

Instructions and SPL resources may be found on the SPL Resources Web page at <http://www.fda.gov/ForIndustry/>

DataStandards/StructuredProductLabeling/default.htm

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
New registrations, including new labeler codes requests ...	39	14.72	574	4.5	2,583
Annual updates of registration information	3,256	2.99	9,735	4.5	43,808
New drug listings	1,567	6.57	10,295	4.5	46,328
New listings for private label distributor	146	10.06	1,469	4.5	6,611
June and December updates of all drug listing information	1,677	11.21	18,799	4.5	84,596
Waiver requests	1	1	1	1	1
Total					183,927

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 resulting from section 510(p) of the FD&C Act as amended by FDAAA	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
One-time preparation of SOP	1,000	1	1,000	40	40,000
SOP maintenance	3,295	1	3,295	1	3,295
Total					43,295

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

Dated: March 20, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-7136 Filed 3-23-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 11, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver

Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: AVAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 203-100, for a fixed-dose combination tablet of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, submitted by Gilead Sciences, Inc. The application proposes an indication for the treatment of HIV-1 infection in adults who are antiretroviral naïve or have no known substitutions associated with resistance to the individual components.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 27, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 19, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to

speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 20, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 20, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-7178 Filed 3-23-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Amendment to Proposed Collection: Comment Request Post-Award Reporting Requirements Including New Research Performance Progress Report Collection

The 60-day **Federal Register** Notice for the proposed revision of information collection Public Health Service (PHS) Post-award Reporting Requirements, published March 5, 2012 (77 FR 13131), neglected to include the OMB information collection approval number. The number is OMB 0925-0002, expiration 06/30/2012. There are no additional corrections or changes to that Notice.

Dated: March 15, 2012.

Joe Ellis,

Director, Office of Policy for Extramural Research Administration, Office of Extramural Research, National Institutes of Health.

[FR Doc. 2012-7238 Filed 3-23-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the PubMed Central National Advisory Committee.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: PubMed Central National Advisory Committee.

Date: June 19, 2012.

Time: 9:30 a.m. to 3 p.m.

Agenda: Review and Analysis of Systems.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: David J. Lipman, M.D., Director, National Center for Biotechnology Information, National Library of Medicine, Building 38, Room 8N805, Bethesda, MD 20894, 301-435-5985, dlipman@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.pubmed.central.nih.gov/about/nac/html>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS.)

Dated: March 20, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-7240 Filed 3-23-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine ; 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 meetings.

The meeting 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 materials, 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: Biomedical Library and Informatics Review Committee

Date: June 7-8, 2012.

Time: June 7, 2012, 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Time: June 8, 2012, 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Arthur A. Petrosian, Ph.D., Chief Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892-7968, 301-496-4253, petrosia@mail.nih.gov

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS.)

Dated: March 20, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-7239 Filed 3-23-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Meetings

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 Literature Selection Technical Review Committee.

The meeting will be open to the public as indicated below, with