SMG 1218.1

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

Effective Date: September 24, 2016

1. OFFICE OF TISSUES AND ADVANCED THERAPIES (DKKBL).

A. Plans and conducts research related to the development, manufacture, and testing of cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products in order to develop and maintain a scientific base for establishing standards for safety, purity, potency, and effectiveness.

B. Develops policy and procedures to ensure the continued safety of human cells, tissues, and cellular and tissue-based products (HCT/Ps) for risk of communicable diseases.

C. Develops policy and procedures governing the pre-market approval review and evaluation of cellular, gene therapy, therapeutic vaccine, plasma-derived, and coagulation products in keeping with the provisions of the Public Health Service (PHS) Act applicable provisions of the Food Drugs & Cosmetics Act (FD&C) Act, Center policies and procedures.

D. Reviews, evaluates and takes appropriate action on Investigational New Drug Applications (INDs), Investigational Device Exemptions (IDEs), Pre-Market Approvals (PMAs), Biologics License Applications (BLAs), New Drug Applications (NDAs), and other regulatory submissions related to therapeutic products and amendments or supplements to these applications.

E. Reviews, evaluates, and takes appropriate action on product applications submitted by manufacturers of, cellular, gene therapy, therapeutic vaccines, plasma-derived and coagulation products, and proposes written and reference standards for cellular, tissue, gene therapy, plasma-derived and coagulation products.

F. Coordinates with the Office of Compliance and Biologics Quality and the Office of Biostatistics and Epidemiology, evaluates clinical experience and reports of adverse events as necessary.

G. Cooperates with other Center components, as appropriate, tests products submitted for release by manufacturers.

H. Participates in inspections of manufacturing facilities for compliance with applicable standards.

I. Administers applicable provisions of the FD&C Act as they pertain to certain devices and drugs that are under the jurisdiction of the Office and cooperates with other Agency components and outside organizations on issues related to these products.

J. Develops, organizes and maintains quality assurance and quality control for reviews of INDs, IDEs, PMAs, NDAs, BLAs and other regulatory activities for products regulated by the Office.

K. Develops, organizes and maintains quality assurance and quality control for the conduct of research in support of standards development to assure the continued safety, purity and potency of products regulated by the Office.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner for Food and Drugs on July 28, 2016, and effective on September 24, 2016.

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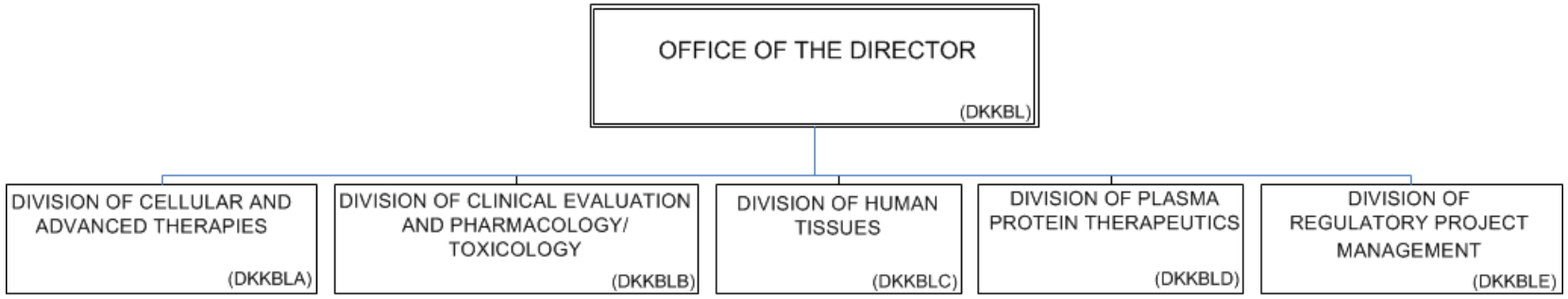
FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF TISSUES AND ADVANCED THERAPIES



STAFF MANUAL GUIDE 1218.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 24, 2016

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

OFFICE OF THE DIRECTOR (DKKBL):

- DIVISION OF CELLULAR AND GENE THERAPY (DKKBLA)
- DIVISION OF CLINICAL EVALUATION AND PHARMACOLOGY/TOXICOLOGY (DKKBLB)
- DIVISION OF HUMAN TISSUES (DKKBLC)
- DIVISION OF PLASMA PROTEIN THERAPEUTICS (DKKBLD)
- DIVISION OF REGULATORY PROJECT MANAGEMENT (DKKBLE)