Abbreviated New Animal Drug Applications—Sections 512(b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1)) (OMB Control Number 0910–0669))—Extension

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA) (Pub. L. 100–670). Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by GADPTRA, any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an abbreviated application is described in section 512(n)(1) of the FD&C Act. Among other things, an abbreviated application is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved drug referenced in the abbreviated application. FDA allows applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review followed by the submission of an Administrative ANADA when FDA finds that all the applicable technical sections for an ANADA are complete. FDA requests that an applicant accompany ANADAs and requests for phased review of data to support ANADAs with the Form FDA 356v to ensure efficient and accurate processing of information to support approval of the generic new animal drug.

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

TABLE 1—ANADAS: ESTIMATED ANNUAL REPORTING BURDEN

FD&C act section 512(b)(2)	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	18	1	18	159	2,862
Phased Review With Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

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

ANADA paperwork burden (section 512(b)(2) of the FD&C Act). Over the past 5 fiscal years, from October 2007 through September 2012, FDA has received an average of 21 ANADAs per year. FDA estimates that preparing the paperwork required under 21 U.S.C. 360b(n)(1) to be contained in an ANADA, whether all of the information is submitted with the ANADA or the applicant submits information for phased review followed by an Administrative ANADA that references that information, will take approximately 159 hours. (FDA is estimating that each ANADA that uses the phased review process will have approximately five phased reviews per application. Therefore, assuming that three respondents will take advantage of the phased review option per year and an average of five phased reviews are submitted per application, times 31.8 hours per phased review, equals 477 total hours per year or 159 hours per application.)

Although over the last 5 fiscal years all sponsors chose to submit traditional ANADAs, some sponsors did indicate an interest in using the phased review option in the future. FDA believes that with time, more and more sponsors will take advantage of the phased review option, as it provides greater flexibility, and estimates that there will be three respondents for the phased review option. FDA also estimates that sponsors of ANADAs take approximately 25 percent less time to put together the information to support an ANADA than a new animal drug application (NADA) because they only need to provide evidence of bioequivalence and not the data required in an NADA to support a full demonstration of safety and effectiveness.

Form FDA 356v. FDA requests that an applicant fill out and send in with an ANADA and requests for phased review of data to support an ANADAs, a Form FDA 356v to ensure efficient and accurate processing of information to support the approval of a generic new animal drug. Records and reports that are required post approval are described in 21 CFR 514.80 and that paperwork is already covered by that rule in OMB control number 0910–0284.

Dated: April 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10088 Filed 4–29–13; 8:45 am]

BILLING CODE 4160–01–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, Member Conflict: Cancer Therapeutics.

Date: May 22, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Careen K Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301)435–3504, *tothct@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group Basic Mechanisms of Cancer Therapeutics Study Section.

Date: May 24, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Four Season Hotel Washington DC, 2800 Pennsylvania Avenue, Washington, DC 20007.

Contact Person: Lambratu Rahman Sesay, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301–451–3493, *rahman-sesayl@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: April 24, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10096 Filed 4–29–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of 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 National Advisory General Medical Sciences Council.

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.

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 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: National Advisory General Medical Sciences Council.

Date: May 16–17, 2013.

Closed: May 16, 2013, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Open: May 17, 2013, 8:30 a.m. to ADJOURNMENT.

Agenda: For the discussion of program policies and issues, opening remarks, report of the Acting Director, NIGMS, and other business of the Council.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Ann A. Hagan, Ph.D., Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC 6200, Bethesda, MD 20892, (301) 594–4499, *hagana@nigms.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 taxis, 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.nigms.nih.gov/About/Council/*)—where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research, National Institutes of Health, HHS)

Dated: April 24, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10095 Filed 4–29–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 the following meeting.

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 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: National Cancer Institute Special Emphasis Panel Early Stage and Advanced Development of Informatics Technology.

Date: July 11–12, 2013.

Time: 7:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Rockville, MD 20852.

Contact Person: Viatcheslav A Soldatenkov, MD, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, West Tower, Room 7W254, Bethesda, MD 20892–8329, 240–276–6378, *soldatenkovv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 24, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10098 Filed 4–29–13; 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 Meeting

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 meeting.

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 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, PAR Panel: Understanding and Promoting Health Literacy.

Date: May 17, 2013.

Time: 12:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Rebecca Henry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, 301–435–1717, *henryrr@mail.nih.gov.*