SMG 1231A.41

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Policy and International Engagement

Office of Policy, Regulations, and Information

Effective Date: May 13, 2024

1. Office of Policy, Regulations, and Information (DCRDA).

A. Leads the development, risk-based prioritization, and clearance of regulations, guidance, *Federal Register* notices, and other policies and procedures documents impacting the Human Foods Program (HFP), in coordination with the HFP Office of Policy Initiatives and Special Projects and other relevant Food and Drug Administration (FDA) components.

B. Leads regulatory and disclosure policy development and analysis activities on behalf of the HFP and coordinates resolution of policy issues involving FDA-regulated food products.

C. Coordinates legislative development and advises on other legislative analysis and review activities of the HFP, including draft and pending foods legislation.

D. Advises on issues relating to federal regulation, including interpretation and compliance with other federal laws, Executive Orders, bulletins and memoranda, delegations of authority, and FDA jurisdiction impacting the HFP.

E. Coordinates all requirements under the Paperwork Reduction Act and Privacy Act in support of the HFP regulation and policy development, and to advance critical foods research.

F. Oversees the disclosure of official records and information under the Freedom of Information Act, Privacy Act, and FDA's public disclosure regulations for the HFP.

2. Regulation and Policy Development Staff (DCRDA1).

A. Develops foods program regulations, guidance, *Federal Register* notices, and other policy documents; coordinates the review and clearance of such documents for publication or posting; and serves as the HFP liaison during internal and external clearance. Leads the evaluation of existing regulatory documents and provides authoritative recommendations to help address new scientific, legal, or policy issues.

B. Advises HFP leadership and staff on the administrative procedures relevant to developing rulemakings, guidance, *Federal Register* notices, or other policy documents, conducting hearings, and issuing and revising delegations of authority. Ensures delegations are up-to-date and that officials have the requisite authority to sign documents and represent the HFP on priority issues.

C. Leads the review of regulations, guidance, and other policy documents prepared by other FDA components, or by other Federal Departments or agencies.

D. Manages and coordinates briefings with other parts of the FDA or Federal government who have clearance responsibility or interest in HFP regulations, guidance, and other policy documents.

E. Develops and clears responses to citizen petitions, petitions for reconsideration, and petitions for stay of administrative action. Serves as the Program's legal point of contact regarding litigation on such petitions or petition responses.

F. Manages HFP regulation and guidance initiation, prioritization, and clearance process and coordinates *Unified Agenda*, regulatory plan, and Foods Program Guidance Agenda entries and updates.

3. Government Information Policy Staff (DCRDA2).

A. Directs the strategic design, development, and implementation of information and disclosure policies for the HFP to ensure compliance with the Freedom of Information Act (FOIA), Privacy Act, Paperwork Reduction Act (PRA), other relevant statutes, and FDA information disclosure regulations.

B. Serves as liaison to FDA's Office of the Commissioner, the Department of Health and Human Services (HHS), and other Federal agencies on legal and policy issues relating to information and disclosure policies that impact the HFP.

C. Provides training for HFP leadership and staff on FOIA, disclosure policy, Privacy Act implementation, PRA policies and procedures, and develops other appropriate instructions, guidelines, and best practices.

D. Manages and coordinates responses to foods related FOIA requests, ensuring requests are processed in accordance with applicable statutes and FDA regulations, policies, and procedures. Provides authoritative advice and strategic policy direction to HFP leadership and staff on issues relating to information disclosure.

E. Manages and coordinates development, analysis, and compliance activities under the PRA and Privacy Act in support of foods regulations, guidance, other policy activities, and critical research. Serves as liaison to the Office of the Commissioner on development and implementation of PRA and Privacy Act policies and strategic initiatives.

4. Authority and Effective Date.

The functional statements for the Office of Policy, Regulations, and Information 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 Policy and International Engagement
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Office of
Policy, Regulations & Information

Regulation & Policy Development Staff
Government Information Policy Staff

(DCRDA)

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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Policy and International Engagement, Office of Policy, Regulations and Information organization structure depicting all the organizational structures reporting to the Director:

Regulation and Policy Development Staff (DCRDA1)

Government Information Policy Staff (DCRDA2)