SMG 1270.22

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Strategic Programs

Office of Business Informatics

Effective Date: December 14, 2018
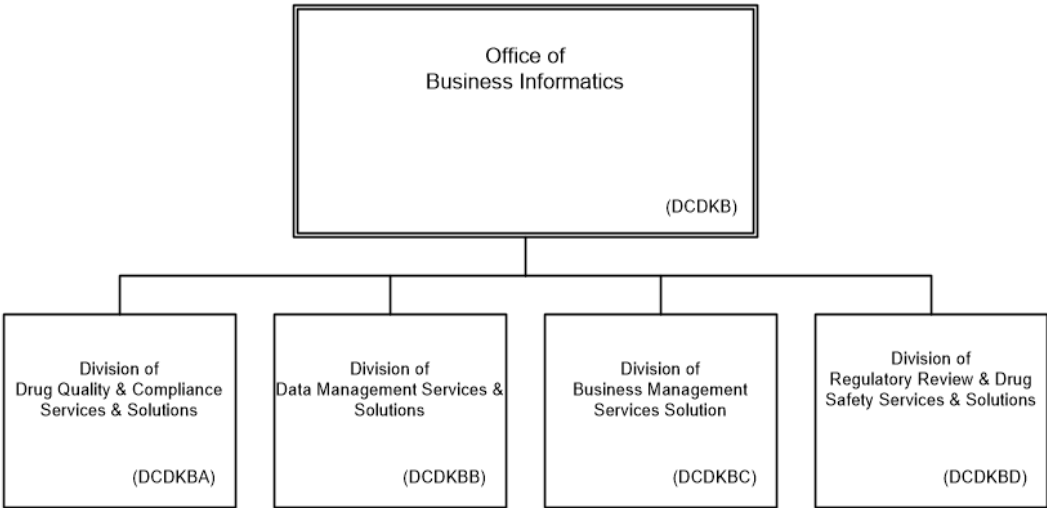
1. **Office of Business Informatics (DCDKB).**

   A. Acts as Center for Drug Evaluation and Research (CDER) strategic business liaison to the Food and Drug Administration (FDA), Office of Information Management.

   B. Chairs and coordinates CDER's review and prioritization of business Information Technology (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 the Office of Business Informatics were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Strategic Programs
Office of Business Informatics

Office of
Business Informatics

(DCDKB)

Division of Drug Quality & Compliance Services & Solutions (DCDKBA)	Division of Data Management Services & Solutions (DCDKBB)	Division of Business Management Services Solution (DCDKBC)	Division of Regulatory Review & Drug Safety Services & Solutions (DCDKBD)

Staff Manual Guide 1270.22
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Strategic Programs, Office of Business Informatics organizational structures depicting all the organizational structures reporting to the Director.

Office of Business Informatics (DCDKB).

These organizations report to the Office of Business Informatics:

Division of Drug Quality & Compliance Services & Solutions (DCDKBA)

Division of Data Management Services & Solutions (DCDKBB)

Division of Business Management Services & Solutions (DCDKBC)

Division of Regulatory Review & Drug Safety Services & Solutions (DCDKBD)