

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

Division of Human Tissues

Effective Date: September 16, 2022

1. Division of Human Tissues (DCBGGC).

- A. Develops, maintains, and administers the Center for Biologics Evaluation and Research (CBER) Human Tissue Program.
- 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.

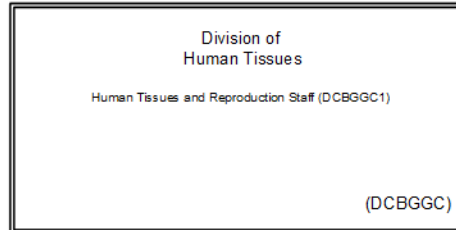
2. Human Tissues and Reproduction Staff (DCBGGC1).

- A. 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.
- B. Assesses consultative clinical and product reviews of tissues performed by other Centers for consistency with the CBER policies and practices.
- C. Serves as the Office resource for evaluation of data obtained through CBER inspections.
- D. Provides expert scientific, medical, and technical advice and assistance to other Center components and to the Food and Drug Administration (FDA) on tissues and related issues.

3. Authority and Effective Date.

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

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Food and Drug Administration
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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, Division of Human Tissues organization structure depicting all the organizational structures reporting to the Director.

Division of Human Tissues (DCBGGC)