DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0015]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adoption of Food and Drug Administration Food Code by Local, State and Tribal Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adoption of FDA Food Code by Local, State and Tribal Governments'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 13, 2007 (72 FR 18659), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0448. The approval expires on June 30, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 21, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0231]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pre-market 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 information collection requirements for premarket approval of medical devices.

DATES: Submit written or electronic comments on the collection of information by August 27, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Pre-market Approval of Medical Devices—21 CFR Part 814 / FDAMA Sections 201; 202; 205; 208; 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 pre-market 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 pre-market 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 (pre-market 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.

The Food and Drug Modernization Act of 1997 (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 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 four PMA applications from hospitals that remanufacture SUDs annually. This figure has been included in table 1 of this document, as part of the reporting burden in § 814.15.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part 800/ Section/FDAMA	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Responses	Total Hours
814.15(b)	10	1	10	2	20
814.20	48	1	48	668	32,064
814.37(a-c) and (e)	48	1	48	167	8,016
814.39(a)	460	1	460	60	27,600
814.39(d)	70	1	70	6	420
814.39(f)	254	1	254	16	4,064
814.82(a)(9)	34	1	34	135	4,590
814.84(b)	34	1	34	10	340
Section 201 (FDAMA) Agreement Meeting	3	1	3	50	150
Section 202 (FDAMA) Expedited Reviews	7	1	7	10	70
Section 205 (FDAMA) Determination Meeting	5	1	5	50	250
Section 208 (FDAMA) Classification Panel Meetings	19	1	19	30	570
Section 209 (FDAMA) 100 day meeting	36	1	36	10	360
Totals	1,028	13	1,028	1,214	78,514

[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 Part 800	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
842 (a) (5) & (6)	1,128	1	1,128	17	19,176

[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 48 PMA original applications, 530 PMA supplements, and 254 30-day notices using FY 2002 through 2006 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.

§ 814.20 (a) through (c) and (e)—Application

The majority of the 32,064 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 48 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 2002 through 2006. 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, identified by manufacturers.

§ 814.37—PMA Amendments and Re-Submitted 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 8,016 burden hours are necessary to satisfy this requirement.

§ 814.39 (a)—PMA Supplements

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 27,600 hours of burden are needed to complete the requirements for regular PMA 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 70 per year based on the numbers received from FY 2002 through FY 2006. 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 420 hours.

§ 814.39(f)—30-Day Notice

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 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 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 4,064 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. On average, approximately half of the submitted PMAs (34), require associated post-approval studies, i.e., follow-up 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 4,590 hours.

§ 814.84(b)—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 340 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 1,400 hours. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was also derived to forecast future expectations with regard to this statutory data.

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

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 75 percent of these having original clinical trial data. Therefore, approximately 34 PMAs a year (48 annual submissions x 70 percent), 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 1,128 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 1,128 holders of approved original PMAs, therefore, is 19,176 hours (1,127 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 (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 21, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for a Nonvoting Industry Representative on the Allergenic Products Advisory Committee and Request for Nominations for a Nonvoting Industry Representative on the Allergenic Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on its Allergenic Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nomination will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating the interest to FDA by July 30, 2007, for vacancies listed in the notice. Concurrently, nomination material for prospective candidates should be sent to FDA by July 30, 2007.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Gail Dapolito (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Gail Dapolito, Center for Biologics Evaluation and Research, Food and Drug Administration (HFM–71), 1401 Rockville Pike, Rockville, MD 20892, 301–827–1289, *gail.dapolito@fda.hhs.gov*

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act of 1997 (FDAMA) (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the biologic manufacturing industries. Although not required for existing committees, to keep within the spirit of FDAMA, the agency intends to add nonvoting industry representatives to its CBER advisory committee identified below.

I. CBER Allergenic Products Advisory Committee

The Committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner of Food and Drugs of its findings regarding the affirmation or revocation of biological product licenses, on the safety, effectiveness, and labeling of the products, on clinical and laboratory studies of such products, on amendments or revisions to regulations governing the manufacture, testing and licensing of allergenic biological products, and on the quality and relevance of FDA's research programs which provide the scientific support for regulating these agents.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **ADDRESSES**) within 30 days of publication of this document. Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the Allergenic Products Advisory Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person within the 30 days. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages, nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the allergenic product manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 21, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

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