

SMG 1218A.3

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Therapeutic Products

Office of Cellular Therapy and Human Tissue CMC

Effective Date: September 16, 2022

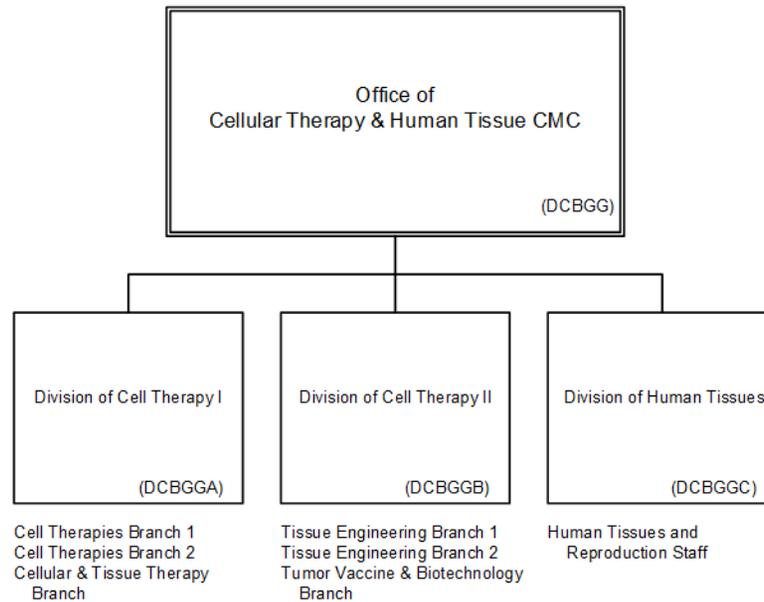
1. Office of Cellular Therapy and Human Tissue CMC (DCBGG).

- A. Provides leadership, direction, coordination, and develops, maintains, and administers the Center for Biologics Evaluation and Research (CBER) cellular therapy and human tissue programs.
- B. Assists in evaluating the adequacy of directions for use, warning, and other information in labeling for tissues regulated by the office. Evaluates adverse reactions reported in association with the use of tissues.
- C. Develops policies and procedures applicable to the review and evaluation of tissues regulated by the office.
- D. Performs consultative reviews of tissue information and data in Biologic License Applications (BLAs), BLA amendments, and Investigational New Drug applications (INDs) in response to requests from other center components.
- E. Assesses consultative clinical and product reviews of tissues performed by other centers for consistency with CBER policies and practices.
- F. Serves as the office resource for evaluation of data obtained through CBER inspections.
- G. Provides expert scientific, medical, and technical advice and assistance to other center components and the Food and Drug Administration (FDA) on cellular therapy, tissues, and related issues.

2. Authority and Effective Date.

The functional statements for the Office of Cellular Therapy and Human Tissue CMC were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Therapeutic Products, Office of Cellular Therapy and Human Tissue CMC organization structure depicting all the organizational structures reporting to the Director:

Office of Cellular Therapy and Human Tissue CMC (DCBGG):

- Division of Cell Therapy I (DCBGGA)
- Division of Cell Therapy II (DCBGGB)
- Division of Human Tissues (DCBGGC)