST FOR RECRUITMENT SUBSTUDY RESPONDENTS—STAGE 1—Continued

[July 2010 to December 2010]

Recruitment strategy/activity	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
Low-intensity CATI Questionnaire	Age-Eligible Women	10,057	1	0.5	5,028
PPG Follow Up Script	Age-Eligible Women	10,057	6	0.1	6,034
Pregnancy Activities					
Low-intensity CATI Questionnaire	Pregnant Women	518	1	0.5	259
Birth-Related Activities					
Low-intensity CATI Questionnaire	Mother/Baby	166	1	0.5	83
Total—Stage 1		97,598			37,709
Two Tier (High): 10 Study Locations Across Both Tiers—Projected for Stage 1 (July 2010–December 2010)					
Screening Activities					
Pregnancy Screening	Age-Eligible Women	15,840	1	0.42	6,653
Preconception Activities					
Pre-Pregnancy Interview	Age-Eligible Women	761	1	0.75	571
PPG Follow Up Script	Age-Eligible Women	761	6	0.1	456
Pregnancy Activities					
Women's Informed Consent Form	Pregnant Women	9,504	1	0.67	6,368
First Pregnancy Interview	Pregnant Women	3,552	1	1	3,552
Second Pregnancy Interview	Pregnant Women	3,552	1	0.75	2,664
Birth-Related Activities					
Birth Visit Interview	Mother/Baby	1,857	1	0.4	743
Total—Stage 1		35,826			21,006
Grand Total, Recruitment Substudy.		334,308			176,876

The estimated annualized cost to respondents is $1,782,053 based on the differential hourly rate estimates in the above table. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Sarah L. Glavin, Ph.D., National Institute of Child Health and Human Development, 31 Center Drive, Room 2A18, Bethesda, Maryland, 20892, or call non-toll free number (301) 496–1877, or e-mail your request, including your address to *glavins@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: June 2, 2010.

Sarah L. Glavin,

NICHD Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–13705 Filed 6–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0250]

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 August 9, 2010.

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*.

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 /Food and Drug Administration Modernization Act of 1997 (FDAMA) Sections 201, 202, 205, 208, and 209 (OMB Control Number 0910–0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either pre-amendments devices that have been classified into class III, or post-amendments devices which are not substantially equivalent to a pre-amendments device, or transitional devices. Class III devices are devices such as implants, life sustaining or life supporting devices, and/or devices which otherwise present a potentially unreasonable risk of illness or injury, and/or are of substantial importance in preventing impairment of human health. Most premarket approval applications (PMAs) are for post-amendments class III devices.

Under section 515 of the act, an application must contain certain specific information, including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties of the principles of operation for such a device. In addition, the application should also include a full description of the methods used in, and the facilities and controls used for the manufacture and processing of the device and labeling specimens. The implementing regulations, contained in part 814 (21 CFR part 814), further specifies the contents of a PMA for a class III medical device and the criteria FDA sets forth in approving, denying, or withdrawing approval of a PMA as well as supplements to PMAs. The purpose of this regulation is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval) medical devices. The regulations under part 814 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 disapproval 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. FDAMA (Public Law 105–115) was enacted on November 21, 1997, to implement revisions to the 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, such as section 515(d)(6) of the act. This section provided that PMA supplements were required for all device changes that affect safety and effectiveness of a device unless such changes are modifications to manufacturing procedures or method of manufacture. This type of manufacturing change now requires a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

To make the PMA process more efficient, in the past several years FDA has done the following: (1) Made changes to the PMA program based on comments received, (2) complied with changes to the program mandated by FDAMA and the Medical Device User Fee Modernization Act, and (3) worked toward completion of its PMA reinvention efforts.

