Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry.'' The draft guidance provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature stored platelets intended for transfusion. The draft guidance provides recommendations for all platelet products, including platelets manufactured by automated methods (apheresis platelets), WBD platelets, pooled platelets (pre-storage and post-storage) and platelets stored in additive solutions. Additionally, this guidance provides licensed blood establishments with recommendations on how to report implementation of manufacturing and labeling changes under 21 CFR 601.12.

The draft guidance replaces the draft guidance of the same title dated March 2016 (81 FR 13798; March 15, 2016).

Most recently, FDA convened a Blood Products Advisory Committee (BPAC) meeting in July 2018 to discuss bacterial contamination of platelets and strategies to control the risk. At this meeting, BPAC considered the scientific evidence and operational considerations of all available strategies to control the risk of bacterial contamination of platelets with 5-day and 7-day dating, including bacterial testing strategies using culture-based devices, rapid bacterial detection devices, and the implementation of pathogen reduction technology. The data presented and BPAC's discussion at the July 2018 meeting provided the foundation for the recommendations in this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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 part 601 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 draft guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Heritable

Disorders in Newborns and Children (Committee). The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of HHS (Secretary). HRSA is seeking nominations of qualified candidates to fill up to five positions on the Committee.

DATES: Written nominations for membership on the Committee must be received on or before January 4, 2019.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Andrea Matthews, Genetic Services Branch, Maternal and Child Health Bureau, HRSA, at *AMatthews@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Andrea Matthews, MCHB, HRSA 5600 Fishers Lane, Room 18–N–34D , Rockville, MD 20857; 301–945–3062; or *AMatthews@hrsa.gov.* A copy of the Committee charter and list of the current membership may be obtained by accessing the Committee website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/about/index.html.*

SUPPLEMENTARY INFORMATION: The Committee was established in 2003 to advise the Secretary regarding newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee provides advice and recommendations to the Secretary concerning the grants and projects authorized under section 1109 of the PHS Act and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders. The Committee meets four times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the RUSP and constitute part of the comprehensive guidelines supported by HRSA pursuant to section 2713 of the PHS Act, codified at 42 U.S.C. 300gg–13. Under this provision, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Nominations: HRSA is requesting nominations for voting members to serve on the Committee to fill one position in 2019 and up to four positions in 2020. The Secretary appoints Committee members with the expertise needed to fulfill the duties of the Advisory Committee. The membership requirements are set forth at 42 U.S.C. 300b–10(c)(2). Nominees sought are medical, technical, or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children with, or at risk for having, heritable disorders; individuals who have expertise in ethics (*e.g.,* bioethics) and infectious diseases and who have worked and published material in the area of newborn screening; members of the public having special expertise about, or concern with, heritable disorders; and/or representatives from such federal agencies, public health constituencies, and medical professional societies. Interested applicants may self-nominate or be nominated by another individual or organization. Nominees must reside in the United States and cannot be funded for international travel.

Individuals selected for appointment to the Committee will be invited to serve for up to 4 years. Members who are not federal officers or permanent federal employees are appointed as special government employees and receive a stipend and reimbursement for per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee, as authorized by 5 U.S.C. 5703 of the FACA for persons employed intermittently in government service. Members who are already officers or employees of the United States Government shall not receive additional compensation for service on the Committee, but receive per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee.

The following information must be included in the package of materials submitted for each individual being nominated for consideration: (1) A statement that includes the name and affiliation of the nominee and a clear statement regarding the basis for the nomination, including the area(s) of expertise that may support eligibility of a nominee for service on the Committee, as described above; (2) confirmation the nominee is willing to serve as a member of the Committee; (3) the nominee's contact information (please include home address, work address, daytime telephone number, and an email address); and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS will endeavor to ensure that the membership of the Committee is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required in order for HRSA to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of the Committee and to identify any required remedial action needed to address the potential conflict.

Authority: Section 1111 of the Public Health Service (PHS) Act, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (42 U.S.C. 300b-10). The Committee is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

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