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/vrpbpac030416/. 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/
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/AboutFDA/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.). The contract proposals and personal information concerning property such as patentable material, confidential trade secrets or commercial秘密, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

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.

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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.

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