

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Open: September 11, 2009, 8:30 a.m. to adjournment.

Agenda: For the discussion of program policies and issues, opening remarks, report of the Director, NIGMS, and other business of the Council.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Ann A. Hagan, PhD, Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC6200, Bethesda, MD 20892-6200. (301) 594-4499.

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Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: http://www.nigms.nih.gov/about/advisory_council.html, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: August 10, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0376]

Office of the Commissioner Reorganization; Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has reorganized the Office of the Commissioner (OC). This reorganization includes the organizations and their substructure components as listed in this document. This reorganization includes the re-alignment of four Deputy-level offices within the Office of the Commissioner: the Office of the Chief Scientist; the Office of Administration (formerly titled the Office of Operations); the Office of Foods; and the Office of Policy, Planning and Budget (formerly titled the Office of Policy, Planning and Preparedness).

FOR FURTHER INFORMATION CONTACT:

Vanessa Starks, Office of Management Programs (HFA-400), Food and Drug Administration, 5600 Fishers Lane, rm. 6B-42, Rockville, MD 20857, 301-827-1463.

Office of the Chief Scientist: The organizational change will allow the agency to better focus the science and research activities under the Chief Scientist. Re-alignments under the Office of the Chief Scientist will include the Office of Counter-Terrorism and Emerging Threats, Office of Critical Path Programs, Office of Scientific Integrity, and the Office of Science and Innovation.

Office of Administration: The Office of Operations will be re-titled the Office of Administration. The Office of Administration will be restructured to strengthen agency wide management programs, budget and shared services operations, as well as the Office of the Commissioner's executive operations. Realignment of the Office of Acquisitions and Grants Services, the Office of Executive Operations, the Office of Information Management, the Office of Management, the Office of Equal Employment Opportunity and Diversity Management, and the establishment of the Office of Financial Operations.

Office of Foods: The Office of Foods will be realigned from the Office of Operations and will report directly to the Commissioner.

Office of Policy, Planning and Budget: The Office of Policy, Planning and Preparedness will be retitled the Office of Policy, Planning and Budget. The realignments from the Office of Policy, Office of Planning, and the Office of Budget Formulation (formerly titled the Office of Budget Formulation and Presentation, Office of Operations).

[Part D, Chapter D-B, (Food and Drug Administration), 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, 72 FR 50112, August 30, 2007) is amended to reflect the restructuring of the Office of the Commissioner (OC), Food and Drug Administration (FDA) as follows].

I. Under Part D, Food and Drug Administration, delete the Office of Commissioner 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
- Office of the Chief Counsel
- Office of the Chief of Staff
- Office of Legislation
- Office of Policy, Planning and Budget
- Office of Counselor to the

Commissioner

- Office of Women's Health
- Office of Special Medical Programs
- Office of External Affairs
- Office of Foods
- Office of the Chief Scientist
- Office of International Programs
- Office of Administration
- Office of Equal Employment Opportunity and Diversity Management Center for Tobacco Products

DA.20 FUNCTIONS.

Office of the Commissioner: The Office of the Commissioner (OC) includes the Commissioner and Deputy Commissioner who are responsible for the efficient and effective implementation of the FDA mission.

Office of the Chief Counsel: 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, the Chief Counsel 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 (DHHS), 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 applies to 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.

Office of the Chief of Staff:

1. Advises and provides integrated policy analysis and strategic consultation to the Commissioner, Deputy Commissioners, and other senior 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 the agency.

2. Provides leadership, coordination and management of the Commissioner's priority policies and issues across the Office of the Commissioner and agency wide. Identifies triages, supervises and tracks related actions from start to finish in conjunction with senior leadership across FDA.

3. Serves as the principal liaison to the Department of Health and Human Services (DHHS) and coordinates and manages activities between FDA and DHHS. Works with the FDA Centers/ Offices to ensure assignments or commitments made related to these activities are carried out.

4. Provides direct support to the Commissioner, Deputy Commissioners, and other FDA senior staff including briefing materials, background information for meetings, responses to outside inquiries, and maintenance and control of the Commissioner's working files.

5. Provides top level leadership and guidance on issues and actions tied to the agency's communications with the Public Health Service, DHHS, and the White House, including correspondence for Assistant Secretary for Health and Secretarial signatures; controls for all agency public correspondence directed to the Commissioner; and the development and operation of tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.

Executive Secretariat:

1. Advises the Commissioner and other key agency officials on activities that affect agency wide programs, projects, and initiatives. Informs appropriate agency staff of the decisions and assignments made by the Commissioner, the Deputy Commissioners, the Chief of Staff and the Associate Commissioners.

2. Develops and maintains management information necessary for

monitoring the Commissioner's and agency's goals and priorities.

3. Assures that materials in support of recommendations presented for the Commissioner's consideration are comprehensive, accurate, fully discussed and encompass the issues involved.

4. Provides correspondence control for the Commissioner and controls and processes all agency public correspondence directed to the Commissioner. Develops and operates tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.

5. Provides direct support to the Commissioner, Deputy Commissioners, Chief of Staff and Associate Commissioners including briefing materials, background information for meetings, responses to outside inquiries, and maintenance and control of the Commissioner's working files.

6. Performs agency wide assignments involving complex problems and issues related to agency programs, strategies and activities, including preparation of special reports for the Department.

7. Coordinates the agency's communications with the Public Health Service, DHHS, and the White House including correspondence for the Assistant Secretary for Health and Secretarial signatures.

Office of Legislation:

1. Advises and assists the Commissioner and other key agency officials concerning legislative needs, pending legislation and oversight activities that affect FDA.

2. Serves as the focal point for overall legislative liaison activities within FDA and between FDA, the Department, PHS and other agencies; and analyzes the legislative needs of FDA and drafts or develops legislative proposals, position papers, and departmental reports on proposed legislation for approval by the Commissioner.

3. Advises and assists members of Congress and congressional committees and staffs in consultation with the Office of the Secretary on agency actions, policies, and issues related to legislation which may affect FDA.

Office of Policy, Planning and Budget:

1. Plans, organizes, and carries out annual and multi-year budgeting in support of FDA's public health mission and programs.

2. Produces three major budget submissions a year (to Health and Human Services (HHS) in June, Office of Management and Budget (OMB) in September, and to Congress in January).

3. Develops and presents required background exhibits, MAX input, and

supplemental requests as necessary; coordinates graphic material for presentations; and coordinates budgetary passback appeals at each level.

4. Tracks Appropriation activities and bills affecting FDA through the legislative process.

5. Responds to requests for budget information and special reports and exhibits.

6. Reviews and analyzes potential budgetary impacts of congressional or administrative proposals, providing expert opinion and recommendations.

7. Clears documents leaving the agency that have budgetary impact or resource information.

8. Tracks special initiatives and agency cross-cutting programs.

Office of Policy:

1. Leads agency wide strategic policy initiatives.

2. Advises and assists the Commissioner and other key agency officials on matters relating to agency policy, and on regulations and guidance development.

3. Serves as the lead agency focal point for developing broad agency policy.

4. Provides strategic policy direction and develops innovative policies for FDA to more effectively and efficiently protect and promote public health.

5. Develops significant and cross-cutting policy and engages in strategic problem solving.

6. Oversees, directs, and coordinates the agency's rulemaking and guidance development activities.

7. Serves as the agency focal point for communications and policies with regard to development of regulations and guidance.

8. Initiates new and more efficient systems and procedures to accomplish agency goals in the rulemaking and guidance development processes.

9. Reviews agency policy documents to ensure consistency in statements regarding agency policies.

10. Provides strategic policy direction for agency budget formulation.

Policy Development and Coordination Staff:

1. Leads the development of cross-cutting or broad agency policies and serves as a cross-agency think tank to develop innovative policies.

2. Advises and assists the Commissioner and other key agency officials concerning information that may affect current or proposed FDA policies.

3. Advises the Commissioner and other key agency officials on the formulation of broad agency policy.

4. Engages in strategic problem solving.

5. Serves as agency liaison for intergovernmental policy development.

6. Coordinates the development, review, and clearance of regulations and guidances.

7. Manages the agency's regulation, guidance review and clearance processes.

8. Reviews policy documents to assess and achieve consistency in policies across documents.

9. Establishes procedures for agency policy formulation and coordinates policy formulation activities throughout the agency.

10. Negotiates the resolution of policy issues involving more than one component of the agency.

11. Coordinates the review and analysis of policies.

12. Initiates and participates in interagency discussions on agency regulations, plans, and policies to improve coordination of Federal, State, or local agencies on a specific regulation or in developing an effective alternative approach.

13. Serves on agency task forces that are critical elements in the initiation, study, and resolution of priority policy issues.

Regulations Policy and Management Staff:

1. Serves as the agency's focal point with the Department of Health and Human Services, Office of Management and Budget, and other Federal agencies for policies and programs concerning regulations development and for the receipt of and response to other agency comments on FDA policy documents.

2. Reviews proposed regulations, final regulations, and other agency documents to be published in the **Federal Register**. Ensures regulations are necessary; consistent with established agency policy; clearly written; enforceable; coordinated with other agency components, the Office of the Chief Counsel, and Federal, State, and local government agencies; appropriately responsive to public participation requirements and applicable executive orders; and responsive to any applicable requirements for assessment of economic and environmental effects.

3. Coordinates, with other agency components, the evaluation of existing regulations to determine whether they are efficiently and/or effectively accomplishing their intended purpose. Identifies and makes recommendations to address regulations that require revision to correspond with current standards and those that should be revoked due to obsolescence.

4. Resolves regulatory policy disagreements between agency

components during the preparation of **Federal Register** documents.

Regulations Editorial Section:

1. Serves as FDA's official liaison within the Office of the Federal Register. Edits, processes, and prepares finished manuscript material for the issuance of agency proposed and final regulations and other documents published in the **Federal Register**.

2. Provides all **Federal Register** document development support functions (including cross-referencing, record retention, incorporation by reference, document tracking, and agency master print books of current Code of Federal Regulations (CFR) materials. Controls numbering and organization of agency codified material to ensure proper structure of regulations being issued.

Office of Planning:

1. Leads agency-wide strategic planning initiatives.

2. Advises and assists the Commissioner and other key agency officials concerning the performance of the FDA planning, evaluation and economic analysis activities.

3. Develops program and planning strategy through analysis and evaluation of issues affecting policies and program performance.

4. Develops, installs, and monitors the agency wide planning system including the long-term plans, strategic action plans, functional and business bioinformatics plans.

5. Leads the FDA Strategic Planning Council.

6. Consults with and supports the agency preparation of legislative proposals, proposed rulemaking, and technical assistance to Congress.

7. Conducts operations research, economic, 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.

8. Evaluates impact of external factors on FDA programs, including industry economics, consumer expectations, and prospective legislation. As necessary, recommends new programs or changes in existing programs and program priorities.

9. Develops FDA evaluation programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.

10. Estimates marginal impact of funding changes on FDA performance and ability to protect public health.

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

12. Acts as FDA liaison to HHS and other Federal activities under the Office of the National Coordinator for Health Information Technology.

13. Leads and coordinates agency-wide effort to plan, evaluate and improve FDA risk communication.

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

Planning Staff:

1. Performs and coordinates the following agency's performance planning functions:

Represents the HHS in and OMB performance planning activities.

Coordinates and reports the agency's performance planning and achievements in accordance with the Government Performance and Results Act.

Consults with the Office of Budget Formulation and collaborates with agency components in preparing and reporting the performance sections of the agency's budget.

Coordinates the agency long range strategic and performance planning in line with the HHS strategic plan.

Maintains, analyzes and reports agency-wide performance information and achievements to external stakeholders.

2. Performs and coordinates the following agency's program performance tracking and management functions:

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.

Coordinates the agency short and long range performance planning objectives and processes.

Assists and consults with agency components in their performance planning for data, trends, targets and achievements.

Maintains, analyzes and reports agency-wide quarterly program performance information.

Performs and coordinates program advisory, planning, and analysis services.

Assists agency components in analyzing and improving their planning processes, performance objectives and goals, as requested.

Works with agency components as requested to identify and implement internal and external best practices to improve overall performance.

Analyzes information by applying mathematical disciplines and principles to make available data and facilitate improved decision-making.

Conducts special operational analysis and planning related studies as requested.

Conducts analysis of resource requests submitted by agency components and develops recommendations for the Commissioner, to fulfill agency and agency requirements.

Staffs the FDA Strategic Planning Council.

Provides operations analysis and project management support to the agency committees and initiatives as needed.

Provides operations analysis and project management support to the Prescription Drug User Fee program.

Evaluation Staff:

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.

4. Recommends and/or implements steps to resolve these issues.

5. Develops the annual evaluation plan for the agency and coordinates with HHS.

6. Conducts special evaluations, analytical and economic-related studies, in support of agency policy development and in resolution of broad agency problems.

7. Evaluates the impact of external factors on agency programs, including consumer expectations and prospective legislation.

8. Evaluates the impact of agency operations and policies on regulated industries and other agency constituents.

9. Provides process expertise to agency components in designing consensus sessions with internal and external stakeholders.

10. Assists and consults with agency components on the design and execution of key program and process re-inventions.

11. Assists and consults with agency scientific review components to enhance transparency, consistency, accountability, and continuous improvement of review processes.

12. Facilitates cross-organizational sharing of key program and process improvements.

Economics Staff:

1. Performs economic analyses for use by agency officials in decisions regarding agency policies.

2. Serves as the agency's chief resource for economic information.

3. Collects and interprets economic data relevant to the agency's public-health mission.

4. Performs and reviews benefit-cost and cost-effectiveness analyses of agency regulations.

5. 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.

6. 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.

7. Conducts economic studies of FDA related industries as a basis for forecasting trends, needs, and major problems affecting the agency.

8. Provides agency representation to Congress, OMB, HHS, and others, as appropriate, on economic issues relating to agency regulations and other current and proposed actions.

