FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Surveys and Interviews With Investigational New Drug (IND) Sponsors To Assess Current Communication Practices With FDA Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act (PDUFA VI)

OMB Control Number 0910—NEW

In Fiscal Year (FY) 2017, FDA published guidance on communications between FDA review staff and drug sponsors during the IND phase of drug development. As part PDUFA VI, FDA committed to a third-party assessment of current IND-phase communication practices, which should reflect this guidance. The contractor for the assessment of IND communication practices is Eastern Research Group, Inc. (ERG).

Therefore, in accordance with the PDUFA VI Commitment Letter, FDA proposes to have ERG conduct surveys and interviews with sponsors of up to 150 active commercial INDs as follows:

- For each formal meeting between FDA review staff and active commercial IND sponsors during the assessment period, send a survey to the sponsor to solicit specific feedback about communication practices employed for that meeting. *For the purpose of this assessment, formal meetings are Type A, B, B (End of Phase), and C meetings during the IND phase of drug development.*
- For each active commercial IND in the assessment, conduct an interview with the sponsor to obtain broader feedback about all communications with FDA review staff during the study period, including telephone and email interactions in addition to meetings.

The purpose of this information collection is to understand active commercial IND sponsor perspectives on communication during drug development with a focus on what is working well, ongoing challenges and pain points, lessons learned, and opportunities for improvement. The contractor will develop anonymized aggregated summaries of survey and interview responses, analyze this information to identify common themes, consider these results along with IND data and feedback from FDA review staff to develop a set of findings and recommendations, and prepare a report to be published on FDA's website. The contractor will keep information collected private; ERG will not disclose personally identifying information to FDA or any other party.

The number of commercial INDs with activity is approximately 4,000 per year. ERG will interview 1 to 3 sponsor representatives at a time for up to 150 INDs during the annual assessment period.

Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
IND sponsors: Surveys	150	1	150	0.17 (10 minutes)	25.50
IND sponsors: Interviews	450	1	450	1.5	675
Total					700.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each IND sponsor a maximum of 10 minutes to complete a survey. Up to 150 respondents will take part in the survey, yielding a maximum burden of 25.5 hours. FDA estimates that it will take each IND sponsor up to 90 minutes to respond to requests for interviews and participate in interviews. Up to 450 respondents will take part in interviews, yielding a maximum burden of 675 hours. FDA's burden estimates are based on experience with information collections for similar types of PDUFA-related assessments.

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17715 Filed 8–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2945]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference.

DATES: The meeting will be held on October 3, 2018, from 11 a.m. to 3:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 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 webcast and will be available at the following link: *https://collaboration.fda.gov/vrbpac1018.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–5771, *serina.hunter-thomas@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 website at *https://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.

SUPPLEMENTARY INFORMATION:

Agenda: On October 3, 2018, the VRBPAC will meet in an open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2019 southern hemisphere 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 website 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 website after the meeting. Background material is available at *https://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 26, 2018. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 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 September 18, 2018. 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 19, 2018.

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 Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://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: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17702 Filed 8–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Secretary's National Advisory Committee on Rural Health and Human Services (NACRHHS) has scheduled a public meeting. Information about NACRHHS and the agenda for this meeting can be found on the NACRHHS website at *https://www.hrsa.gov/advisory-committees/rural-health/index.html.*

DATES: September 10, 2018, 8:30 a.m.–5:15 p.m. ET; September 11, 2018, 8:30 a.m.–5:15 p.m. ET; September 12, 2018, 8:30 a.m.–11:15 a.m. ET.

ADDRESSES: On September 10, the address for the meeting is The Duke Endowment, 800 East Morehead Street, Charlotte, NC 28202.

On the morning of September 11, NACRHHS will break into subcommittees. One subcommittee will travel to Happy Valley Medical Center, 1345 NC Highway 268, Lenoir, NC 28645. The other subcommittee will travel to Winnsboro Smiles Dental Clinic, 124 N Congress Street, Winnsboro, SC 29180. In the afternoon, at approximately 4:00 p.m. ET., NACRHHS will reconvene at the AC Hotel Charlotte City Center, 220 E Trade Street, Charlotte, NC 28202.

On September 12, the address for the meeting is AC Hotel Charlotte City Center, 220 E Trade Street, Charlotte, NC 28202.

FOR FURTHER INFORMATION CONTACT: Steven Hirsch, Administrative Coordinator at the Federal Office of Rural Health Policy, HRSA, 5600 Fishers Lane, 17W59D, Rockville, Maryland 20857; 301–443–7322; or *shirsch@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACRHHS provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning both rural health and rural human services.

During the September meetings, NACRHHS will discuss the issues of chronic obstructive pulmonary disease, one of the leading causes of mortality in rural areas, and the provision of oral health services in rural areas. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments.