

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

Effective Date: July 8, 2011

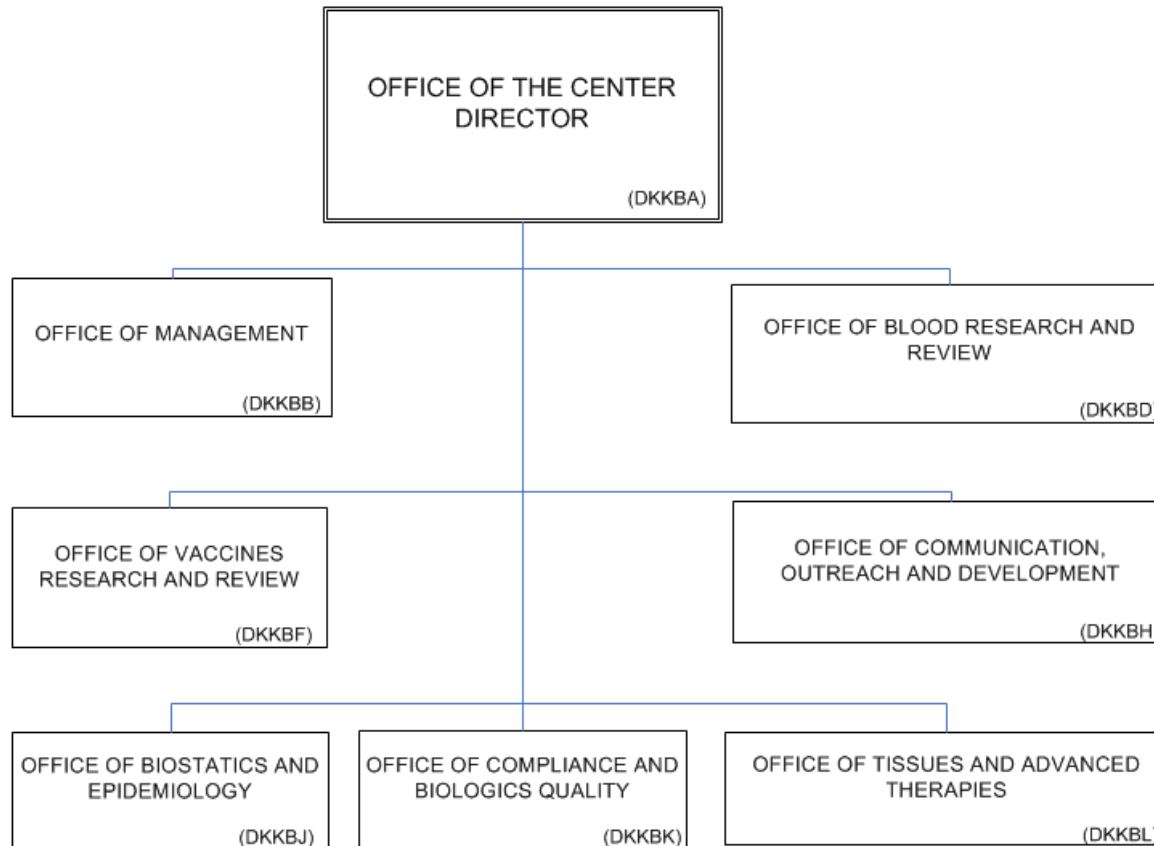
1. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (DKKB).

- A. Administers regulation of biological products under the biological product control provisions of the Public Health Service Act and applicable provisions of the Federal Food, Drug, and Cosmetic Act.
- B. Provides dominant focus in FDA for coordination of the Acquired Immune Deficiency Syndrome (AIDS) program.
- C. Inspects manufacturers' facilities for compliance with standards, tests products submitted for release, establishes written and physical standards, and approves licensing of manufacturers to produce biological products.
- D. Plans and conducts research related to the development, manufacture, testing, and use of both new and old biological products to develop a scientific base for establishing standards designed to ensure the continued safety, purity, potency, and efficacy of biological products.
- E. Coordinates with the Center for Drug Evaluation and Research regarding activities for biological drug products. Such activities include research, compliance, and product review and approval.
- F. Plans and conducts research on the preparation, preservation, and safety of blood and blood products, the methods of testing safety, purity, potency, and efficacy of such products of therapeutic use, and the immunological problems concerned with products, testing, and use of diagnostic reagents employed in grouping and typing blood.
- G. In carrying out these functions, cooperates with other Agency components of FDA, other PHS organizations, governmental and international agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of biological products.

2. AUTHORITY AND EFFECTIVE DATE.

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

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**



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The following is the Food and Drug Administration, Center for Biologics Evaluation and Research organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE CENTER DIRECTOR (DKKBA):

- OFFICE OF MANAGEMENT (DKKBB)
- OFFICE OF BLOOD RESEARCH AND REVIEW (DKKBD)
- OFFICE OF VACCINES RESEARCH AND REVIEW (DKKBF)
- OFFICE OF COMMUNICATION, OUTREACH AND DEVELOPMENT (DKKBH)
- OFFICE OF BIostatISTICS AND EPIDEMIOLOGY (DKKBJ)
- OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY (DKK BK)
- OFFICE OF TISSUE AND ADVANCED THERAPIES (DKKBL)