Risk Communication Staff:

1. Coordinates development of agency policies on risk communication practices.

2. Coordinates agency strategic planning activities concerning risk communications.

3. Coordinates agency research agenda for risk communication methods.

4. Facilitates development and sharing of risk communication best practices and standard operating procedures.

5. Conducts risk communications research on methodological and cross-cutting issues.

6. Leads management and coordination of the FDA Risk Communication Advisory Committee.

Business Process Planning Staff:

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 the FDA Bioinformatics Board and its associated Business Review Boards.

3. Coordinates and maintains the strategic and performance layers of the Enterprise Architecture, in support of the Office of Information Management.

4. Establishes and maintains agency standards for business process modeling.

5. Provides business process modeling, analysis, and planning services to agency programs and initiatives as needed.

Office of Budget Formulation:

1. Plans, organizes, and carries out annual and multi-year budgeting in support of FDA's public health mission and programs.

2. Produces three major budget submissions a year (to Health and Human Services (HHS) in June, Office of Management and Budget (OMB) in September, and to Congress in January).

3. Develops and presents required background exhibits, MAX input, and supplemental requests as necessary; coordinates graphic material for presentations; and coordinates budgetary passback appeals at each level.

4. Tracks Appropriation activities and bills affecting FDA through the legislative process.

5. Responds to numerous requests for budget information and special reports and exhibits.

6. Reviews and analyzes potential budgetary impacts of congressional or administrative proposals, providing expert opinion and recommendations.

7. Clears documents leaving the agency that have budgetary impact or resource information.

8. Tracks special initiatives and agency cross-cutting programs.

Office of the Counselor to the Commissioner:

1. Formulates and renders advice to the Commissioner related to policy development, interpretation and integration that cuts across program lines or which is not well defined.

2. Provides a leadership role in advocating for and advancing the Commissioner's priorities.

3. Reviews recommendations for actions and reviews other materials to ensure that all points of view and program interests are developed for consideration and fully analyzed.

4. Provides top level leadership for the development of, and management of emergency and crisis management policies and programs for FDA to ensure that a structure exists for FDA to respond rapidly to an emergency or crisis situation in which FDA-regulated products need to be utilized or deployed.

5. Coordinates FDA participation in internal and external counter-terrorism and emergency exercises.

6. Implements the continuity of operation plans and operation of the emergency and the crisis operation center.

7. Coordinates agency evaluation of emergency and crisis situations to determine appropriate internal and external referrals for further action.

Office of Crisis Management:

1. Serves as the first responder for Food and Drug Administration (FDA) in

emergency and crisis situations involving FDA regulated products or in situations in which FDA regulated products are needed to be utilized or deployed.

2. Assists in the development of, and will manage, emergency and crisis management policies and programs for FDA to ensure that a structure exists to respond rapidly to an emergency or crisis situation.

3. Serves as agency emergency coordinator to HHS Office of the Assistant Secretary for Preparedness and Response (OASPR) and as liaison to HHS Secretary's Office of Security and Strategic Information (OSSI). Provides OASPR situational awareness of all FDA-related emergencies and ensures that FDA's emergency operations procedures are in alignment with national and HHS procedures. Participates in OSSI intelligence briefings and provides secure fax capability for the agency.

4. Participates in international initiatives to ensure FDA's capability and readiness to work with foreign counterparts in responding to international emergencies involving or impacting FDA-regulated products and to share information with international counterparts during such emergencies.

5. Manages the FDA Emergency Operations Network Incident Management System (EON IMS), a system for capturing large amounts of near real time information about emergencies related to FDA-regulated products for use by senior agency decision makers in assessing and managing response activities. Provides Offices and Centers geographical information system maps created by EON IMS's GIS mapping component for use in strategic planning of agency emergency response activities.

6. Develops and updates agency emergency operations plans and incident specific annexes, ensuring their alignment and compliance with the National Response Framework and its Emergency Support Functions and the National Incident Management System.

7. Plans and conducts agency exercises to test emergency operations plans. Plans and coordinates FDA's participation in emergency exercises sponsored by other Departments and agencies, including national and international level exercises.

8. Oversees the FDA Emergency Call Center which provides after normal-hours service for responding to public inquiries and reports related to FDA-regulated products as well as surge capacity service for managing increased volumes of inquiries due to an event involving an FDA-regulated product.

9. Manages FDA's Emergency Operations Center (EOC), activating the EOC with augmented staffing from relevant Centers and Offices to monitor emergency situations, triage complaints and alerts, issue mission assignments to organizational components, coordinate overall agency response operations, and communicate with external partners requesting technical and material support. FDA's EOC serves as the central point of contact with the Department of Homeland Security's National Operations Center, DHHS Secretary's Operation Center, CDC Emergency Operations Center, USDA/FSIS Situation Room, and other Federal EOCs as appropriate.

10. Coordinates agency evaluation of emergency responses and crisis situations to determine appropriate internal and external referral for further action and recommended changes in agency procedures.

11. Oversees the work of the Office of Emergency Operations.

Office of Emergency Operations:

1. Serves as the agency focal point for emergency preparedness and response operating the 24-hour, 7-day-a-week emergency response system.

2. Provides support and assistance to Food and Drug Administration (FDA) offices in managing the agency's response to emergency incidents and situations involving FDA regulated products and disasters.

3. Assists in the development and coordination of the agency's emergency preparedness and response activities.

4. Serves as the agency focal point for the review and analysis of preliminary information about threats and hazards, and assists in the early recognition of emergencies, outbreaks, natural disasters, and terrorism or other criminal acts, in direct coordination with individual headquarters and field emergency coordination units.

5. Coordinates FDA emergency activities with other Federal agencies, State, local and foreign government officials and industry associations.

6. Identifies and advocates emergency training needs for FDA personnel and participates in the design, implementation, and presentation of the training programs.

7. Provides guidance to agency emergency response staff in the use of the Incident Command System to manage single or multi-agency response activities.

8. Represents the agency at interagency, intra-agency, State, local and foreign government and industry association meetings and conferences on emergency preparedness and response.

9. Manages the National Consumer Complaint System which monitors reports of problems with FDA-regulated products for potential emergencies.

10. Participates in daily National Biosurveillance Integration Center conference calls sponsored by Department of Homeland Security to provide a secure forum for interagency information sharing for early recognition of biological events of national concern, both natural and man-made, to make a timely response possible.

11. Oversees and tests the agency's ability to communicate through the Government Electronic Telecommunications Service (GETS) which provides global telecommunications (secure voice, facsimile and data communications) capability for organizations that perform national security and emergency preparedness functions.

Office of Women's Health:

1. Serves as the principal advisor to the Commissioner and other key agency officials on scientific, ethical and policy issues relating to women's health.

2. Provides leadership and policy direction for the agency regarding issues of women's health and coordinates efforts to establish and advance a women's health agenda for the agency.

3. Monitors the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and the completion of gender analysis.

4. Identifies and monitors the progress of crosscutting and multidisciplinary women's health initiatives including changing needs, areas that require study and new challenges to the health of women as they relate to FDA's mission.

5. Serves as the agency's liaison with other agencies, industry, and professional associations with regard to the health of women.

Office of Special Medical Programs:

1. Serves as the agency focal point for special programs that are cross-cutting and medical in nature.

2. Manages the activities of the agency's effort to ensure that medical products used in pediatric applications are properly overseen.

