

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Executive Programs

Effective Date: May 13, 2024

1. Office of Executive Programs (DCRB).

- A. Manages high priority, strategically aligned projects for the Human Foods Program (HFP), including the Food and Drug Administration's (FDA) inspections and investigations program and maintains and monitors project schedules. Analyses of the project portfolio, considering factors such as scope, risk, and resource needs. Offers guidance and recommends solutions to senior leadership regarding project prioritization and based on availability of resources and project risks.
- B. Provides executive leadership and coordination of significant, emerging, sensitive, or cross-cutting issues to ensure strategic and timely actions on major policy and legislative issues for the HFP, including FDA's inspections and investigations program.
- C. Coordinates and manages the flow of documents, communications, correspondence and other materials from Congress, industry, consumer groups and the public, for the HFP, including FDA's inspection and investigations program activities.

2. Project and Portfolio Management Staff 1 (DCRB1).

- A. Serves as the primary resource for managing high priority, strategically aligned projects for the HFP Office of Surveillance Strategy and Risk Prioritization; Office of Coordinated Outbreak Response, Evaluation, and Emergency Preparedness; Office of Integrated Food Safety System Partnerships; and the Office of Policy and International Engagement, including FDA's inspections and investigations program.
- B. Continuously monitors and reports on the status of its portfolio, tracking of resource requirements, risks, and alignment with the HFP priorities, including FDA's inspections and investigations program. Serve as a partner to HFP

offices and FDA's inspections and investigations program functions by providing project management staff and leading the project management function for projects aligned to Program priorities.

- C. Works with the Office of Strategic Programs (OSP) to plan and execute projects that are initiated as part of the OSP's strategic planning process. Performs thorough analyses of the project portfolio, considering factors such as risk, scope, and resource needs.
- D. Responsible for developing, maintaining, and communicating project management standards and best practices.

3. Project and Portfolio Management Staff 2 (DCRB2).

- A. Serves as the primary resource for managing high priority, strategically aligned projects for the HFP; Nutrition Center of Excellence, Office of Microbiological Food Safety; Office of Food Chemical Safety, and Dietary Supplements, and Innovation; and Office of Compliance and Enforcement.
- B. Continuously monitors and reports on the status of its project portfolio, tracking of resource requirements, risks, and alignment with the Program's priorities, including FDA's inspections and investigations program. Serve as a partner to HFP offices and FDA's inspections and investigations program functions by providing project management staff and leading the project management function for projects aligned to Program priorities.

4. Legislative and Program Issue Coordination and Executive Correspondence Staff (DCRB3).

- A. Leads and coordinates on emerging priorities to identify and address evolving challenges and collaborative decision-making to effectively mitigate risks for the Human Foods Program (HFP), including Food and Drug Administration's (FDA's) inspections and investigations program activities. This includes facilitating timely communication and coordinating multi-organization responses across the FDA on human food issues.
- B. Serves as the HFP liaison to the FDA congressional affairs components. Leads legislative strategy and the coordination and preparation for Congressional briefings, reports to Congress and requests for information and technical assistance on draft and pending legislation for the HFP, including FDA's inspections and investigations program activities.
- C. Provides comprehensive support to the Deputy Commissioner for Human Foods and key HFP officials by conducting research, analysis, and preparing reports to inform decision-making. Coordinate and manage briefings and decisional meetings of the Deputy Commissioner. Documents and tracks decisions made by key HFP officials.

- D. Reviews documents for external dissemination for sensitive topics to identify any potential risks, provide recommendations to protect sensitive information, and ensure responsible handling of the documents.
- E. Reviews and clears documents requiring Deputy Commissioner approval to ensure accurate and timely processing by reviewing, verifying, and approving relevant information, while adhering to established policies and procedures. Supports and enables effective decision-making and operational efficiency at the executive level.
- F. Serves as the HFP liaison to the FDA Executive Secretariat, Department of Health and Human Services (HHS), Office of the Inspector General (OIG), Government Accountability Office (GAO), and other Federal government agencies. Responsible for the management and coordination of OIG, GAO and congressional studies, investigations, and audits for the Program.
- G. Facilitates the efficient flow of information using centralized communications, task management, and stakeholder management processes, including Executive and Legislative Branch correspondence, and data call management.
- H. Manages and facilitates federal agency coordination on related policy issues. Conducts and manages internal governing body meetings with HFP executive leaders and other respective FDA executive leaders. Oversees records management for the Office of the HFP Deputy Commissioner, maintains guidelines and protocols for the proper handling, retention, and disposal of government records, ensuring compliance with applicable laws and regulations.
- I. Establishes and implements standard operating procedures for decision-making and clearance processes for the HFP, including of HFP Memorandum of Understandings (MOUs) after the MOU has received office level clearance and clearing proposed MOUs with HFP leadership, other FDA Centers (as needed), FDA Office of the Chief Counsel (OCC), and the FDA acquisition and grants organization in addition to posting the final MOU to FDA.gov. Provides necessary assistance and guidance to HFP staff on the MOU clearance process.

5. Authority and Effective Date.

The functional statements for the Office of Executive Programs were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Human Foods Program
Office of Executive Programs**

Office of
Executive Programs

Project & Portfolio Management Staff 1
Project & Portfolio Management Staff 2
Legislative & Program Issue Coordination & Executive
Correspondence Staff

(DCRB)

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Executive Programs organization structure depicting all the organizational structures reporting to the Director:

Project and Portfolio Management Staff 1 (DCRB1)

Project and Portfolio Management Staff 2 (DCRB2)

Legislative and Program Issue Coordination and Executive Correspondence Staff (DCRB3)