

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 725 active PMA’s that could be subject to these requirements, based on actual FDA data, and approximately 30 new PMA’s are approved every year. The aggregate burden for the estimated 422 PMA holders of approved original PMA’s 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 PMA’s (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.

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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

Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 712E, Washington, DC 20201. Nomination materials, including attachments, may be submitted electronically to cfsac@hhs.gov.

FOR FURTHER INFORMATION CONTACT: CDR Gustavo Seinos, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201. Inquiries may also be made to cfsac@hhs.gov.

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of HHS, through the ASH, on issues related to ME/CFS. The CFSAC advises and makes recommendations on a broad range of topics including: (1) Opportunities to improve knowledge and research about the epidemiology, etiologies, biomarkers and risk factors for ME/CFS; (2) research on the diagnosis, treatment, and management of ME/CFS and potential impact of treatment options; (3) strategies to inform the public, health care professionals, and the biomedical academic and research communities about ME/CFS advances; (4) partnerships to improve the quality of life of ME/CFS patients; and (5) strategies to insure that input from ME/CFS patients and caregivers is incorporated into HHS policy and research. The CFSAC charter is available at: <http://www.hhs.gov/advcomcfs/charter/index.html>.

Management and support services for Committee activities are provided by staff from within the OASH. The ASH provides direction and guidance for services performed to support CFSAC activities and operation.

Nominations: OASH is requesting nominations to fill CFSAC positions scheduled to be vacated at the end of 2016. The Committee composition consists of seven scientists with demonstrated expertise in biomedical research applicable to ME/CFS, four individuals with demonstrated expertise in health care delivery, private health care services, insurance, and three patients/care givers of ME/CFS. The vacant positions are in the biomedical research category. Individuals selected for appointment to the Committee will serve as voting members and may be

invited to serve terms of up to four years.

CFSAC members are authorized to receive a stipend for conducting Committee related business, including attending Committee meetings. Committee members also are authorized to receive per diem and reimbursement for travel expenses incurred for conducting Committee related business. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and knowledge in the designated fields or disciplines, as well as expert knowledge of the broad issues and topics pertinent to ME/CFS.

Nomination materials should be typewritten. If mailed, please submit original documents. The nomination materials should be submitted (postmarked or received) no later than 5:00 p.m. EDT on the specified date. The following information must be part of the nomination package submitted for each individual being nominated: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.*, specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, and daytime telephone number; (3) the home and/or work address, telephone number, and email address of the individual being nominated; and (4) a current copy of the nominee's curriculum vitae or resume, which should not exceed 10 pages. An individual may self-nominate. Federal employees should not be nominated for consideration of appointment to this Committee. Nominations that do not contain all of the above information will not be considered.

Electronic submissions: Nomination materials, including attachments, may be submitted electronically to cfsac@hhs.gov.

Regular, Express, or Overnight Mail: Written documents may be submitted to the following addressee only: CDR Gustavo Seinos, MPH, Designated Federal Officer, CFSAC, Office on Women's Health, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201.

Telephone and facsimile submissions cannot be accepted.

Appointment to the Committee is made by the Secretary of HHS. The Department makes every effort to ensure that the membership of federal advisory committees is fairly balanced in terms of points of view represented. Every effort

is made to ensure that a broad representation of geographic areas, females, ethnic and minority groups, and people with disabilities are given consideration for membership on federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. Nominations must state that the nominee is willing to serve as a member of CFSAC and appears to have no conflict of interest that would preclude membership. Candidates who are selected for appointment to the Committee are required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts for an ethics analysis to be conducted to identify potential conflicts of interest.

Dated: October 14, 2016.

Nicole Greene,

Deputy Director, Office on Women's Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Human Genome Research Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL HUMAN GENOME RESEARCH INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Human Genome Research Institute.

Date: November 1-2, 2016.

Time: November 1, 2016, 6:00 p.m. to 9:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.