5. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to citizen petitions.

6. Supplements to petitions for stay of agency action.

7. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to petitions for stay of agency action.

8. The letter submitted by a petitioner withdrawing a deficient petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act.

Section 505(q)(1)(B) and (C) of the FD&C Act and the guidance state that if FDA determines that a delay in approval of an ANDA, section 505(b)(2) application, or biosimilar biological product application is necessary based on a petition subject to section 505(q), the applicant may submit to the petition docket clarifications or additional data to allow FDA to review the petition promptly. This information collection is not included in this analysis because it is approved under OMB control number 0910–0001.

In the **Federal Register** of October 1, 2013 (78 FR 60288), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received that pertained to the information collection analysis.

Based on FDA's knowledge of citizen petitions and petitions for stay of agency action subject to section 505(q) of the FD&C Act that have been submitted to FDA, as well as the Agency's familiarity with the time needed to prepare a supplement, a certification, and a verification, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification for citizen petitions (505(q)(1)(H))	26	1.15	32	0.5 (30 min.)	16
Certification for petitions for stay of agency action (505(q)(1)(H))	1	1	1	0.5 (30 min.)	0.5
Verification for comments to citizen petitions (505(q)(1)(I))	9	1.33	12	0.5 (30 min.)	6
Verification for comments to petitions for stay of agency action (505(q)(1)(I))	1	1	1	0.5 (30 min.)	0.5
Verification for supplements to citizen petitions (505(q)(1)(I))	7	1.43	10	0.5 (30 min.)	5
Supplements to petitions for stay of agency action	1	1	1	6	6
Verification for supplements to petitions for stay of agency action (505(q)(1)(I))	1	1	1	0.5 (30 min.)	0.5
Letter withdrawing a petition for stay of agency action	1	1	1	0.5 (30 min.)	0.5
Total Hours		35			

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

Dated: March 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05190 Filed 3–10–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0264]

Draft Guidance for Industry on Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of drug products for the treatment of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 12, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit 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: Janet Maynard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3185, Silver Spring, MD 20993–0002, 301–796–2300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of drug products for the treatment of CFS/ME.

Currently, there are no approved therapies indicated to treat CFS/ME. The lack of approved therapies indicated for the treatment of CFS/ME represents a public health concern. To foster drug development in CFS/ME, this draft guidance outlines the following key issues in drug development in CFS/ME:

- The case definitions or criteria for CFS/ME that could be used to define a patient population in the context of drug development

• Recommendations for establishing efficacy in CFS/ME based on patient-reported symptoms and measurements of exercise capacity

• Recommended trial design and duration

• Recommendations for establishing safety in CFS/ME

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drug products for the treatment of CFS/ME. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.*

Dated: March 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05189 Filed 3–10–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, March 17, 2014, 01:00 p.m. to March 17, 2014, 03:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on February 18, 2014, 79 FRN 9245.

The panel name has been changed to ''NIMH R25 HIV/AIDS APPLICATIONS.'' The previous notice incorrectly listed these as ''R34'' applications. This meeting will remain at the same time and is closed to the public.

Dated: March 5, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–05166 Filed 3–10–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Program Project: Genome-Scale Data Analysis Review.

Date: April 2–3, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA: Endocrinology, Metabolism and Nutrition.

Date: April 3, 2014.

Time: 7:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, 301–408–9901, *sheardn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Iron Homeostasis Regulation.

Date: April 3–4, 2014.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting),

Contact Person: Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7760, Bethesda, MD 20892, (301) 435–1747, *rosenzweign@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: March 4, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–05161 Filed 3–10–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which