

SMG 1270.2

**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

Effective Date: 04/24/2013

1. OFFICE OF STRATEGIC PROGRAMS (DKKNT).

- A. Advises and assists key Agency Officials concerning the performance of the FDA CDER strategic programs, analysis, and business informatics activities.
- B. Directs CDER Office of Evaluation and 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, and 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 drug product quality, efficacy, and safety to international groups and regulatory authorities.

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.