

- Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

4. How has your condition affected your social interactions, including relationships with family and friends?

5. How has your condition affected your mood (for example: depression, apathy, patience/tolerance for frustration)?

#### Topic 2: Patients' Perspectives on Current Approaches To Treating HD

1. What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification and exercise.)

(a) What specific symptoms do your treatments address?

(b) How has your treatment regimen changed over time, and why?

2. How well does your current treatment regimen treat the most significant symptoms of your disease?

(a) How well do these treatments improve your ability to do specific activities that are important to you in your daily life?

(b) How well have these treatments worked for you as your condition has changed over time?

3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, interacts with other medications, need to visit your doctor more frequently, etc.)

4. Assuming there is no complete cure for your condition, what would you look for in an ideal treatment for your condition or a specific aspect of your condition?

#### C. Parkinson's Disease Discussion Questions

##### Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include difficulty moving, pain, constipation, difficulty concentrating or remembering, daytime sleepiness, etc.)

2. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include daily hygiene, feeding, dressing, etc.)

- How do your symptoms affect your daily life on the best days? On the worst days?

3. How has your ability to cope with symptoms changed over time?

- Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

4. What worries you most about your condition?

5. How has your condition affected your social interactions, including relationships with family and friends?

#### Topic 2: Patients' Perspectives on Current Approaches To Treating PD

1. What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification and exercise.)

- What specific symptoms do your treatments address (for example: depression, constipation, memory difficulty, sleepiness, ability to move)?

2. How well does your current treatment regimen treat the most significant symptoms of your disease?

- How well do these treatments improve your ability to do specific activities that are important to you in your daily life?

3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, need to visit your doctor or take medications frequently, cause sleepiness, etc.)

4. Assuming there is no complete cure for your condition, what would you look for in an ideal treatment for your condition or a specific aspect of your condition?

#### III. Meeting Attendance and Participation

If you wish to attend this meeting, visit <https://pfddhuntingtonparkinson.eventbrite.com>. Please register by September 14, 2015. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. When you register, you can indicate whether you plan to attend the morning session on HD, the afternoon session on PD, or both. You will also be asked to indicate in your registration if you plan to attend in person or via the webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special

accommodations because of a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to [PatientFocused@fda.hhs.gov](mailto:PatientFocused@fda.hhs.gov) a brief summary of responses to the topic questions by September 8, 2015. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

#### IV. Comments

Regardless if you attend the public meeting, you can submit electronic or written responses to the questions pertaining to HD Topics 1 and 2 and PD Topics 1 and 2 to the public docket (see **ADDRESSES**) by November 23, 2015. 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>.

#### V. Transcripts

As soon as a transcript is available, FDA will post it at <http://www.fda.gov/Drugs/NewsEvents/ucm451807.htm>.

Dated: July 13, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-17556 Filed 7-16-15; 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 September 15, 2015, from 8:30 a.m. to 2:30 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. 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>.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link <https://collaboration.fda.gov/cbervrhpac0915/>.

*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, 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 September 15, 2015, from 8:30 a.m. to 2:30 p.m., the committee will meet in open session to discuss and make recommendations on the safety and immunogenicity of Seasonal Trivalent Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59 (FLUAD) manufactured by Novartis.

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 September 8, 2015. Oral presentations from the public will be scheduled between approximately 12:15 p.m. to 1:15 p.m. on September 15, 2015. 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 August 31, 2015. 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 September 1, 2015.

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 physical disabilities or special needs. If you require special 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: July 10, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-17559 Filed 7-16-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection

#### Activities: Proposed Collection: Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this Information Collection Request must be received no later than September 15, 2015.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 10C-03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Bureau of Health Workforce (BHW) Uniform Data System (UDS).

OMB No. 0915-XXXX-NEW.

*Abstract:* The UDS is the Bureau of Primary Health Care's (BPHC's) annual reporting system for HRSA-supported health centers. The UDS is a program performance reporting system that tracks a variety of information, including patient demographics, services provided, staffing, clinical indicators, utilization rates, costs, and revenues. BHW proposes that HRSA Nurse Managed Health Clinic (NMHC) grantees and Interprofessional Collaborative Practice (IPCP) program cooperative agreement awardees also submit data into the UDS.