A. Strengths and Weaknesses of the Existing OTC Drug Review

- What aspects of the OTC Drug Review continue to function effectively?
- Which aspects of the OTC Drug Review are most in need of change?
- Are there additional mechanisms to eligibility for the OTC Drug Review that could be explored? If so, what should be the parameters of eligibility?
- Why is the NDA deviation process rarely used by industry? Are there changes to that process that would make it a more appealing and appropriate alternative pathway?

B. Preliminary Concepts for Modernization Described in This Document

We welcome views on the following preliminary concepts identified by FDA for modernizing the OTC Drug Review:

- Ideas for a streamlined process that would allow us to promptly resolve all TFMs.
- Issue monographs by administrative order.
- Issue regulations to require product specific information and expand the use of guidances.
- Expand the NDA deviation process.

C. Your Suggestions for Modifications or Alternatives to the OTC Drug Review

- What alternatives or changes to the OTC Drug Review would modernize or improve FDA's regulation of monograph drugs?
- What changes can facilitate speedier finalization of the remaining monographs?
- How can the Agency most expeditiously address emerging safety issues for drugs regulated under the OTC Drug Review?
- Are there specific changes to the OTC Drug Review that the Agency could employ to address the lack of pediatric data for some final monographs?
- Should the only alternative to marketing an OTC drug under an OTC monograph be an NDA or abbreviated NDA approval? If not, what could another alternative be?
- Are there other regulatory mechanisms (not necessarily used for the regulation of drug products) that are used by other agencies in the United States or in other countries that FDA could consider using to regulate OTC drugs products?

IV. Attendance and/or Participation in the Public Hearing

The public hearing is free and seating will be on a first-come, first-served basis. If you wish to make an oral presentation during the hearing, you must register by submitting either an electronic or a written request by 5 p.m. on March 12, 2014, to Mary Gross or Georgiann Ienzi (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic requests to *CDEROTCMONOGRAPH@fda.hhs.gov.* We recommend that you register early because seating is limited. You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, email address, and type of organization you represent (e.g., industry, consumer organization, etc.). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. FDA encourages individuals and organizations with common interests to coordinate and give a joint, consolidated presentation. Registrants will receive confirmation once they have been accepted to attend the meeting. FDA may limit both the number of participants from individual organizations and the total number of attendees based on space limitations. Registered presenters should check in before the hearing.

Participants should submit a copy of each presentation to Mary Gross or Georgiann Ienzi (see **FOR FURTHER INFORMATION CONTACT**) no later than 5 p.m. on March 12, 2014. We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see *Comments and Transcripts*). FDA will post an agenda of the public hearing and other background material at least 3 days before the public hearing and additional information will be available at: *http://www.fda.gov/Drugs/NewsEvents/ucm380446.htm* (select this hearing from the events list).

We will mail, email, or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called risk forfeiting their scheduled time.

If you need special accommodations due to a disability, contact Mary Gross or Georgiann Ienzi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the hearing.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the relevant centers.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). (See section VII for more details.) To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03884 Filed 2–21–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Study of Women's Health Across the Nation (SWAN).

Date: March 13, 2014.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Isis S. Mikhail, MD, MPH, DRPH, Scientific Review Officer, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2c212, Bethesda, MD 20892, 301–402–7702, *MIKHAILI@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 18, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–03774 Filed 2–21–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health 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: National Institute of Mental Health Special Emphasis Panel; Intervention Conflicts Panel Review.

Date: March 10, 2014.

Time: 1:15 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: A. Roger Little, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health National Institutes of Health, 6001 Executive Blvd., Room 6132, Bethesda, MD 20892–9609, 301–402–5844, *alittle@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; National Cooperative Reprogrammed Cell Research Groups (NCRCRG) to Study Mental Illness.

Date: March 14, 2014.

Time: 1:00 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: Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892–9606, 301–443–1606, *charlesvi@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH Innovative Pilot Studies—Mechanism of Action—Treating Psychiatric Disorders.

Date: March 17, 2014.

Time: 1:00 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: Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892–9606, 301–443–1606, *charlesvi@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 18, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–03775 Filed 2–21–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; IBD R01 Review.

Date: March 18, 2014.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, *rw175w@nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary Studies to ASSESS–AKI.

Date: April 9, 2014.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 18, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–03770 Filed 2–21–14; 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 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.