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 In the draft guidance, we explain how those provisions will be applied pending those consultations and rulemaking.

Among other things, the draft guidance restates the provisions in section 503A that remain in effect, describes FDA's interim policies with respect to specific provisions in section 503A that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FDA is issuing the draft guidance as level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking regarding section 503A of the FD&C Act and human drug compounding.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,