This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Principles of Premarket Pathways for Combination Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 3 and in the guidance ''How to Prepare a Pre-Request for Designation (Pre-RFD)'' have been approved under OMB control number 0910–0523. The collections of information for applications for FDA approval to market a new drug (certain provisions of 21 CFR part 314) have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under 0910–0338; and the collections of information in section 351(k) of the Public Health Service Act (42 U.S.C. 262) have been approved under 0910–0719. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 860, subparts A through C, have been approved under OMB control number 0910–0138; the collections of information in the guidance document ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756; and the collections of information in 21 CFR part 860, subpart D, for De Novo classifications have been approved under OMB control number 0910–0844.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01925 Filed 1–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Advisory Committee; Vaccines and Related Biological Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Vaccines and Related Biological Products 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 Vaccines and Related Biological Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the December 31, 2023, expiration date.

DATES: Authority for the Vaccines and Related Biological Products Advisory Committee will expire on December 31, 2023, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 240–402–8006, *Prabhakara.Atreya@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective vaccines and related biological products for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which FDA has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 15 voting members, including the Chairperson (the Chair). Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. 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. Ex Officio voting members, one each from the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health may be included. 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. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall 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 temporarily as voting members when: (1) Expertise is required that is not available among current voting standing

members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/charter-vaccines-and-related-biological-products-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: January 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01858 Filed 1–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Childhood Vaccines

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Commission on Childhood Vaccines (ACCV) will hold public meetings for the 2022 calendar year (CY). Information about the ACCV, agendas, and materials for these meetings can be found on the ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.*

DATES: ACCV meetings will be held on:

- March 3, 2022, 10:00 a.m. Eastern Time (ET)–4:00 p.m. ET;
- June 2, 2022, 10:00 a.m. ET–4:00 p.m. ET;
- September 1, 2022, 10:00 a.m. ET–4:00 p.m. ET; and
- December 1, 2022, 10:00 a.m. ET–4:00 p.m. ET.

ADDRESSES: Meetings may be held in-person or virtually. For updates on how the meeting will be held, visit the ACCV website 30 business days before the meeting date, where instructions for joining meetings either in-person or remotely will be posted. In-person ACCV meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting information updates, go to the ACCV website meeting page at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 08N186B, Rockville, Maryland 20857; 301–443–6634; or *ACCV@HRSA.gov.*

SUPPLEMENTARY INFORMATION: The ACCV provides advice and recommendations to the Secretary of HHS on policy, program development, and other issues related to the implementation of the National Vaccine Injury Compensation Program and concerning other matters as described under section 2119 of the Public Health Service Act (42 U.S.C. 300aa–19).

Since priorities dictate meeting times, be advised that times and agenda items are subject to change. Refer to the ACCV website listed above for any meeting updates that may occur. For CY 2022 meetings, agenda items may include, but are not limited to: Updates from the Division of Injury Compensation Programs, Department of Justice, Office of Infectious Disease and HIV/AIDS Policy (HHS), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). Refer to the ACCV website listed above for all current and updated information concerning the CY 2022 ACCV meetings, including draft agendas and meeting materials posted 5 calendar days before the meeting(s).

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the requested order and may be limited as time allows. Requests to submit a written statement or make oral comments to ACCV should be sent to Annie Herzog using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Annie Herzog using the contact information listed above at least 10 business days before the meeting(s) they wish to attend. If in-person meetings occur, they will be held in a federal government building and attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days before the meeting to facilitate their entry into the building. All attendees are required to present government-issued identification before entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–01848 Filed 1–28–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Mechanisms of Emotion, Stress and Health Study Section.

Date: February 24–25, 2022.

Time: 10:00 a.m. to 8:00 p.m.