3. Oversees the implementation of the orphan products provisions of the Federal Food, Drug and Cosmetic Act.

4. Administers and manages the Office Good Clinical Practice.

5. Provides executive leadership to the Office of Combination Products to ensure that appropriate jurisdictional decisions are made for the regulation of those products.

Office of Good Clinical Practice:

1. Advises and assists the Commissioner, and other key officials on Good Clinical Practice (including human subject protection) issues arising in clinical trials regulated by the FDA that have an impact on policy, direction, and long-range goals.

2. Supports and administers FDA's Human Subject Protection (HSP)/ Bioresearch Monitoring (BIMO) Council that manages and sets agency policy on Good Laboratory Practices, Bioresearch Monitoring, and Good Clinical Practices.

3. Represents the agency to other government agencies, State and local governments, industry, academia, consumer organizations, Congress, national and international organizations, and the scientific community on Good Clinical Practice policy issues.

4. Provides leadership and direction on human subject protection and Good Clinical Practice matters and stimulates the application of these principles in the FDA.

5. Evaluates the adequacy of Good Clinical Practice resources available to the agency and initiates action as appropriate.

6. Coordinates agency policies related to the protection of human subjects in research, including institutional review and ethical considerations.

7. Plans training programs for external use and for FDA staff on the agency's Good Clinical Practice policies.

8. Coordinates and provides oversight of Good Clinical Practice policy working groups developed on the recommendation of the agency HSP/BIMO Council.

9. Fosters the science of bioresearch monitoring within the Centers and the Office of Regulatory Affairs and coordinates for the Office of the Commissioner.

10. Serves as the agency coordinating point for Good Clinical Practice regulation, harmonization, and outreach activities.

11. Serves as liaison between the agency's HSP/BIMO Council and the agency's Management Council.

12. Coordinates and assists in implementation of regulations, policies, operational initiatives, and program priorities related to clinical bioresearch monitoring as developed by the HSP/BIMO Council.

13. Monitors agency activities and leads the development of a quality assurance and quality improvement program to ensure uniform application of clinical bioresearch monitoring policies across the agency.

14. Serves as a liaison with other Federal agencies and outside organizations, the regulated industry, and public interest groups on clinical bioresearch monitoring policy and regulatory matters.

Office of Combination Products:

1. Serves as the agency focal point for combination products (i.e., drug-device, drug-biologic, device-biologic or drug-biologic-device products).

2. Serves as the agency Product Jurisdiction Office and administers 21 CFR Part 3. (Assigns agency centers with primary jurisdiction for combination products.)

3. Advises the Commissioner and other key agency officials on policy formulation, execution, cross-cutting and precedent setting issues involving combination products.

4. Develops regulations, guidances, policies, procedures, and processes to facilitate the agency's regulation, review, and oversight of combination products.

5. Reviews and updates agreements, guidance or practices specific to assignment of combination products. Prepares reports to Congress on the activities and impact of the Office.

6. Serves as the focal point for employees and stakeholders to resolve issues arising during assignment, premarket review or postmarket regulation of combination products.

7. Ensures timely and effective premarket review by overseeing the timeliness of and coordinating reviews involving more than one agency center.

8. Ensures consistency and appropriateness of postmarket regulation of combination products.

9. Resolves disputes presented regarding the timeliness of the premarket review of a combination product.

10. Advises the Chief Scientist on disputes presented regarding the substance of the premarket review of a combination product.

11. Makes determinations as to whether an individual component product will be regulated as a human drug, human biologic, or human medical device.

Office of Orphan Products Development

1. Manages the implementation of the provisions of the Orphan Drug Act and its amendments and manages a program to encourage the development of drugs of limited commercial value for use in rare or common diseases and conditions.

2. Develops and communicates agency policy and makes decisions on approval of sponsor requests and incentives under the Federal Food,

Drug, and Cosmetic Act, including orphan drug protocol assistance per section 525, orphan drug designation per section 526, orphan drug exclusivity per section 527, orphan drug grants and contracts to support clinical research and other areas of agency policy related to the development of products for rare disorders.

3. Represents the Commissioner or serves as the agency's principal authority and spokesperson to the PHS Orphan Products Board, other governmental committees and industry, professional, and consumer associations, requesting agency participation in orphan product development activities.

4. Reviews investigational new drug and biologics applications and investigational device exemptions to locate the existence of products under investigational study that show evidence of effectiveness for rare or common diseases but lack commercial sponsorship. Assists sponsors, researchers, and investigators in communicating with agency regulatory officials and expediting solutions to problems in obtaining investigational or market approval status.

5. Manages an extramural program of clinical research to evaluate safety and effectiveness of orphan products by funding grants and contracts, requesting applications for funding, organizing peer review of applications, monitoring and guiding investigators, and evaluating study results.

Office of Pediatric Therapeutics:

1. Coordinates and facilitates all activities of the Food and Drug Administration that may have any effect on the population, the practice of pediatrics, or may in any way involve pediatric issues.

2. Coordinates the review of and communicates internally and externally any report of an adverse event of a drug which received pediatric exclusivity.

3. Provides for the review of adverse event reports and other new safety information and obtains recommendations whether FDA should take action.

4. Coordinates with all Department of Health and Human Service and FDA employees who exercise responsibilities relating to pediatric therapeutics.

5. Serves as the FDA focal point for all issues involving ethics with respect to the pediatric populations.

6. Coordinates with the Office of International Programs while serving as the agency focal point for international pediatric activities.

Office of External Affairs:

1. Advises the Commissioner, Deputy Commissioners and other key agency

officials on FDA's communications to the media, Congress, and the general public on issues that affect agency-wide programs, projects, strategies, partnerships and initiatives.

2. Advises and assists the Commissioner and other key officials on all public information programs; acts as the focal point for disseminating news on FDA activities and as a liaison with the Public Health Service and the Department on public information programs.

3. Advises the Commissioner, Deputy Commissioners and other senior staff throughout FDA on sensitive and controversial programs and initiatives that impact external stakeholder groups.

4. Serves as an information resource to FDA and provides advice to the Commissioner and other key agency officials on matters related to serious and life-threatening diseases; patient advocacy, and health professional organizations; minority health and other special health issues.

Office of External Relations:

1. Advises the Commissioner, Deputy Commissioners and other key agency officials on agency-level activities and issues that affect agency wide programs, projects, strategies, partnerships, and initiatives.

2. Advises the Commissioner, Deputy Commissioners and senior staff throughout FDA on sensitive and controversial programs and initiatives that impact external stakeholder groups.

3. Coordinates activities involving emergency or crises situations and resolves complex problems and issues related to agency programs that are sensitive and controversial which impact upon agency relations with other Federal agencies and foreign governments.

4. Oversees and directs the agency's ombudsman and editorial functions to ensure coherence in decision making and the efficient operation of these functions internally and across agency jurisdictions.

5. Provides leadership and direction to assure the efficient and effective planning, performance and evaluation of oversight activities.

6. Provides direction, coordination and oversight of the agency's consumer activities and serves as the agency's focal point for national consumer groups.

7. Advises the Commissioner, Deputy Commissioners and senior staff throughout FDA on sensitive and controversial programs and initiatives that impact external stakeholder groups.

8. Serves as the agency's focal point to provide direction, coordination and oversight of the agency's stakeholder

relations with national consumer groups, patient advocacy organizations, health professionals, academia, trade associations, ethnic and minority groups, and Tribes.

9. Coordinates speaker requests for industry programs that cover multi-center issues; identifies potential conflict of interest speaker requests.

10. Assists in the programmatic design, development and planning with internal and external organizations regarding educational and informational activities intended to educate regulated industry.

Communications Staff:

1. Identifies consumer communication and educational requirements for the agency and creates, implements, and coordinates appropriate programs conducted through the media, agency public affairs specialists, and other communication sources.

2. Plans, designs, produces, publishes, and disseminates audiovisual materials, exhibits, posters, publications, and periodicals, including *FDA Consumer*; participates in the planning and development of all publications and audiovisual aspects of communications programs directed at mass audiences.

3. Provides centralized agency graphic arts and editorial services for public information materials.

4. Acts as the agency's public information liaison with the Department for all publications and audiovisual needs; provides prepublication clearance of publications, exhibits, and audiovisual materials in accordance with procedures established by the agency, PHS, the Department, OMB, and the White House.

Office of Public Affairs:

1. Advises and assists the Commissioner and other key officials on all public information programs; acts as the focal point for disseminating news on FDA activities and as a liaison with the Public Health Service and the Department on public information programs.

2. Plans, develops, implements, and monitors policy and programs on agency media relations, and consumer information and education programs conducted through the media, FDA's public affairs specialists, and other communications sources.

3. Plans, develops, produces, and publishes agency publications and graphic arts materials.

4. Executes Freedom of Information denial authority for the agency.

5. Directs the effective utilization of all management resources by coordinating the management, facilities,

budget, and equipment resources for the Office of Public Affairs.

6. Reviews organizational, management, and administrative policies of the Office to appraise the efficiency and effectiveness of operations.

7. Identifies potential management problems and/or needs and plans, develops and conducts management studies.

8. Coordinates speaker requests for industry programs that cover multi-center issues; identifies potential conflict of interest speaker requests.

9. Assists in the programmatic design, development, and planning with internal and external organizations regarding educational and informational activities intended to educate regulated industry.

10. Advises and assists top level agency officials on electronic media matters involving mass media communications.

11. Plans, develops, and implements agency wide broadcast media strategies for disseminating regulatory and educational materials to the public through the mass media.

12. Serves as the agency focal point for preparing, clearing and disseminating electronic media requests representing agency policy and responding to electronic media inquiries; maintains liaison with broadcast media contacts.

13. Establishes policy for and coordinates all broadcast media information activities, including on-camera interviews and responses to media inquiries; prepares position and policy statements for use by agency employees in responding to broadcast media questions; tracks issues of potential interest to the media.

14. Plans and coordinates all broadcast media training for the agency.

Print Media Staff:

1. Advises and assists top level agency officials on printed press matters involving mass media communications.

2. Plans, develops, and implements agency wide print media strategies for disseminating regulatory and educational material to the public through the mass media.

3. Serves as the agency focal point for preparing, clearing, and disseminating press releases and other print media statements representing agency policy and responding to media inquiries; maintains liaison with news media and pertinent publications.

4. Establishes policy for and coordinates all print media information activities, including news interviews and responses to inquiries; prepares position and policy statements for use

by agency employees in responding to print media questions; tracks issues of potential interest to the media.

5. Coordinates the research and drafting of major public statements by the Commissioner including transmittal documents and supportive statements for use in transactions with the Department, other agencies, and the White House; provides editorial consultation and review for manuscripts, articles, and speeches written by the staff offices serving the Commissioner to ensure consistency of information and policy interpretation.

6. Compiles, publishes, and distributes the weekly FDA Enforcement Report and the FDA Public Calendar; maintains the FDA Daily Clipping Service; and coordinates the Daily Media Report.

Web Site Management Staff:

1. Responsible for the content and design of the FDA Web site (www.fda.gov). Develops and interprets the agency's Web policies, and serves as advocates for FDA's Web presence and catalysts for creative use of the Web by the agency.

2. Works closely, as partners, with the FDA Office of Information Resources Management (OIRM), which is responsible for the technical operations of FDA's Web site.

3. Works closely with the Web site contacts in each of the Centers and principal offices within the Office of the Commissioner (OC) to plan, coordinate, execute and evaluate the agency's Web site operations.

4. Serves as the focal point and contact with the agency, Department, and other Federal Government Web site programs and operations.

5. Provides direction, strategic planning assistance, and management coordination on agency Web site programs.

6. Establishes, manages, and monitors the implementation of agency standards and policies for information published on agency Web sites.

7. Provides Web-related information management strategy input through a collaborative effort with OIRM and the Web site operations staffs in the centers and OC.

8. Designs, develops, implements, monitors, and manages information published on the agency's Web site.

9. Delivers the agency's messages to the public through the agency's Web site.

10. Provides Web-related electronic information dissemination services to the agency and the public.

Office of Special Health Issues:

1. Serves as an information resource to FDA and provides advice to the

Commissioner and other key agency officials on matters related to serious and life-threatening diseases; patient advocacy, and health professional organizations; minority health and other special health issues.

2. Coordinates interactions between FDA and health professional organizations and patient advocacy groups dealing with serious and life-threatening diseases and other special health issues.

3. Serves as a focal point to coordinate contacts between FDA and other Federal agencies to ensure effective coordination and communication on serious and life-threatening diseases and other special health issues.

4. Provides internal coordination on FDA activities related to serious and life-threatening diseases, patient advocacy and health professional organizations, and other special health issues.

5. Assists in the planning, administration, development, and evaluation of FDA policies related to serious and life-threatening diseases, patient advocacy and health professional organizations, and other special health issues.

Medwatch Staff:

1. Coordinates and implements policies and initiatives relating to human medical product adverse events, including the MedWatch Partners Program, the MedWatch Web site, and the MedWatch e-list.

2. Conducts outreach and education to health professionals, patients and the public to facilitate the reporting of serious harm and injury associated with the use of human medical products.

3. Reviews, updates, and disseminates medical product safety alerts and safety labeling changes.

Office of Foods:

1. Provides executive leadership and management to all FDA food-related programs.

2. Exercises, on behalf of the Commissioner, direct line authority over the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine.

3. Exercises, on behalf of the Commissioner, all food-related legal authorities that the Commissioner is empowered to exercise under the Federal Food, Drug, and Cosmetic Act, as amended, the Public Health Service Act, and other applicable laws.

4. Directs efforts to integrate the programs of CFSAN, CVM, and the Office of Regulatory Affairs (ORA) and thereby ensure the optimal use of all available FDA resources and tools to improve the safety, nutritional quality and proper labeling of the food supply.

5. Directs the development of integrated strategies, plans, policies, and budgets to build FDA's food-related scientific and regulatory capacities and programs, including recruitment and training of key personnel and development of information systems.

6. Represents FDA on food-related matters in dealings with the Office of the Secretary of HHS, the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, the White House and other elements of the executive branch.

