product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for lenalidomide capsules.

Revlimid (lenalidomide capsules), approved by FDA on December 27, 2005, is a thalidomide analogue indicated for the treatment of: Multiple myeloma, in combination with dexamethasone, in patients who have received at least one prior therapy and also in patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. Revlimid is designated as the reference listed drug, and therefore any ANDAs for generic lenalidomide capsules must demonstrate BE to the Revlimid prior to approval. There are no approved ANDAs for this product.

In June 2010, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for lenalidomide capsules. In that draft guidance, FDA recommended studies in the 15 milligram (mg) and 25 mg strengths of lenalidomide capsules to demonstrate BE. FDA has now determined that a BE study in the 15 mg strength is unnecessary and is revising the guidance to remove that recommendation. FDA also is revising the guidance to recommend that a request for a waiver of in vivo testing be submitted for the 2.5 mg, 5 mg, 10 mg, and 15 mg strengths based on: (1) Acceptable fasting and fed bioequivalence studies on the 25 mg strength, (2) proportional similarity of the formulations across all strengths, and (3) acceptable in vitro dissolution testing of all strengths.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for lenalidomide capsules. They do not create or confer any rights for or on any person and do 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. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. 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*.

III. Electronic Access

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

Dated: October 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27004 Filed 11–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: National Database for Autism Research (NDAR) Data Access Request

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act (PRA) of 1995, the National Institute of Mental Health (NIMH), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 22, 2012, page 37683–37684 (2 pages) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: National Database for Autism Research (NDAR) Data Access Request. *Type of Information Collection Request:* 0925–NEW. *Need and Use of Information Collection:* The NDAR Data Access Request form is necessary for ''Recipient'' Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from the NDAR Central Repository for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the NDAR datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. *Frequency of Response:* Once per request. *Affected Public:* Individuals. *Type of Respondents:* Researchers interested in obtaining access to study data and images from the NDAR Central Repository for research purposes. There are no capital, operating, and/or maintenance costs to the respondents.

There are two scenarios for completing the form. The first where the Principal Investigator (PI) completes the entire NDAR Data Access Request form, and the second where the PI has the Research Assistant begin filling out the form and PI provides the final reviews and signs it. The total estimated annual burden hours to complete data request form is listed below.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Form	Number of respondents	Frequency of response	Average time per response (in hours)	Total annual burden hours
NDAR Data Access Request	40	1	95/60	63

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Keisha Shropshire, NIMH PRA Liaison, Science Policy & Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Blvd., MSC 9667, Bethesda, MD 20892, or call non-toll-free number (301) 443–4335 or Email your request, including your address to: *kshropsh@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: October 17, 2012.

Sue Murrin,

Executive Officer, NIMH, NIH.

[FR Doc. 2012–27085 Filed 11–5–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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 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: National Institute on Minority Health and Health Disparities Special Emphasis Panel; NIMHD Community-Based Participatory Research (CBPR) Initiative in Reducing and Eliminating Health Disparities: Dissemination Phase (R24).

Date: December 17–18, 2012.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Robert Nettey, M.D., Chief, Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 496–3996, *netteyr@mail.nih.gov*.

Dated: October 31, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–26986 Filed 11–5–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Board of Scientific Advisors, November 5, 2012, 9:00 a.m. to November 5, 2012, 5:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on September 27, 2012, 77FR59406.

This notice is amended to change the adjournment time to 3:45 p.m. The meeting is open to the public.

Dated: October 31, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–26987 Filed 11–5–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, November 27, 2012, 8:00 a.m. to November 27, 2012, 3:00 p.m., National Institutes of Health, Neurosciences Building, 6001 Executive Boulevard, Conference Room C, Rockville, MD 20852, which was published in the **Federal Register** on October 10, 2012, 77 FR 61614.

This notice is amended to change the location, date and time to November 26, 2012, 2:00 p.m. to 4:00 p.m., Executive Plaza North, 6130 Executive Boulevard, Room 6042, Rockville, MD 20852. The meeting is closed to the public.

Dated: October 31, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–26988 Filed 11–5–12; 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; Program Project: Mass Spectrometry Resource.

Date: November 26–28, 2012.

Time: 7:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bentley Hotel, 500 East 62nd Street, New York, NY 10065.

Contact Person: Arnold Revzin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146,