

The reorganization will improve FDA's ability to carry out its public health mission by realigning and dedicating resources within the organization to modernize clinical trials. The clinical trial innovation work tracks will place DCI at the forefront to robustly meet policy development, implementation, and analysis needs in areas such as Artificial Intelligence (AI), Digital Health Technologies (DHTs), Real-World Evidence (RWE), and other rapidly advancing sectors in the dynamic clinical trial ecosystem.

The CDER, OMP, Office of Medical Policy Initiatives retitled the Division of Clinical Trial Quality to the Division of Clinical Innovations.

The reorganization will enhance the office's ability to attract and retain a diverse workforce representative of our nation and bring like scientists and policy experts together from across the organization, thereby facilitating collaboration and efficient use of shared resources while advancing key innovations in drug development. By developing responsive policies, the Division of Clinical Innovations will modernize the policy environment to ensure that CDER is providing the needed regulatory perspective to guide the appropriate use of such tools and technologies.

The FDA's CDER, OMP has been restructured as follows:

DCDH ORGANIZATION. The CDER OMP (DCDH) is headed by the Director, OMP and includes the following:
Office of Medical Policy (DCDH)
Office of Prescription Drug Promotion (DCDHA)
Division of Advertising and Promotion Review II (DCDHAA)
Division of Advertising and Promotion Review I (DCDHAB)
Division of Promotion Policy, Research and Operations (DCDHAC)
Office of Medical Policy Initiatives (DCDHB)
Division of Medical Policy Development (DCDHBA)
Division of Medical Policy Programs (DCDHBB)
Division of Clinical Innovations (DCDHBC)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>.

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

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 Secretary's Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Council) has scheduled a public meeting. Information about ACBSCT and the agenda for the meeting can be found on the ACBSCT website at <https://bloodstemcell.hrsa.gov/about/advisory-council>.

DATES: Thursday, January 23, 2025, 3:00 p.m.–5:00 p.m. Eastern Standard Time.

ADDRESSES: This meeting will be held virtually by webinar. A link to register and join the meeting will be posted at least 10 days prior to the meeting at <https://bloodstemcell.hrsa.gov/about/advisory-council>.

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Designated Federal Official, Division of Transplantation, Health Systems Bureau, HRSA, 5600 Fishers Lane, 8W–67, Rockville, Maryland 20857; 301–443–8036; or ACBSCTHRSA@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACBSCT provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under the authority of 42 U.S.C. 274k (Section 379 of the Public Health Service Act), Public Law 109–129, as amended. The Council may transmit its recommendations through the Administrator of HRSA on matters related to the activities of the C.W. Bill

Young Cell Transplantation Program and National Cord Blood Inventory.

The agenda for the January 23, 2025, meeting is being finalized and may include the following topics: graft versus host disease and late effects, strategies for selecting cord blood units for transplantation, HHS' approach for reviewing the state of the science and recommendations on the appropriateness of the inclusion of adult stem cells and birthing tissues as new types of therapies in the C.W. Bill Young Cell Transplantation Program, and other areas to increase blood stem cell donation and transplantation. Agenda items are subject to change as priorities dictate. Refer to ACBSCT's website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings; oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACBSCT should be sent to Shelley Tims Grant, using the contact information above at least 3 business days prior to the meeting. Individuals who plan to attend and need special assistance or other reasonable accommodations should notify ACBSCT at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Notice for Extension of Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: Indian Health Service Customer Service Satisfaction and Similar Surveys

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–