7. Represents FDA on food-related matters in dealings with Congress.

8. Represents FDA on food-related matters in dealings with foreign governments and international organizations.

9. Directs FDA efforts to build an integrated national food safety system in collaboration with other Federal agencies and State and local governments.

10. Directs a program of public outreach and communications on food safety, nutrition, and other food-related issues to advance FDA's public health and consumer protection goals.

Office of the Chief Scientist:

1. Provides strategic leadership, innovation and expertise to enhance and support scientific excellence, integrity and capacity to achieve the Food and Drug Administration's public health mission. Key activities include:

Fostering development and use of innovative technologies to meet public health needs, including through its Office of Science and Innovation, the Critical Path Initiative and cross-Center working groups.

Supporting scientific excellence and the professional development of FDA scientists in all areas (i.e. population/statistical, review, laboratory and manufacturing sciences), including through the Commissioner's Fellowship Program, continuing education, and through relationships and staff exchanges with Universities and others.

Providing strategic leadership and support for high quality, collaborative, peer-reviewed scientific activities at FDA that advance regulatory science and address important public health and regulatory issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness. This includes support for the National Center for Toxicological Research to serve as a national FDA resource for mission driven regulatory science.

Supporting scientific outreach, training, collaboration in research, development and Critical Path activities that advance FDA's mission, with other

Federal agencies, global regulatory partners, academia (e.g., through planned Centers of Excellence in Regulatory Science), innovators, and consumers.

Supporting science and public health activities to effectively anticipate and respond to emerging deliberate and natural threats to U.S. and global health and security including through the Office of Counterterrorism and Emerging Threats and a planned Center for Innovation in Medicine and Public Health.

Providing core scientific leadership and technical expertise, and ensuring agency capacity, for advanced bioinformatics activities needed to support FDA programs (e.g. scientific computing to allow analysis of large health care and safety datasets, genomic and other complex laboratory data, and simulation and modeling). Serve as an agency and government resource for excellence, methods development, outreach and partnerships in advanced bioinformatics science.

Leading agency efforts to protect and enhance scientific integrity, and, where substantive scientific differences of opinion arise and require review at the FDA level, addressing them through appropriate processes intended to protect both FDA's mission and the integrity of its science.

Office of Counter-Terrorism and Emerging Threats:

1. Develops and implements a comprehensive counterterrorism strategy for FDA to identify and address gaps in current efforts to safeguard food and medical products from adulteration or disruption of supplies due to terrorist activities.

2. Develops and coordinates the implementation of crosscutting policies to facilitate the availability of safe and effective medical countermeasures against chemical, biological, radiological, and nuclear agents of concern.

3. Provides policy leadership for FDA's Emergency Use Authorization (EUA) activities for terrorism and public health emergencies, including emerging threats.

4. Develops and implements, in collaboration with the Centers and Offices and with external partners, comprehensive FDA plans and strategies for pandemic influenza preparedness and other emerging threats.

5. Provides policy leadership by promoting the goals and needs for counterterrorism and other emerging threats in the agency budgeting and priority-setting processes.

6. Coordinates the portfolio of FDA counterterrorism and pandemic influenza policy and planning initiatives and serves as the point of entry to the agency on counter-terrorism and emerging threats policy and planning matters.

7. On behalf of the Office of the Commissioner, facilitates intra- and inter-agency communications on counterterrorism policy and pandemic influenza preparedness.

Office of Critical Path Programs:

1. Serves as the focus for cross-center scientific and medical initiatives and policy development related to the Critical Path (CP) initiative and related activities in the Office of the Commissioner.

2. Assists the Chief Scientist in planning, executing, and monitoring projects, including, CP-related cross-center and interagency projects and collaborations with other agencies, academia, and industry as identified by the Office of the Commissioner and the Department of Health and Human Services.

3. Serves as the focus for cross center bioinformatics activities, including data management and analysis. Supports agency Bioinformatics Board and Data Councils.

4. Performs project development, project management, policy and document development and clearance, and related tasks as directed by the Chief Scientist.

5. Coordinates related administrative activities (e.g., personnel, communication, staffing, purchasing, and CP-related travel).

Office of Scientific Integrity:

1. Helps ensure consistent understanding, application and implementation of regulatory standards throughout FDA to ensure integrity and accountability of FDA functions and processes.

2. Provides advice and guidance to the Commissioner, Chief Scientist, and other key officials regarding premarket approval processes for all FDA-regulated products including requirements pertaining to applications, petitions, amendments and supplements; and product, processing, packaging and emerging product technologies.

3. Advises and assists senior FDA leadership in coordinating responses to allegations of patterns of deviations by FDA or its components from appropriate standards of conduct and performance. Also advises and assists senior FDA leadership in preventing such deviations.

4. Investigates and resolves informal complaints and disagreements, whether

generated internally or externally, with respect to the administrative processing of various applications for products regulated by the agency as well as regarding the fair and even-handed application of agency policy and procedures in this process.

5. Processes all formal appeals, or requests for review, that are submitted to the Office of the Commissioner, whether generated internally or externally, including requests for hearings, appeals from administrative actions, and requests to review decisions at a lower level of the agency. Examples include, but are not limited to, requests for hearings in debarment and disqualification proceedings, requests to review decisions by the Centers, the Office of Regulatory Affairs, and elsewhere in the Office of the Commissioner under 21 CFR 10.75, appeals of formal or informal hearings, and agency-level scientific dispute resolution matters.

6. Advises and assists the Chief Scientist and senior leadership in evaluating and resolving all formal appeals, requests for review, and requests for hearings submitted to the Office of the Commissioner and coordinates responses to such appeals and requests.

7. Develops regulations and procedures to promote an efficient and effective process for addressing and resolving formal appeals, requests for review, and requests for hearings, as well as any other types of disputes suitable for formal resolution in the Office of the Commissioner.

8. Leads Advisory Committee Oversight and Management Staff, working in close collaboration with all FDA Centers to provide consistency in and continuously improve the operations of agency advisory committees.

9. Serves as the liaison between the Office of the Secretary, the Department Committee Management Office, all of FDA's Center advisory committee support staff, and other organizations/offices within FDA.

10. Ensures that all FDA committee management activities are consistent with the provisions of Federal Advisory Committee Act, departmental policies, and related regulations and statutes.

11. Coordinates with the Office of Appeals, within the Office of Scientific Integrity, to determine whether an informal complaint should be construed and treated as a request for formal review by the Office of the Commissioner under established regulations or procedures.

Office of Science and Innovation:

1. Provides strategic leadership, coordination, infrastructure and support for excellence and innovation in FDA science that will advance the agency's ability to protect and promote the health of the public. Key activities include:

Providing support for high quality, collaborative, peer-reviewed scientific activities throughout FDA that address important public health and regulatory issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness.

Fostering development and use of innovative technologies to meet public health needs, including through a planned Center for Innovation in Medicine and Public Health and through core scientific capacity to support FDA's regulatory functions and decision making.

Supporting excellence and the professional development of FDA scientists in all areas (i.e. population/statistical, review, laboratory and manufacturing sciences), including through the Commissioner's Fellowship Program, continuing education and professional activities (including clinical activities, cross agency working groups, and through relationships and staff exchanges with Universities and others.

