consider it acceptable to collect certain data in the postmarket setting, rather than premarket under certain circumstances when FDA has uncertainty regarding certain benefits or risks of the device, but the degree of uncertainty is acceptable in the context of the overall benefit-risk profile of the device at the time of premarket approval. The purpose of this draft guidance document is to assist stakeholders with understanding PAS requirements imposed as a condition of a PMA by providing:

- Procedural information;
- recommendations concerning the format, content, and review of PAS-related submissions; and
- updates to the final guidance entitled ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' dated June 2009, including:
  - Recommendations to help facilitate FDA's review of a PAS protocol in a timely manner;
  - recommendations for study timelines including enrollment milestones and study completion;
  - revised definitions to PAS status categories that we believe better reflect progress of the PAS; and
  - revised FDA review time goals for PAS-related submissions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order.'' 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19043 and complete title to identify the guidance you are requesting.

III. 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 the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian use devices; Humanitarian device exemption	0910–0332

Dated: May 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11216 Filed 5–26–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Organ Transplantation

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 Organ Transplantation (ACOT or Committee). ACOT provides advice and recommendations to the Secretary of HHS (Secretary) on matters pertaining to organ donation, procurement, allocation, and transplantation; maximizing the number of deceased donor organs available for transplantation; supporting the safety of living organ donation proposed policies of the Organ Procurement and Transplantation Network (OPTN) and OPTN operations; and the latest advances in the science of transplantation.

Authority: In accordance with 42 CFR 121.12, the Secretary established ACOT pursuant to 42 U.S.C. 217a. The Committee is governed by the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

DATES: Written nominations for membership on the ACOT will be received on a continuous basis.

ADDRESSES: Nomination packages must be submitted to the Executive Secretary, ACOT, Healthcare Systems Bureau, HRSA, Room 08W67, 5600 Fishers Lane, Rockville, Maryland 20857, or via email to: *ACOTHRSA@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Shelley Grant, Executive Secretary, ACOT, at (301) 443–8036 or email *sgrant@hrsa.gov.* A copy of the ACOT charter and list of current members may be obtained by accessing the ACOT website at *https://www.organdonor.gov/about-dot/acot.html.*

SUPPLEMENTARY INFORMATION: In accordance with the Amended Final Rule of the OPTN (42 CFR part 121), the ACOT was established pursuant to 42 U.S.C. 217a and, in accordance with Public Law 92–463, was first chartered on September 1, 2000. The ACOT meets up to three times during the fiscal year.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on ACOT. The Secretary appoints ACOT members with the expertise needed to fulfill the duties of the Advisory Committee. Nominees sought are individuals knowledgeable in such fields as deceased and living organ donation, health care public policy, transplantation medicine and surgery, critical care medicine, and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences,

economics, and statistics, as well as representatives of transplant candidates, transplant recipients, living organ donors, and family members of deceased and living organ donors. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to the Committee will be invited to serve for a term up to 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACOT meetings and/or conducting other business on behalf of the ACOT, as authorized by 5 U.S.C. 5703 of FACA for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual being nominated for consideration: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of ACOT), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee; (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted; 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 endeavors to ensure that the membership of ACOT is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and 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, or 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 for HRSA ethics officials to determine whether there is a conflict between the SGE's public duties as a member of ACOT and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–11209 Filed 5–26–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Council on Blood Stem Cell Transplantation

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 Council on Blood Stem Cell Transplantation (ACBSCT or Council). ACBSCT shall advise the Secretary of HHS (Secretary), through the HRSA Administrator, on the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program (Program).

Authority: The Council was established to implement a statutory requirement of the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109–129). The Council is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

DATES: Written nominations for membership on ACBSCT will be received continuously.

ADDRESSES: Nomination packages must be submitted to the Executive Secretary, ACBSCT, Healthcare Systems Bureau, HRSA, Room 08W60, 5600 Fishers Lane, Rockville, Maryland 20857, or sent via email to: *ACBSCTHRSA@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Shelley Grant, Executive Secretary, ACBSCT, at (301) 443–8036 or email *sgrant@hrsa.gov.* A copy of the ACBSCT charter and a list of current members may be obtained by accessing the ACBSCT website at *https://bloodcell.transplant.hrsa.gov/about/advisory_council/index.html.*

SUPPLEMENTARY INFORMATION: ACBSCT was established pursuant to Public Law 109–129 as amended by Public Law 111–264; 42 U.S.C. 274k; Section 379 of the Public Health Service Act. In accordance with Public Law 92–463, the ACBSCT was chartered on December 19, 2006. ACBSCT meets up to three times during the fiscal year.

ACBSCT shall, as requested by the Secretary, discuss and make recommendations regarding the Program. It shall provide a consolidated, comprehensive source of expert, unbiased analysis and recommendations to the Secretary on the latest advances in the science of blood stem cell transplantation. ACBSCT shall advise, assist, consult, and make recommendations, at the request of the Secretary, on (1) broad Program policy in areas such as the necessary size and composition of the adult donor pool available through the Program and the composition of the National Cord Blood Inventory, (2) requirements regarding informed consent for cord blood donation, (3) accreditation requirements for cord blood banks, (4) the scientific factors that define a cord blood unit as high quality, (5) public and professional education to encourage the ethical recruitment of genetically diverse donors and ethical donation practices, (6) criteria for selecting the appropriate blood stem source for transplantation, (7) program priorities; (8) research priorities, and (9) the scope and design of the Stem Cell Therapeutic Outcomes Database.

At the request of the Secretary, ACBSCT shall also review and advise on issues relating more broadly to the field of blood stem cell transplantation, such as regulatory policy pertaining to the compatibility of international regulations, and actions that may be taken by state and federal governments and public and private insurers to increase donation and access to transplantation. ACBSCT shall also make recommendations regarding research on emerging therapies using cells from bone marrow and cord blood. The Council may meet up to three times during the fiscal year.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on ACBSCT. The Council shall consist of up to 25 members who are SGEs and 6 ex-officio, non-voting members. The Secretary appoints ACBSCT SGEs with the expertise needed to fulfill the duties of the Council. HRSA is seeking nominees who are outstanding authorities and representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of bone marrow transplants; recipients of cord blood transplants; persons who require such transplants; family members of such a recipient or