

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 Program and Strategic Analysis

Effective Date: December 14, 2018

1. Office of Program and Strategic Analysis (DCDKA).

- A. Directs the long-range planning processes, including strategic and program planning, and coordinates with the Office of Commissioner and Department of Health and Human Services (DHHS) long-range planning process.
- B. Assists and consults with components in development and implementation of proposals related to key strategic initiatives and priorities.
- C. Evaluates the impact of operations and policies on external stakeholders, including patients, consumers, health care providers, regulated industry and other constituents.
- D. Develops analytic approaches and conducts analyses for special evaluation studies to inform Center strategy and policy position on emerging issues in drug regulation.
- E. Coordinates the performance planning in accordance with the Government Performance and Results Act.

2. Program Evaluation and Implementation Staff (DCDKA1).

- A. Conducts a wide range of qualitative and quantitative analyses to answer key questions of operations, informing internal strategy and decision-making, as well as Center strategy with respect to the external stakeholder environment.
- B. Provides project management and other technical services to direct or coordinate implementation of significant initiatives and to improve the efficiency and effectiveness of resources and key business processes.

- C. Evaluates impact of external factors (e.g. industry behavior, proposed legislation) on Center programs. As necessary, recommends new initiatives or changes in existing programs and priorities.
- D. Conducts program evaluation studies and special operational analyses to assess the impact of Center initiatives to improve effectiveness and efficiency.
- E. Leads and coordinates Center-wide development of strategic and operational plans.

3. Economics Staff (DCDKA2).

- A. Serves as the technical expert and knowledge resource regarding the commercial business and economics of drug development (branded drugs and biologics, generics, biosimilars, and Over-The-Counter products) to inform Center leadership of industry trends and to support decision-making.
- B. Conducts a wide range of analyses of regulated industry trends that may be relevant to operations and policies, and other market and public policy factors that may have implications on the strategic and operational environment of the Center.
- C. Conducts special quantitative and qualitative data analysis, as requested, applying economic analysis, statistical analysis, decision analysis, cost-benefit analysis, and operations research to support senior management decisions.
- D. Evaluates impact of proposed policies on external stakeholders to support Center, Agency, and Department decision-making.
- E. Conducts regulatory policy impact analyses, including alternative courses of action or identified policy options for management consideration.

4. Performance Analysis and Data Services Staff (DCDKA3).

- A. Supports senior management through centralized program performance reporting for branded drugs and biologics, generics, and biosimilars. Determines Center reporting requirements as regulations, policies, and program need change.
- B. Serves as technical expert in development of specialized and informative SMG management reports using the corporate databases.
- C. Provides additional data analysis and information to address specific questions and issues using the corporate databases and other appropriate data sources.

D. Coordinates data and information requests (e.g., for Press Inquiries, Freedom of Information (FOIs), Congressional reports, General Accounting Office (GAO) and Office of Inspector General (OIG) studies).

5. Lean Management Staff (DCDKA4).

A. Serves as the coordinator and focal point for Lean Management.

B. Provides consultation on application of Lean Management concepts.

C. Conducts lean management analyses on identified cross-cutting internal processes, recommending business process improvements as appropriate to improve the efficiency.

6. Authority and Effective Date.

The functional statements for the Office of Program and Strategic Analysis 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 Programs and Strategic Analysis**

Office of
Programs & Strategic Analysis
Program Evaluation & Implementation Staff
Economics Staff
Performance Analysis & Data Services Staff
Lean Management Staff

(DCDKA)

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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, Office of Program and Strategic Analysis organizational structures depicting all the organizational structures reporting to the Director.

Office of Program & Strategic Analysis (DCDKA).

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

Program Evaluation & Implementation Staff

Economics Staff

Performance Analysis & Data Service Staff

Lean Management Staff