

SMG 1218.4

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF TISSUES AND ADVANCED THERAPIES

DIVISION OF HUMAN TISSUES

Effective Date: July 8, 2011

1. DIVISION OF HUMAN TISSUES (DKKBLC).

- 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.
- D. Performs consultative reviews of tissue information and data in Biologic License Applications (BLA)s, BLA amendments, and Investigational New Drug Applications (IND)s in response to requests from other Center components.
- E. Assesses consultative clinical and product reviews of tissues performed by other Centers for consistency with the CBER policies and practices.
- F. Serves as the Office resource for evaluation of data obtained through the CBER inspections.
- G. Provides expert scientific, medical, and technical advice and assistance to other Center components and to the Agency on tissues and related issues.

2. HUMAN TISSUES AND REPRODUCTION BRANCH (DKKBLC1)

- A. Develops, maintains and administers CBER's 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.
- D. Performs consultative reviews of tissue information and data in BLAs, BLA amendments, and INDs in response to request from other Center components.
- E. Assesses consultative clinical and product reviews of tissues performed by other Centers for consistency with the CBER policies and practices.
- F. Serves as the Office resource for evaluation of data obtained through the CBER inspections.
- G. Provides expert scientific, medical, and technical advice and assistance to other Center components and to the Agency on tissues and related issues.

3. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary of Health and Human Services on July 8, 2011.

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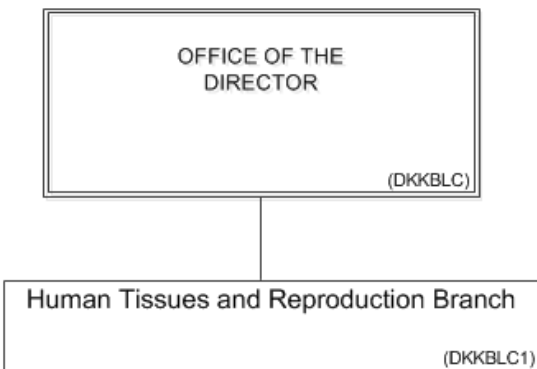
FOOD AND DRUG ADMINISTRATION

Office of Medical Products and Tobacco

Center for Center for Biologics Evaluation and Research

Office of Advanced Tissues and Therapies

Division of Human Tissues



Staff Manual Guide 1218.4
Organizations and Functions
Effective Date: September 24, 2016

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Center for Biologics Evaluation and Research, Office of Advanced Tissues and Therapies, Division of Human Tissues organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKBLC):

- Human Tissues and Reproduction Branch (DKKBLC1)