1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision with change of a currently approved; *Title of Information Collection:* Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits; *Use:* This information collection includes the process for organizations wishing to provide healthcare services under MA plans. These organizations must complete an application annually (if required), file a bid, and receive final approval from CMS. The MA application process has two options for applicants that include (1) request for new MA product or (2) request for expanding the service area of an existing product. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the current requirements for participation in the MA program and to make a decision related to contract award. This collection process is the only mechanism for organizations to complete the required MA application process. The application process is open to all health plans that want to participate in the MA program. The application is distinct and separate from the bid process, and CMS issues a determination on the application prior to bid submissions, or before the first Monday in June.

Collection of this information is mandated by the Code of Federal Regulations, MMA, and CMS regulations at 42 CFR 422, subpart K, in ''Application Procedures and Contracts for Medicare Advantage Organizations.'' In addition, the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) further amended titles XVII and XIX of the Social Security Act. *Form Number:* CMS–10237 (OMB control number: 0938–0935); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 435; *Total Annual Responses:* 435; *Total Annual Hours:* 6,754. (For policy questions regarding this collection contact Keith Penn-Jones at 410–786–3104.)

Dated: December 31, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–28477 Filed 1–3–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

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. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on March 4, 2020, from 8:30 a.m. to 5:10 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., 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/vrbpac030420/.* 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: Kathleen Hayes or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993–0002, 301–796–7864, *Kathleen.Hayes@fda.hhs.gov,* or 301–796–4620, *monique.hill@fda.hhs.gov,* respectively; or the 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 March 4, 2020, under Topic I, the Center for Biologics Evaluation and Research's (CBER) VRBPAC 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 2020 to 2021 influenza season. Also, on March 4, 2020, under Topic II, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Respiratory and Special Pathogens (LRSP), Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, CBER.

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 February 26, 2020. Oral presentations from the public will be scheduled between approximately 12:50 p.m. and 1:35 p.m. for the influenza strain selection portion of the meeting and 3:55 p.m. to 4:10 p.m. for the overview portion of the LRSP Site Visit. 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 18, 2020. 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 19, 2020.

Closed Committee Deliberations: On March 4, 2020, from 4:10 p.m. to 5:10 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

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 Kathleen Hayes (see **FOR FURTHER INFORMATION CONTACT**) 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: December 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28508 Filed 1–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2809]

Advisory Committee; Patient Engagement Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Patient Engagement Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Patient Engagement Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until October 6, 2021.

DATES: Authority for the Patient Engagement Advisory Committee would have expired on October 6, 2019, unless the Commissioner had formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993–0002, 301–796–8398, *Letise.Williams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3 FDA is announcing the renewal of the Patient Engagement Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Patient Engagement Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective devices for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee provides advice to the Commissioner of Food and Drugs on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

Pursuant to its Charter the Committee shall consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks and clinical outcomes to patients and research subjects. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

The Commissioner or designee shall also have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve