

**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 PROGRAM AND STRATEGIC ANALYSIS

Effective Date: 04/24/2013

1. OFFICE OF PROGRAM AND STRATEGIC ANALYSIS (DKKNTA).

- 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 (DKKNTA1).

- 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 (DKKNTA2).

- 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 (DKKNTA3).

- 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

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 (DKKNTA4).

- 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 this office were approved by the Director, Center for Drug Evaluation and Research on April 24, 2013.