for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product PLEGRIDY (peginterferon beta–1a). PLEGRIDY is indicated for treatment of patients with relapsing forms of multiple sclerosis. Subsequent to this approval, the USPTO received patent term restoration applications for PLEGRIDY (U.S. Patent Nos. 7,446,173; 8,017,733; and 8,524,660) from Biogen Idec MA Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 15, 2015, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of PLEGRIDY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for PLEGRIDY is 2,643 days. Of this time, 2,186 days occurred during the testing phase of the regulatory review period, while 457 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* May 23, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 23, 2007.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): May 16, 2013. FDA has verified the applicant's claim that the biologics license application (BLA) for PLEGRIDY (BLA 125499) was initially submitted on May 16, 2013.

3. *The date the application was approved:* August 15, 2014. FDA has verified the applicant's claim that BLA 125499 was approved on August 15, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,284 days, 762 days, or 346 days of patent term extension, respectively.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25222 Filed 10–18–16; 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; 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 December 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0825 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Approval of Medical Devices'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@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—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 average fiscal year (FY) annual rate of receipt of PMA submissions data FY 2013 through 2015 and our expectation 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 35 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 2013 through 2015. 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 that 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.

§ 814.39(a)—PMA Supplements. This information collection includes the requirements for the range of PMA supplements (panel track, 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 supplement 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 88 per year based on the numbers received from FY 2013 through FY 2015. 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 528 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.

§ 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.

§ 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.

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 725 active PMAs that could be subject to these requirements, based on actual FDA data, and approximately 30 new PMAs are approved every year. The aggregate burden for the estimated 422 PMA holders of approved original PMAs for the next few years is estimated to be 7,174 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.

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)	35	1	35	668	23,380
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e))	1,222	1	1,222	167	204,074
PMA supplements (814.39(a))	695	1	695	60	41,700
Special PMA supplement—changes being affected (814.39(d))	88	1	88	6	528
30-day notice (814.39(f))	1,710	1	1,710	16	27,360
Postapproval requirements (814.82(a)(9))	340	1	340	135	45,900
Periodic reports (814.84(b))	695	1	695	10	6,950
Agreement meeting (520(g)(7))	1	1	1	50	50
Expedited review request (515(d)(5) of the FD&C Act)	6	1	6	10	60
Determination Meeting (513(1)(3)(D) of the FD&C Act)	1	1	1	50	50
Panel meeting (515(c)(3) of the FD&C Act)	9	1	9	30	270
Day 100 meeting (515(d)(3) of the FD&C Act)	19	1	19	10	190
Total					350,562

[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))	422	1	422	17	7,174

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

Dated: October 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25232 Filed 10–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Applications From Individuals Interested in Being Appointed to the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

Authority: 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office of the Assistant Secretary for Health (OASH), within the Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Chronic Fatigue Syndrome Advisory Committee (CFSAC). CFSAC provides advice and recommendations to the Secretary of HHS, through the Assistant Secretary for Health (ASH), on a broad range of issues and topics related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The appointments of two Committee members are scheduled to end during the 2016 calendar year. Nominations of qualified candidates are being sought to fill the positions that are scheduled to be vacated.

DATES: Applications for individuals to be considered for appointment to the Committee must be received no later than 5 p.m. EDT on November 18, 2016 at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Commander, (CDR) Gustavo Seinos, MPH, Designated