The purpose of the public meeting is to report on FDA's progress implementing the Action Plan, to discuss how stakeholders have been affected by these changes, and to solicit feedback and recommendations for further implementation from interested parties and stakeholders.

Some questions we would like the public to comment on during the meeting include:

1. What approaches have been successful in addressing key barriers to recruiting diverse clinical trial populations?
2. What are your key limitations to conducting meaningful data analysis of underrepresented groups?
3. What have you learned about best practices for recruiting a broad representation of subjects for clinical trials? Which practices have been successful and why? Which have not and why?
4. What communication strategies have you successfully used that were also sensitive to the needs of underrepresented populations?
5. What are potential methods FDA should consider using to effectively communicate meaningful information on demographic analyses to a diverse public?
6. What are some of the actual or potential unintended consequences of data transparency you have encountered related to reporting demographic subgroup analysis?

Stakeholders are invited to provide brief comments on these topics during the public comment portion of the meeting, but are not limited to discussing only the previous topics. Since the day-long meeting may not provide enough time to fully address all of these issues, we encourage interested groups to submit longer explanations and comments to the docket.

II. Registration and Request for Oral Presentations

FDA will try to accommodate all participant requests to speak; however, the duration of comments may be limited by time constraints. Those wishing to make oral presentations will be asked to send a brief summary of their comments and registration information (including name, title, firm name, address, telephone, email address, and fax number), and should register by February 1, 2016, by emailing *FDASIA907@fda.hhs.gov.*

All other participants are asked to register online at: *http://www.fda.gov/ForHealthProfessionals/LearningActivities/ucm470074.htm* by February 13, 2016, whether they plan to attend in person or listen to the meeting on a live Webcast. Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the meeting will be based on space availability. Information on how to access the Webcast will be posted approximately 5 days before the meeting at: *http://www.fda.gov/ForHealthProfessionals/LearningActivities/ucm470074.htm.*

If you need special accommodations due to a disability, please contact *FDASIA907@fda.hhs.gov* at least 7 days in advance. Persons attending the public meeting are advised that FDA is not responsible for providing access to electrical outlets.

Dated: December 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–33261 Filed 1–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 4, 2016, from 8:30 a.m. to 3 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be Web cast and will be available at the following link *https://collaboration.fda.gov/vrbpac030416/.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Sujata Vijh or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993–0002, 240–402–7107 or 240–402–8158, email: *Sujata.vijh@fda.hhs.gov* or *denise.royster@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On March 4, 2016, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2016–2017 influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 19, 2016. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 1:40 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 10, 2016. Time allotted for each presentation may be

limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 11, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Sujata Vijh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–33263 Filed 1–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel; X01's BRAC Review.

Date: January 14, 2016.

Time: 1:00 p.m. to 2:30 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: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3205, MSC 9529, Bethesda, MD 20892–9529, 301–435–9223, *joel.saydoff@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. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: December 31, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–33256 Filed 1–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Development of Primer and Reference Tool to Assess Neonatal Abstinence Syndrome (1210).

Date: January 15, 2016.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–402–6626, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: December 31, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–33252 Filed 1–5–16; 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, Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders.

Date: January 21, 2016.

Time: 12:30 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: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892–9606, 301–443–9699, *bursteinme@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Interventions.

Date: January 28, 2016.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.