to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 15, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013–27874 Filed 11–20–13; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review, 30-Day Comment Request: Certificate of Confidentiality Electronic Application System

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research (OER), 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 April 29, 2013, page 2590 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 Office of Extramural Research (OER), 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.

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: NIH Desk Officer.

DATES: Comment 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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Dr. Ann Hardy, NIH Extramural Human Research Protections Officer and NIH Human Research Protections Officer, Certificates of Confidentiality, 3701 Rockledge Dr., Rm. 3002, Bethesda, MD 20892, or call non-toll-free number (301) 435–2690 or Email your request, including your address to: hardyan@od.nih.gov. Formal requests for additional plans and instruments must be requested in writing.


Need and Use of Information Collection: This application system will provide one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. § 241(d)), CoCs are issued by the agencies of Department of Health and Human Services (DHHS), including NIH, to authorize researchers conducting sensitive research to protect the privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). The NIH ICs collectively issue approximately 1000 new CoCs each year for eligible research projects. However, the process for submitting a CoC request is not consistent across the ICs which creates confusion for applicants. To make the application process consistent across the entire agency, OER is proposing to use an electronic application system that will be accessed by research organizations that wish to request a CoC from any NIH IC. Having one system for all CoC applications to NIH will be efficient for both applicants and NIH staff who process these requests. As is currently done, NIH will use the information in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,500.

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Dated: November 13, 2013.

Seleda Perryman,
Chief, Project Clearance Officer, Office of Policy for Extramural Research Administration, National Institutes of Health.

[FR Doc. 2013–27874 Filed 11–20–13; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, 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: National Advisory Board on Medical Rehabilitation Research.

Date: December 2–3, 2013.

Time: December 2, 2013, 8:30 a.m. to 5:00 p.m.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 USC, 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 Drug Abuse Special Emphasis Panel;

Revision Applications to Promote CRAN [R01] Review.

Date: December 16, 2013.
Time: 12:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).
Contact Person: Melanie J. Gray, Program Analyst, Office of Federal Advisory Committee Policy.

Date: December 17, 2013.
Time: 2:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).
Contact Person: Melanie J. Gray, Program Analyst, Office of Federal Advisory Committee Policy.

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 Director’s Consumer Liaison Group, October 17, 2013, 10:00 a.m. to October 17, 2013, 04:30 p.m., National Institutes of Health, Building 31, C-Wing, 31 Center Drive, Room 10, Bethesda, MD, 20892 which was published in the Federal Register on September 18, 2013, 78FR57400. Due to the absence of either an FY 2014 appropriation or Continuing Resolution for the Department of Health and Human Services, the DCLG meeting is rescheduled for December 2, 2013 from 9:30 a.m. to 4:00 p.m. Additionally, the meeting location has changed to the Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814. The meeting is open to the public and the following agenda topics will be discussed: Proposed organizational change: DEA, Biomedical Cloud Technology, Optimizing Big Data to Advance Research, and Advocate and Organizational Engagement.

Dated: November 15, 2013.
Melanie J. Gray,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P