

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

Effective Date: December 14, 2018

1. Office of Strategic Programs (DCDK).

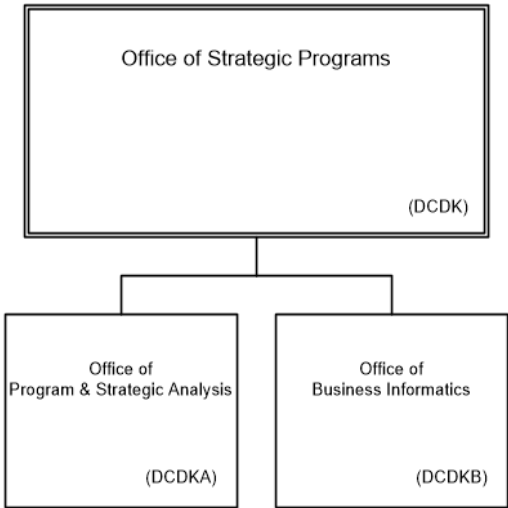
- A. Advises and assists key Agency Officials concerning the performance of the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) strategic programs, analysis, and business informatics activities.
- B. Directs CDER Office of Program and Strategic Analysis and Office of Business Informatics.
- C. Leads Center-wide strategic and operational programs and analysis.
- D. Leads business process analysis and business process planning to ensure effective design, development and utilization of information systems, electronic data and analytic tools to optimize regulatory business processes.
- E. Develops, installs, and monitors Center-wide business process and performance tracking systems.
- F. Advises and assists key Center and Agency Officials concerning the planning and performance, strategic information management, and business process support.
- G. Serves as Chief Liaison to Office of the Commissioner for strategic and business information needs, a process planning and analysis of business needs, plans and performance results, including briefings for the Commissioner, senior management, and external stakeholders, including Health and Human Services, Office of Management and Budget, Congress, patient and consumer advocates, and regulated industry.
- H. Directs and coordinates the international activities of the Center to facilitate international drug regulatory cooperation and harmonization. Provides outreach,

information, and regulatory cooperation related to rug product quality, efficacy, and safety to international groups and regulatory authorities.

2. Authority and Effective Date.

The functional statements for the Office of Strategic Programs 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**



Program Evaluation & Implementation Staff
Economics Staff
Performance Analysis & Data Services Staff
Lean Management Staff

Division of Drug Quality & Compliance Services & Solutions
Division of Data Management Services & Solutions
Division of Business Management Services & Solutions
Division of Regulatory Review & Drug Safety Services & Solutions

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

Office of Strategic Programs (DCDK).

These organizations report to the Office of Strategic Programs:

Office of Program & Strategic Analysis (DCDKA)

Office of Business Informatics (DCDKB)

These organizations report to the Office of Program & Strategic Analysis:

Program Evaluation & Implementation Staff

Economics Staff

Performance Analysis & Data Service Staff

Lean Management Staff

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)