satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications). All other applicable provisions of the FD&C Act remain in effect for compounded drugs, however, even if the conditions in section 503A are met.

The conditions of section 503A of the FD&C Act included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug, and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and struck down as unconstitutional by the U.S. Supreme Court in 2002.[1] Now that section 503A has been amended by the Drug Quality and Security Act to remove the unconstitutional advertising, promotion, and solicitation provisions, it is necessary to explain FDA's current thinking with regard to section 503A. Several provisions of section 503A require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement. In the draft guidance, we explain how those provisions will be applied pending those consultations and rulemaking.

Among other things, the draft guidance restates the provisions in section 503A that remain in effect, describes FDA's interim policies with respect to specific provisions in section 503A that require implementing regulations or other actions, and contains a non-exhaustive list of potential enforcement actions against individuals or firms that compound human drug products.

FDA is issuing the draft guidance as level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking regarding section 503A of the FD&C Act and human drug compounding. 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.

[1] See *Thompson* v. *Western States Med. Ctr.,* 535 U.S. 357 (2002).

II. Withdrawal of 1998 Guidance and 2002 CPG

In a notice published in the **Federal Register** of November 23, 1998 (63 FR 64723), FDA announced the availability of a guidance entitled ''Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act,'' which is now being withdrawn. In a notice published in the **Federal Register** of June 7, 2002 (67 FR 39409), FDA announced the availability of CPG Section 460.200 of the Compliance Program Guidance Manual entitled ''Pharmacy Compounding,'' which is also now being withdrawn. These two documents are being withdrawn because they are no longer consistent with FDA's current thinking on the issues they address.

III. Request for Comments

Interested persons may submit either electronic comments regarding the draft guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or by FAX: 301–827–6870. It is only necessary to send one set of comments. Identify comments with the docket number found in the 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/GuidanceCompliance RegulatoryInformation/Guidances/default.htm*

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–28963 Filed 12–2–13; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 Institute of General Medical Sciences Special Emphasis Panel; Collaborations for Macromolecular Interactions in Cells (R01).

Date: December 6, 2013.

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

Agenda: To review and evaluate grant applications.

Place: The Serrano Hotel, 405 Taylor Street, San Francisco, CA 94102.

Contact Person: Margaret J. Weidman, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18B, Bethesda, MD 20892–4874, 301–594–3663, *weidmanma@nigms.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 29, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–29020 Filed 12–3–13; 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 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: Molecular and Cellular Neurodegeneration.

Date: January 6, 2014.

Time: 1:00 p.m. to 5:00 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: Carole L Jelsema, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7850, Bethesda, MD 20892, (301) 435–1248, *jelsemac@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Cardiovascular Development, Differentiation and Disease.

Date: January 7, 2014

Time: 1:00 p.m. to 3:30 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: Delvin Knight, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 4128, Bethesda, MD 20892–7814, 301.435.1850, *knightdr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Molecular and Cellular Neurodevelopment.

Date: January 7, 2014.

Time: 1:00 p.m. to 4:30 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: Carole L Jelsema, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7850, Bethesda, MD 20892, (301) 435–1248, *jelsemac@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: November 27, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–29008 Filed 12–3–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2013–0779]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of an extension to the following collections of information: 1625–0007, Characteristics of Liquid Chemicals Proposed for Bulk Water Movement and 1625–0100, Advance Notice of Vessel Arrival. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before January 3, 2014.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2013–0779] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at *http://www.regulations.gov*. (b) To OIRA by email via: *OIRA-submission@omb.eop.gov.*

(2) *Mail:* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at Room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov*.

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov*. Additionally, copies are available from: COMMANDANT (CG–611), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE., STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Anthony Smith, Office of Information Management, telephone 202–475–3532 or fax 202–372–8405, for questions on these documents. Contact Ms. Barbara Hairston, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collections; (2) the accuracy of the estimated burden of the Collections; (3) ways to enhance the quality, utility, and clarity of information subject to the Collections; and (4) ways to minimize the burden of the Collections on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICRs referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast