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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

OFFICE OF THE COMMISSIONER

Statement of Organizations, Functions, and Delegations of
Authority

Part D, Chapter D-B, (Food and Drug Administration), of the
Statement of Organization, Functions, and Delegations of
Authority for the Department of Health and Human Services (35 FR
3685, February 25, 1970, and 60 FR 56605, November 9, 1995, 64
FR 36361, July 6, 1999, and in pertinent part at 57 FR 54239) is
being amended to reflect the restructuring of the Office of the
Commissioner (OC), Food and Drug Administration (FDA). This
reorganization includes the establishment of four Deputy-level
offices within the Office of the Commissioner, the changes are
as follows:

I. Under Part D, Food and Drug Administration, delete the Office
of the Commissioner (DA) in its entirety and replace with the
following:

DA.10 ORGANIZATION. The Food and Drug Administration (FDA) is
headed by the Commissioner, Food and Drug and includes the
following organizational units:

Office of the Commissioner (DA)

Office of the Chief Counsel (DAA)

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Office of the Chief of Staff (DAB)

Office of International and Special Programs (DAL)

Office of Operations (DAM)

Office of Policy, Planning and Preparedness (DAH)

Office of Scientific and Medical Programs (DAE)

DA.20 FUNCTIONS

A. **OFFICE OF THE COMMISSIONER (DA)** - The Office of the Commissioner (OC) includes the Commissioner and Deputy Commissioner who are responsible for the efficient and effective implementation of FDA mission.

B. **OFFICE OF THE CHIEF COUNSEL (DAA)** - The Office of the Chief Counsel (OCC) is also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

1. Is subject to the professional supervision and control of the General Counsel, Department of Health and Human Services (HHS), and represents FDA in court proceedings and administrative hearings with respect to programs administered by FDA.

2. Provides legal advice and policy guidance for programs administered by FDA.

3. Acts as liaison to the Department of Justice and other Federal agencies for programs administered by FDA.

4. Drafts or reviews all proposed and final regulations and Federal Register notices prepared by FDA.

5. Performs legal research and gives legal opinions on regulatory issues, actions, and petitions submitted to FDA.

6. Reviews proposed legislation affecting FDA that originates in HHS or on which Congress requests the views of the Department.

7. Provides legal advice and assistance to the Office of the Secretary on matters within the expertise of the Chief Counsel.

C. **OFFICE OF THE CHIEF OF STAFF (DAB)** - The Office of the Chief of Staff (OCOS):

1. Advises and provides integrated policy analysis and strategic consultation to the Commissioner, Deputy Commissioners, Associate Commissioners, Center Directors and other FDA officials on activities and issues that affect significant agency programs, projects and initiatives. Often this function involves the most difficult problems, crisis situations and extremely complex issues of FDA.

2. Provides leadership, coordination and management of the Commissioner's priority policies and issues across the Office of

the Commissioner and FDA-wide. Identifies, triages, supervises and tracks related actions from start to finish in conjunction with senior leadership across FDA.

3. Provides direct support to the Commissioner of Food and Drugs and serves as major point of contact between the FDA Centers and Offices and the Commissioner.

4. Serves as the principal liaison to HHS and coordinates and manages activities between FDA and HHS. Works with the FDA Centers and Offices to ensure assignments or commitments made related to these activities are carried out.

5. Serves as one of the Commissioner's primary strategic liaisons with staff, partners, and the community at large.

6. Manages budget and resources and provides operation oversight for the FDA'S Office of Legislation, Office of the Executive Secretariat, Office of Public Affairs, and Office of External Relations 7. Provides top level leadership and guidance on issues and actions tied to the FDA's external communications, public affairs, and legislative matters.

D. **OFFICE OF INTERNATIONAL & SPECIAL PROGRAMS (DAL)**. The Office of International and Special Programs (OISP):

1. Serves as FDA focal point for all international matters, pediatric matters, and combination product matters.

2. Advises the Commissioner and other key FDA officials on FDA's formulation and execution and cross cutting and precedent setting issues involving international, pediatric, and combination product matters.

3. Serves as the agency liaison with other U.S. Government components, international and foreign governments (including Washington, DC embassies) for policy formulation and execution impacting FDA and FDA regulated products.

4. Directs and monitors FDA strategic planning, priority-setting, and resource allocation processes for FDA international, pediatric and combination product matters.

5. Provides leadership to FDA program areas for international, pediatric and combination product activities.

6. Serves as the focal point for FDA international visitor program.

7. Serves as the focal point for FDA and the authority for policies and procedures pertaining to international travel.

8. Serves as the focal point for international-related training (external and internal).

9. Serves as the focal point for FDA international technical cooperation and assistance activities.

10. Serves as FDA focal point for all information exchange with foreign counterparts on international matters to ensure consistency internally and externally.

11. Serves as FDA focal point for contacts with foreign governments and international organizations (including Washington, D.C. embassies).

12. Serves as FDA focal point for planning and coordinating meetings involving international, pediatric and combination product matters.

E. **OFFICE OF OPERATIONS (DAM)** - The Office of Operations (OO):

1. Provides executive direction, leadership, coordination, and guidance for the overall day-to-day operations of FDA assuring the timely and effective implementation of operations and high quality delivery of services across FDA and its Centers.

2. Oversees the day-to-day operational activities and the interaction and execution of new program initiatives across all Centers, Field offices, Regions, and the Office of the Commissioner.

3. Advises and assists the Commissioner, Deputy Commissioners, Chief of Staff, Chief Counsel, Center Directors, and other key FDA officials on various management and business processes, compliance-oriented and legislative matters of FDA.

4. Works with other senior FDA leadership to make decisions that are consistent with broad conceptual guidelines of the Commissioner, to meet the changing needs of FDA and new legislation.

5. Leads FDA effort to analyze agency business processes for process modernization and bioinformatics support.

6. Leads and coordinates the Prescription Drug User Fee Act program initiative for Performance Management and quality systems studies.

7. Coordinates FDA's business process planning function in support of business process improvement and automation efforts.

8. Provides executive leadership and operational oversight to the Office of the Commissioner.

9. Assures that the conduct of FDA administrative and financial management activities, including budget, finance, human resources, organization, methods, and similar support activities effectively support program operations.

10. Provides FDA's administrative management services including information technology, communications, financial transaction functions, procurement, facilities, and equal employment opportunity and diversity management. Utilizes a call center to address all administrative and information

technology management issues, and monitors and analyzes operational performance and customer satisfaction.

11. Plans, directs and coordinates a comprehensive financial management program for FDA encompassing the areas of automated financial systems, fiscal accounting, voucher audit, and financial reporting. Issues periodic reports regarding the status of FDA's financial management and develops financial inputs for FDA's programs and financial plans.

12. Provides leadership and direction regarding all aspects of a variety of FDA management programs including internal controls, OIG liaison, organization management, delegations of authority, freedom of information, privacy act, and regulatory dockets management as well as programs related to ethics and conflict of interest matters.

13. Advises the Commissioner and other key Agency officials on administrative management and budget matters for components within the Office of the Commissioner (OC).

14. Provides advice and guidance with regard to formulation and development of administrative management policies, procedures, and controls.

15. Provides advice and assistance to the Commissioner and senior management officials on information technology resources and programs. Establishes and oversees implementation of the

FDA information technology policy and governance, procedures and processes to bring the Agency in conformance with the Clinger/Cohen Act. Establishes, directs and leads FDA level programs and all strategic aspects of information technology including: information technology (IT) shared services, telecommunications, security, strategic planning, capital planning and investment control, and enterprise architecture.

16. Plans, organizes, and carries out annual and multi-year budgeting in support of FDA's public health mission and programs. Provides staff assistance in justifying budgets through executive and congressional echelons. After appropriation, develops an orderly expenditure plan.

17. Serves as the first responder for FDA in emergency and crisis situations involving FDA regulated products or in situations where FDA regulated products are needed to be utilized or deployed.

F. **OFFICE OF POLICY, PLANNING AND PREPAREDNESS (DAH)** - The Office of Policy, Planning and Preparedness (OPPP):

1. Advises the Commissioner and other key FDA officials on matters relating to policy, development of regulations and guidance, legislative issues, and planning and evaluation activities, and counter-terrorism and emerging threats.

2. Participates with the Commissioner in the formulation of the basic policies and operational philosophy, which guide FDA in effectively implementing its responsibilities.

3. Oversees and directs the FDA's rulemaking activities and regulations and guidance development system.

4. Serves as FDA focal point for developing and maintaining communications, policies, and programs with regard to regulations development.

5. Oversees and directs FDA planning and evaluation activities, including the development of programs and planning strategies through analysis and evaluation of issues affecting policies and program performance.

G. OFFICE OF SCIENTIFIC AND MEDICAL PROGRAMS (DAE). The Office of Scientific and Medical Programs (OSMP):

1. Serves as the focus for scientific medical and related activities in the Office of the Commissioner.

2. Assists the Deputy Commissioner/Chief Medical Officer in planning, executing and monitoring FDA scientific and medical projects and programs.

3. Operates the following FDA programs: a. Orphan Drug Program; b. Women's Health Program; c. Good Clinical Practices Program; d. Critical Path Initiative Program; and e. FDA Fellowship Program.

4. Performs scientific research on the safety of regulated products through the National Center for Toxicological Research.

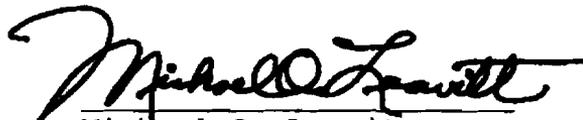
5. Manages FDA's committee on Research Involving Human Subjects and FDA's Science Board.

6. Represents the FDA on U.S. government committees and other Federal agencies on matters involving science or technology.

7. Manages processes related to research coordination and scientific peer review activities at FDA.

II. **Delegations of Authority.** Pending further delegation, directives or orders by the Commissioner of the Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

AUG 23 2007
Date


Michael O. Leavitt
Secretary