

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF STRATEGIC PROGRAMS

OFFICE OF BUSINESS INFORMATICS

Effective Date: 04/24/2013

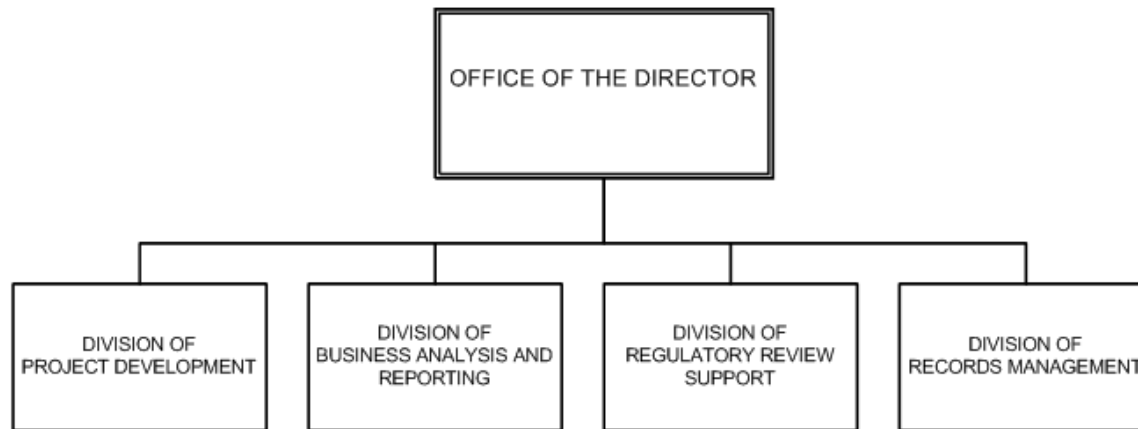
1. OFFICE OF BUSINESS INFORMATICS (DKKNTB).

- A. Acts as CDER strategic business liaison to the FDA Office of Information Management.
- B. Chairs and coordinates CDER's review and prioritization of business IT system needs, CDER IT Investment Review Board functions and recommendations regarding IT investment prioritization.
- C. Represents CDER in the FDA BioInformatics Board, ensuring that CDER's needs are reflected in enterprise initiatives, and vice versa.
- D. Facilitates and coordinates the development and implementation of tools and systems for access to and analysis of data used to support regulatory decisions.
- E. Provides support to the business community in business process changes and/or implementation of information technology. Processes re-engineering and development of business cases for IT needs.
- F. Standardizes business information management processes and facilitates the development of information management project proposals.
- G. Publishes regulations, guidance documents and MaPPs to support electronic submissions.
- H. Provides business project management support to IT systems development projects.
- I. Develops and maintains the business and data layers of the enterprise architecture.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Director, Center for Drug Evaluation and Research on April 24, 2013.

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Staff Manual Guide 1270.22
Organizations and Functions
Effective Date: April 24, 2013

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Strategic Programs, Office of Business Informatics organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF RECORDS MANAGEMENT
- DIVISION OF REGULATORY REVIEW SUPPORT
- DIVISION OF BUSINESS ANALYSIS AND REPORTING
- DIVISION OF PROJECT DEVELOPMENT