

SMG 1118.7

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF POLICY, PLANNING, LEGISLATION, AND ANALYSIS

OFFICE OF PLANNING

Effective Date: September 26, 2014

1. OFFICE OF PLANNING (DNNB).

- A. Leads agency-wide strategic planning initiatives.
- B. Advises and assists the Commissioner and other key agency officials concerning the performance of the Agency planning, evaluation and economic analysis activities.
- C. Develops program and planning strategy through analysis and evaluation of issues affecting policies and program performance.
- D. Develops, installs, and monitors the agency wide planning system including the long-term plans, strategic action plans, and program implementation plans.
- E. Leads the Agency Strategic Planning Council.
- F. Consults with and supports the agency preparation of legislative proposals, budget proposals, proposed rulemaking, and technical assistance to Congress.
- G. Conducts operations research, economic, social science, and special studies as a basis for forecasting trends, needs, and major problems requiring solutions, and provides assistance and consultation in these areas to operating units.
- H. Evaluates impact of external factors on Agency programs, including industry economics, consumer expectations, and prospective legislation. As necessary, recommends new programs or changes in existing programs and program priorities.

- I. Develops Agency evaluation programs and systems to evaluate overall Agency program accomplishments against objectives and priorities, recommending changes as necessary.
- J. Estimates marginal impact of funding changes on Agency performance and ability to protect and promote public health.
- K. Leads effort to analyze agency business processes for process modernization and bioinformatics support.
- L. Coordinates the development of public health and program outcome measures, and monitors and reports on the status of those measures. Develops logic models that link agency activities and outputs to public health outcomes.
- M. Leads and coordinates agency-wide effort to plan, evaluate and improve Agency risk communication.
- N. Coordinates and performs user fee program evaluations and analyses. Leads and coordinates the Prescription Drug User Fee Act program initiative for Performance Management and quality systems studies.
- O. Leads, performs, and coordinates the agency's organizational change planning function. Helps programs assess and define the need for change, develop effective communications, and align the organization to the change initiative.

2. PLANNING STAFF (DNNB1).

- A. Performs and coordinates the agency's performance planning functions:
 - 1. Represents the agency in DHHS and OMB performance planning activities.
 - 2. Coordinates and reports the agency's performance planning and achievements in accordance with the Government Performance and Results Modernization Act.
 - 3. Consults with the Office of Budget and collaborates with agency components in preparing and reporting the performance sections of the agency's budget.
 - 4. Coordinates the agency long range strategic and performance planning in line with the DHHS strategic plan.

5. Maintains, analyzes and reports agency-wide performance information and achievements to external stakeholders.
- B. Performs and coordinates the agency's program performance tracking and management functions:
1. Coordinates the development and improvement of the agency's program performance measures, data and goals on a continuous basis to ensure alignment to agency's missions and objectives.
 2. Coordinates the agency short and long range performance planning objectives and processes.
 3. Assists and consults with agency components in their performance planning for data, trends, targets and achievements.
 4. Maintains, analyzes and reports agency-wide quarterly program performance information.
- C. Performs and coordinates program advisory, planning, and analysis services:
1. Assists agency components in analyzing and improving their planning processes, performance objectives and goals, as requested.
 2. Works with agency components as requested to identify and implement internal and external best practices to improve overall performance.
 3. Analyzes information by applying mathematical disciplines and principles to make available data and facilitate improved decision-making.
 4. Conducts special operational analysis and planning related studies as requested.
 5. Conducts analysis of resource requests submitted by agency components and develops recommendations for the Commissioner, to fulfill agency, DHHS, and OMB requirements.
- D. Provides operations analysis and project management support to the agency committees and initiatives as needed.
- E. Represents the performance and planning aspects of the agency's program integrity function.

3. PROGRAM EVALUATION AND PROCESS IMPROVEMENT STAFF (DNNB2).

- A. Leads, performs, and coordinates the agency's program evaluation function:
1. Prepares annual User Fee performance reports to Congress.
 2. Performs agency program and policy evaluations and analytical studies. Recommends alternative courses of action to increase effectiveness of agency allocation of resources and to improve program and project performance.
 3. Performs analyses of significantly broad agency issues identified in the planning process. Recommends and/or implements steps to resolve these issues.
 4. Develops the annual evaluation plan for the agency and coordinates with DHHS.
 5. Conducts special evaluation, analytical, and economic-related studies in support of agency policy development and in resolution of broad agency problems.
 6. Evaluates the impact of external factors on agency programs, including consumer expectations and prospective legislation.
 7. Evaluates the impact of agency operations and policies on regulated industries and other agency constituents.
 8. Provides process expertise to agency components in designing consensus sessions with internal and external stakeholders.
 9. Assists and consults with agency components on the design and execution of key program and process re-inventions.
 10. Assists and consults with agency scientific review components to enhance transparency, consistency, accountability, and continuous improvement of review processes.
 11. Facilitates cross-organizational sharing of key program and process improvements.
- B. Leads, performs, and coordinates the agency's business process planning function:

1. Coordinates the agency's business process planning function in support of business process improvement and automation efforts.
2. Provides business process planning, operations analysis, and project management support to agency information management programs.
3. Provides business process modeling, analysis, and planning services to agency programs and initiatives.

4. ECONOMICS STAFF (DNNB3).

- A. Performs economic analyses and special studies for use by agency officials in decisions regarding agency policies.
- B. Serves as the agency's chief resource for economic information.
- C. Collects and interprets economic data relevant to the agency's public-health mission.
- D. Performs and reviews benefit-cost and cost-effectiveness analyses of agency regulations.
- E. Advises and assists the Commissioner and other key agency officials on a day to day basis concerning economic factors relating to current and proposed agency activities.
- F. Provides economic research material for use by agency officials in preparing testimony before congressional committees and in developing replies to inquiries directed to the agency.
- G. Conducts economic studies of Agency related industries as a basis for forecasting trends, needs, and major problems affecting the agency.
- H. Provides agency representation to Congress, OMB, DHHS, and others, as appropriate, on economic issues relating to agency regulations and other current and proposed actions.

5. RISK COMMUNICATION STAFF (DNNB4).

- A. Coordinates development of agency policies on risk communication practices.
- B. Coordinates agency strategic planning activities concerning risk communications.
- C. Coordinates agency research agenda for risk communication methods.

- D. Facilitates development and sharing of risk communication best practices and standard operating procedures.
- E. Conducts risk communications research on methodological and cross-cutting issues.
- F. Leads management and coordination of the Agency Risk Communication Advisory Committee.
- G. Staffs Agency's Communications Council.

6. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Human Services, and effective on September 26, 2014.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF POLICY, PLANNING, LEGISLATION, AND ANALYSIS
OFFICE OF PLANNING**

OFFICE OF THE DIRECTOR	(DNNB)
Planning Staff	(DNNB1)
Program Evaluation & Process Improvement Staff	(DNNB2)
Economic Staff	(DNNB3)
Risk Communications Staff	(DNNB4)

STAFF MANUAL GUIDE 1118.7
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Policy, Planning, Legislation, and Analysis, Office of Planning organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR--(DNNB):

- Planning Staff--(DNNB1)
- Program Evaluation and Process Improvement Staff--(DNNB2)
- Economic Staff--(DNNB3)
- Risk Communication Staff--(DNNB4)