Addressing scientific and public health priorities through support of high quality, peer reviewed scientific research, programs and related activities, both within and outside FDA and collaboratively, and through dissemination of new scientific information, methods and approaches.

Supporting scientific outreach, training, and collaboration in research and development activities that advance FDA's mission, including with sister agencies, global regulatory partners, academia (e.g., through planned Centers of Excellence in Regulatory Science), innovators, and consumers.

Seeking input from both FDA programs, stakeholders and outside advisors, including the FDA Science Board, to help define, review and meet FDA scientific needs and priorities to support our public health mission.

Office of International Programs:

1. Serves as the agency focal point for all international matters.

2. Serves as the primary 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.

3. Provides leadership to agency program areas for international activities.

4. Serves as the focal point for the agency and the authority for policies and procedures pertaining to international travel.

5. Serves as the focal point and final clearing authority for all international technical cooperation and assistance activities.

6. Serves as the agency focal point and final clearing authority for all international programs and interactions with foreign counterpart regulatory agencies, international organizations, foreign embassies, all foreign officials, and with agency and all other United States Government components when international issues are involved.

7. Directs, manages, and leads agency strategic planning, priority-setting and resource allocation processes for agency international programs.

8. Serves as the agency focal point and final clearing authority for trade issues involving e.g., North American Free Trade Agreement (NAFTA), World Trade Organization (WTO), Free Trade Area of the Americas (FTAA), Asia Pacific Economic Cooperation (APEC), and United States Trade Representative (USTR).

9. Serves as the agency focal point and final clearing authority for formal arrangements with foreign governments e.g., memoranda of understanding (MOU), mutual recognition agreements (MRAs), exchange of letters, partnerships, equivalence issues, country assessments, and confidentiality commitments.

10. Serves as the agency focal point on policies and procedures for sharing public and non-public information and, in conjunction with the Office of Regulatory Affairs, import/export policy issues.

11. Manages the agency's foreign offices, including FDA staff deployed in foreign locations and all related budgeting, strategic planning, priority setting and resource allocation.

Office of Administration:

1. The Office of Administration (OA) will focus on enhancing agency wide administrative operations and overseeing a variety of agency-wide management programs, information management, financial and shared services operations, as well as the Office of the Commissioner's executive operations.

2. Provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative operations of the agency assuring the timely and effective implementation and high quality delivery of services across the agency and centers.

3. Advises and assists the Commissioner, Deputy Commissioners,

Chief of Staff, and other key agency officials on various administrative management and business activities of the agency. Chairs the Prescription Drug User Fee Act (PDUFA) Review Board, which oversees financial management of the PDUFA program.

4. Assures that the conduct of agency administrative and financial management activities, including budget, finance, personnel, organization, methods, and similar support activities, effectively support program operations.

5. Utilizes a call center to address all administrative and information technology management issues, and monitors and analyzes operational performance and customer satisfaction.

6. 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 the agency's programs and financial plans.

7. Provides leadership and direction regarding all aspects of a variety of agency management programs including 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.

8. Advises the Commissioner and other key agency officials on administrative management and budget matters for components within the Office of the Commissioner. Provides advice and guidance with regard to formulation and development of administrative management policies, procedures, and controls.

9. Provides advice and assistance to the Commissioner and senior management officials on information management resources and programs. Establishes and oversees implementation of the FDA information management policy and governance, procedures and processes to ensure the agency is in conformance with the Clinger/Cohen Act. Establishes, directs and leads agency level programs and all strategic aspects of information management including: information technology (IT) shared services, telecommunications, security, strategic planning, capital planning and investment control, and enterprise architecture.

Office of Equal Employment Opportunity and Diversity Management:

1. Advises and assists the Commissioner and other key officials on

equal employment opportunity (EEO), Diversity, and Civil Rights activities which impact on policy development and execution of program goals.

2. Serves as the agency focal point and liaison to the Department, other Federal agencies, State and local governments, and other organizations regarding EEO, Diversity, and Civil Rights matters.

3. Develops and recommends policies and priorities designed to implement the intent of the Office of Personnel Management, Equal Employment Opportunity Commission, and Office of Civil Rights, Department of Health and Human Services requirements under Executive Orders, regulations, EEO and Civil Rights legislation.

4. Provides leadership, direction, and technical guidance to the agency on EEO, Diversity, and Civil Rights matters.

5. Examines the use and impact of administrative mechanisms on work assignments, pay systems, award systems, performance appraisal systems, promotion patterns, reorganization impacts, delegations of authority, management controls, information and documentation systems, and similar functions of management as they impact upon equal employment opportunities for all employees within the agency.

6. Issues policies, publications and information dissemination services to agency employees including Commissioner Policy Statements, brochures, the EEO Counselors Manual, etc.

Compliance Staff:

1. Develops plans, programs, and procedures designed to assure the prompt adjudication of complaints of alleged discrimination based on race, color, sex, age, religion, national origin, handicap, and sexual orientation.

2. Provides sign language interpreting services and manages the interpreting services contracts.

Conflict Prevention and Resolution Staff:

1. Provides confidential, informal assistance to employees and managers in resolving work-related concerns.

2. Develops and coordinates effective resolution processes and procedures.

3. Offers a variety of services and programs to address likely sources of conflict such as performance appraisals, harassment, mentoring relationships, and scientific collaboration.

4. Operates as a neutral, independent, and confidential resource providing informal assistance to FDA scientists, administrators, and support staff in addressing work-related issues. Assists in resolving conflicts and addressing concerns prior to and within established grievances processes.

5. Provides a neutral and impartial resource where employees can candidly discuss issues and explore options informally.

6. Provides alternative dispute resolution and mediation services as needed.

7. Develops and maintains training and technical assistance for agency EEO specialists, counselors, special emphasis/program representatives, employees, supervisory personnel, and other key officials.

Diversity Staff:

1. Develops and oversees agency diversity initiatives and the diversity databank.

2. Develops, implements, and monitors the agency's Affirmative Employment Plan and directs the agency's Affirmative Employment programs to achieve specific objectives.

3. Develops labor-management partnerships on EEO and Diversity matters. Provides sign language interpreting services and manages the interpreting services contracts.

Office of Acquisitions and Grants Services:

1. Serves as the agency focal point for developing, coordinating, and implementing FDA policies and procedures pertaining to acquisitions, interagency agreements, technology transfer and grants management; coordinates all administrative matters related to acquisitions, grants, cooperative agreements, interagency agreements, memoranda of understanding and technology transfer.

2. Provides acquisition management information and overall policy and technical support to all levels of the Office, agency, Department, and the Federal government in the areas of technology transfer, patents and acquisition and assistance matters.

3. Maintains liaison with the Department on contracts and grants/assistance management policy and procedural and operating matters; serves as the FDA focal point for the processing of audit reports and for liaison with the agency Office of Inspector General.

4. Provides the oversight function to all levels of the agency in the Small Business contracting program.

5. Provides technical and legal guidance in all areas of the agency printing management program.

6. Develops policy for printing to insure timely and cost effective implementation of the agency printing program.

Division of Acquisition Operations:

1. Responsible for mission specific contracts and simplified acquisitions, including research and development

requirements and lab supply and equipment requirements.

