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 broadcast on the internet and will be available at the following link: https://collaboration.fda.gov/vrbpac1018.

If you require accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/default.htm. Interested persons may contact the 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.

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; or shirsch@hrsa.gov.
Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACRHHS should be sent to Steven Hirsch, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Steven Hirsch at the address and phone number listed above at least 10 business days prior to the meeting.

Amy P. McNulty,
Acting Director, Division of the Executive Secretariat.

FOR FURTHER INFORMATION CONTACT:
Tracey Randolph, Program Analyst, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: ORI oversees and directs U.S. Public Health Service (PHS) research integrity activities on behalf of the Secretary of U.S. Department of Health and Human Services (HHS), with the exception of the regulatory research integrity activities of the Food and Drug Administration. ORI is a program office within the Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ORI’s Division of Education and Integrity (DEI) has among its duties the responsibility to develop and implement activities and programs to teach RCR and train Research Integrity Officers (RIOs) as well as others that are involved in research integrity, such as Institutional Officials (IOs) and institutional counsel. Consistent with ORI’s mission and the applicable statutory authority, 42 U.S.C. 289b, ORI Workshops aim to provide clarification and technical information on the HHS regulations for handling research misconduct allegations and on education in RCR to foster integrity in research. ORI Workshops are moderately sized, convening over one to three days, and typically accepting between 20 and 50 attendees. Co-sponsors will assist with workshop and agenda development, coordination, financial management, and meeting logistics in conjunction with ORI staff. Co-sponsors can charge registration fees to recover costs associated with the events; however, co-sponsors may not set registration fees at an amount higher than necessary to recover related event expenses. Further, co-sponsors are solely responsible for collecting and handling any registration fees collected.

Eligibility for Co-Sponsorship: The co-sponsoring entity must have demonstrated interest and experience in the responsible conduct of research (RCR) or the handling of research misconduct allegations. The co-sponsoring entity must participate substantively in the co-sponsored activity.

Eligibility for Co-Sponsorship: The agency’s policies and procedures or any other events must be outlined in a co-sponsorship agreement. The determination concerning activities by the co-sponsors that respond to this notice, will set forth the details of the co-sponsored activity, including the requirements that any fees collected by the co-sponsor shall be limited to the amount necessary to cover the co-sponsor’s related event expenses. This co-sponsorship agreement does not represent an endorsement by ORI of an individual co-sponsor’s policies, positions, or activities. Additionally, this agreement will not affect any determination concerning activities by the co-sponsors that are regulated by ORI.

Dated: August 9, 2018.
Scott J. Moore,
Deputy Director, Office of Research Integrity.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.