Respondents to this information collection are persons filing a PMA application or a PMA supplement with FDA for approval of certain class III medical devices. 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, 1976 (the enactment date of the Medical Device Amendments). In addition, hospitals that reuse single use devices (SUDs) are also included in the definition of manufacturers. It is expected that FDA will receive one PMA application from hospitals that remanufacture SUDs annually. This figure has been included in table 1 of this document, as part of the reporting burden in § 814.20.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ FDAMA Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.15(b)	8	1	8	2	16

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section/ FDAMA Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.20	36	1	36	668	24,048
814.37(a) through (c) and (e)	36	1	36	167	6,012
814.39(a)	670	1	670	60	40,200
814.39(d)	68	1	68	6	408
814.39(f)	505	1	505	16	8,080
814.82(a)(9)	18	1	18	135	2,430
814.84(b)	648	1	648	10	6,480
Section 201 (FDAMA) Agreement Meeting	3	1	3	50	150
Section 202 (FDAMA) Expedited Review Request	5	1	5	10	50
Section 205 (FDAMA) Effectiveness Meeting	5	1	5	50	250
Section 208 (FDAMA) Classification Panel Meetings	20	1	20	30	600
Section 209 (FDAMA) 100-day meeting	28	1	28	10	280
Totals	2,050	13	2,050	1,214	89,004

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.82(a)(5) and (a)(6)	698	1	698	17	11,866

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

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year (FY) annual rate of receipt of 36 PMA original applications, 532 PMA supplements, and 505 30-day notices using FY 2005 through 2009 data. The burden data for PMAs is based on data provided by manufacturers by device type and cost element in an earlier study. The specific burden elements for which FDA has data are as follows:

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

Reporting Burden

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

- *§ 814.15—Research Conducted Outside the United States*

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

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

The majority of the 24,048 hourly burden estimate is due in part to this requirement. 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 36 manufacturers, including hospital re-manufacturers of SUDs, will be affected by these requirements which are based on the actual average of FDA receipt of new PMA applications in FY 2005 through 2009. FDA's estimate of the hours per response (668) was derived through FDA's experience and consultation with industry and trade associations. In addition, FDA also based its estimate on the results of an earlier study which accounts for the bulk of the hourly burden for this requirement, which is identified by manufacturers.

- *§ 814.37—PMA Amendments and Resubmitted PMAs*

As part of the review process, FDA often requests PMA applicant to submit

additional information regarding the device necessary for FDA to file the PMA or to complete its review and make a final decision. The PMA applicant may, also on their own initiative, submit additional information to FDA during the review process. These amendments contain information ranging from additional test results, re-analysis of the original data set to revised device labeling. Almost all PMAs received by the Agency have amendments submitted during the review process. FDA estimates that 6,012 burden hours are necessary to satisfy this requirement.

• *PMA Supplements in § 814.39(a)*

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 20 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 40,200 hours of burden are needed to complete the requirements for regular PMA supplements.

• *Special PMA Supplements—Changes Being Affected in § 814.39(d)*

These types of supplements are 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 68 per year based on the numbers received from FY 2005 through FY 2009. 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 408 hours.

• *30–Day Notice in § 814.39(f)*

Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under § 814.39(a) and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 (21 CFR part 820). The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice, that it is not adequate. FDA estimates the burden to satisfy this requirement is 8,080 hours.

• *Post-Approval Requirements in § 814.82(a)(9)*

Post-approval requirements concern approved PMAs that were not reclassified and require a periodic report. After approval, all PMAs require a submission of an annual report. On average, approximately half of the submitted PMAs (18), 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 2,430 hours.

• *Reports in § 814.84(b)*

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 6,480 hours.

Statutory Reporting Burden Estimate (FDAMA)

The total statutory reporting burden under the requirements of sections 201, 202, 205, 208, and 209 of FDAMA is estimated to be 1,230 hours. This burden estimate was based on actual real and estimated FDA data tracked from FY 2005 through FY 2009, and an estimate was also derived to forecast future expectations with regard to this statutory data.

Recordkeeping in § 814.82(a)(5) and (a)(6)

The recordkeeping burden under this section requires the maintenance of records, used to trace patients and the organization and the indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved with 90 percent of these having original clinical trial data. Therefore, approximately 25 PMAs a year would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of an active PMA application must maintain these records.

PMAs have been required since 1976, and there are 698 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 698 holders of approved original PMAs, therefore, is 11,866 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.

Dated: June 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13763 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–E–0165 and FDA–2009–E–0169]

Determination of Regulatory Review Period for Purposes of Patent Extension; ABLAVAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ABLAVAR (previously the trade name of the product was VASOVIST) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims the human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.