products stored at room temperature in plasma or additive solutions, including platelets manufactured by automated methods (apheresis platelets), and WBD single and pooled (pre-storage and post-storage) platelets. Additionally, the guidance provides licensed blood establishments with recommendations on how to report implementation of manufacturing and labeling changes.

Room temperature stored platelets are associated with a higher risk of sepsis and related fatality than any other transfusable blood component. The risk of bacterial contamination of platelets is a leading risk of infection from blood transfusion, and this risk has persisted despite the implementation of numerous interventions, including a commonly used method of a single culture test after collection of the platelets.

FDA has established regulations to address the control of bacterial contamination of platelets. Under 21 CFR 606.145(a), blood establishments and transfusion services must assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices, or other adequate and appropriate methods found acceptable for this purpose by FDA. The guidance provides recommendations to control the risk of bacterial contamination of platelets with 5-day and 7-day dating, including bacterial testing strategies (using culture-based and rapid bacterial detection devices) and the implementation of pathogen reduction devices. In the **Federal Register** of December 6, 2018 (83 FR 62872), FDA announced the availability of the revised draft guidance of the same title dated December 2018. FDA received numerous comments on the draft guidance, including comments on the potential impact of the recommendations on platelet availability, and those comments were considered as the guidance was finalized. In response to comments, the final guidance provides recommendations for additional culture-based testing strategies for apheresis platelets and pre-storage pools of WBD platelets and revised recommendations for testing single unit and post-storage pools of WBD platelets. In addition, revisions were made to clarify recommendations related to labeling, dating periods, inventory management, and culture incubation periods. The guidance announced in this notice finalizes the draft guidance dated December 2018.

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 bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 601 and 610 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 606 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR part 607 have been approved under OMB control number 0910–0052.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov*.

Dated: September 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21228 Filed 10–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0573]

Blood 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 Blood Products Advisory Committee (BPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues related to blood and products derived from blood. The committee will discuss scientific considerations for cold stored platelet products intended for transfusion. The meeting will be open to the public.

DATES: The meeting will be held on November 22, 2019, from 8:30 a.m. to 4:45 p.m.

ADDRESSES: Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20993. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*. Information about the Tommy Douglas Conference Center may be accessed at: *https://www.tommydouglascenter.com/*.

For those unable to attend in person, the meeting will also be webcast; please see the following link for webcast and other meeting information: *https://www.fda.gov/advisory-committees/blood-products-advisory-committee/2019-meeting-materials-blood-products-advisory-committee*.

FOR FURTHER INFORMATION CONTACT: Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054, *christina.vert@fda.hhs.gov,* or 240–402–8106, *joanne.lipkind@fda.hhs.gov,* respectively, 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 November 22, 2019, the BPAC will meet in open session to discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, duration of storage and clinical indications for use. The committee will hear presentations on available characterization and

functional studies of cold stored platelets, clinical studies, and the potential role of cold stored platelets in clinical care in military and civilian patient populations. The committee will also discuss the clinical studies needed to support the indications for use of cold stored platelet products stored beyond 3 days.

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. For those unable to attend in person, the meeting will also be webcast; please see the following link for webcast and other meeting information: *https://www.fda.gov/advisory-committees/blood-products-advisory-committee/2019-meeting-materials-blood-products-advisory-committee.*

Procedure: On November 22, 2019, from 8:30 a.m. to 4:45 p.m., the meeting is open to the public. 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 November 13, 2019. Oral presentations from the public will be scheduled between approximately 2:35 p.m. and 3:35 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 November 4, 2019. 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 November 5, 2019.

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 Christina Vert (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: September 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21399 Filed 10–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Infant Mortality

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, HHS is hereby giving notice that the Advisory Committee on Infant Mortality (ACIM or the Committee) has been renewed.

DATES: The effective date of the charter renewal is September 30, 2019.

FOR FURTHER INFORMATION CONTACT: David S. de la Cruz, Ph.D., MPH, Designated Federal Official (DFO), HRSA, Maternal and Child Health Bureau, 5600 Fishers Lane, 18N25, Rockville, Maryland 20857; 301–443–0543; or *dcruz@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees. ACIM advises the Secretary of HHS on department activities and programs directed at reducing infant mortality and improving the health status of pregnant women and infants. ACIM represents a public-private partnership at the highest level to provide guidance and focus attention on the policies and resources required to address the reduction of infant mortality and the improvement of the health status of pregnant women and infants. With a focus on life course, the Committee also addresses disparities in maternal health to improve maternal health outcomes, including preventing and reducing maternal mortality and severe maternal morbidity. The Committee also provides advice on how best to coordinate the myriad of federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting infant mortality and maternal health.

The charter renewal for ACIM was approved on September 30, 2019, which also stands as the filing date. Renewal of the ACIM charter gives authorization for the Committee to operate until September 30, 2021. A copy of the ACIM charter is available on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Executive Secretariat.

[FR Doc. 2019–21439 Filed 10–1–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Performance Review Board Members

Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**.

The following persons may be named to serve on the Performance Review Boards from 2019 to 2021, which oversee the evaluation of performance appraisals and compensation for Senior Executive Service, Senior Level/Senior Technical, and Title 42 executive equivalent members of the Department of Health and Human Services.

Last name	First name
AGNEW	ANN
ALEXANDER	THOMAS
ALVAREZ	JUAN CARLOS
AMES	KAREN