2. Responsible for acquisition of service contracts and simplified acquisitions, including but not limited to, furniture, security, events management, temporary services, moving, library support, custodial, etc.

Division of Acquisition Support And Grants:

1. Develops acquisition policy. Provides customer relation support, responding to contract related FOIA requests, and ratifying unauthorized procurements.

2. Provides current policies and procedures to assist the FDA community to develop and transfer Federal technology to the commercial marketplace.

3. Negotiates, awards and monitors Federal funds awarded through various grant mechanisms.

4. Awards and administers Inter-agency Agreements (IAGs). Assigns Memorandum of Understanding (MOU) tracking number and maintains MOU files.

5. Provides managerial oversight of the agency's purchase card program. Serves as liaison with the bank, processing administrative functions, providing training and other assistance to ensure that participants understand their responsibilities under the program.

Division of Acquisition Programs:

1. Responsible for all information technology related contracts and simplified acquisitions related requirements.

2. Provides facility support, construction and renovation, architect/engineering services contracts and simplified acquisitions for all headquarter locations, Irvine, San Juan, and Dauphin Island.

3. Provides contracts to support the MQSA, Food, Tissue and Medicated Feed/BSE Programs. These contracts commission the States to conduct inspections to ensure the quality and safety of the nations' food, animal feed and medical devices.

4. Responsible for simplified acquisitions for ORA Headquarters and the Office of Criminal Investigations.

Division of Information Technology:

1. Responsible for all information technology related contracts and simplified acquisitions related requirements.

Office of Executive Operations:

1. Develops policy and provides guidance, advice and oversight to Office of the Commissioner (OC) staff with regard to programmatic FDA and OC administrative management policies, procedures, and controls.

2. Advises the Commissioner and other key agency officials on

administrative, financial and information management matters for components within the Office of the Commissioner (OC).

3. Manages the OC budget formulation and execution activities. Provides advice, guidance and direction on the administration of the OC budget.

4. Manages a variety of program administrative services including but not limited to travel, space, time and attendance, property, etc. for OC offices with appropriate officials. Establishes and maintains liaison with administrative staff throughout the OC to keep abreast of current policies and procedures.

5. Serves as OC liaison for acquisitions and grants activities ensuring compliance with agency and Federal contracting policies.

6. Coordinates and provides guidance and oversight concerning OC information management activities including those related to activities of FDA Bioinformatics Board.

7. Advises the Commissioner and Deputy Commissioners and other senior staff concerning all OC human capital programs and activities.

Office of Financial Operations:

1. Plans, directs, and coordinates a comprehensive financial management operations program for FDA encompassing the areas of budget analysis, execution, automated financial systems, fiscal accounting, voucher audit, financial services related to accounts payable, travel support and payroll liaison, and financial reporting. Provides staff assistance in justifying budgets through executive and congressional echelons. After appropriation, develops an orderly expenditure plan.

Office of Financial Management:

1. Plans, directs, and coordinates a comprehensive financial management program for FDA encompassing the areas of budget analysis, formulation and execution, automated financial systems, fiscal accounting, voucher audit, and financial reporting. Provides staff assistance in justifying budgets through executive and congressional echelons. After appropriation, develops an orderly expenditure plan.

2. Develops apportionment plans and issues allotments for expenditures.

3. Makes periodic reports regarding the status of FDA's financial management.

4. Develops financial inputs for the agency's programs and financial plans.

Division of Accounting:

1. Plan, evaluate and coordinate activities to ensure Food and Drug Administration (FDA) is in compliance

with Federal government accounting policy and procedures.

2. Principal contact to ensure FDA compliance with Chief Financial Officers Act (CFO) audit activities.

3. Devise and implement new and creative mechanisms to streamline administrative procedures; for example, implementation or electronic certification for treasury schedules expansion of lock box techniques.

4. Operates the Prompt Pay System for FDA, which pays over 50,000 invoices annually, providing integrity checks throughout the system from receipt of the invoice to payment.

5. Maintains over 400 headquarters and field users of automated financial systems as they request assistance with problems and special requests using various systems and special reports.

6. Operates and maintains the FDA District Electronic Certification System, which processes payments for vendors and travelers for all FDA districts while complying with Treasury's directive on EFT payments.

7. Produces daily, biweekly, monthly and yearly budgetary reports for field and headquarters components.

8. Liaison with Shared Services Organization.

User Fee Staff:

1. Manages and oversees the receipt, deposit, and allocation of user fees paid by industry.

2. Prepares annual revenue reports for submission to Congress.

3. Reports on FDA's compliance with Congressional mandates.

4. Develops, manages user fee systems.

Division of Budget Execution and Control:

1. Provides guidance and advice on the management and development of the budgets for FDA's Office of the Commissioner and Headquarters. Conducts analysis about agency-level and cross-component accounts, trends, and projects. Interpret agency requirements and establish FDA policy/procedures on all phases of budget execution.

2. Apportions funds appropriated by Congress among components and oversees transfers of funds between components.

3. Completes detailed reviews and analyses of components' financial operating plans at the end of each quarter. Ensures budgetary resources are used in a manner consistent with the agency's mission and are not over spent or obligated beyond appropriate limits.

4. Manages key agency-level accounts and shared costs, such as FDA rent and central accounts.

5. Assists in the preparation of historical budget-related data,

congressional inquiries, and data for budget formulation and hearings.

6. Reviews and clears all Inter-agency Agreements (IAG's) to assure that they comply with appropriation law and are included in FDA resource plans; monitor collection of reimbursable earnings and identify and solve related problems as necessary.

7. Maintains FDA staffing ceiling records, proposes ceiling adjustments as needed, monitors FTE usage, alerts management to potential overburn/underburn problems, and prepares recurring reports and special analyses as necessary on FTE levels.

8. Continuously surfaces, and provides recommendations and support to resolve PDUFA/MDUFMA issues (design status of funds and FTE reports; develop criteria to allocate collections). Maintains tracking system for allocating PDUFA/MDUFMA non-PDUFA, and AIDS funds, and prepare reports.

9. Conducts year-end closeout of appropriations with the Division of Accounting, FDA Centers and Offices. Prepares all necessary end-of-fiscal-year budget and staffing reports by organization and by program, and enter all past-year data.

Office of Financial Services:

1. Plans, directs, and coordinates day-to-day operations for financial services related to accounts payable, travel support and payroll liaison.

Division of Payment Services:

1. Performs billing and collecting services for headquarters accounts. Maintains internal control over processing of transactions to accounts, including application of batch controls to ensure accurate coding and making of necessary accounting transaction adjustments and corrections.

2. Maintains liaison with the Department of Central Payroll on headquarters payroll operations. Reconciles payroll data with accounts. Maintains tax withholding files. Issues withholding statements.

3. Processes employee time records; resolves payroll errors and assists employees with pay problems; issues new procedures as needed.

4. Participates in reengineering the payroll process to streamline correction of errors and reduce first time errors; and participates in timekeeper training.

5. Processes all purchase orders, receiving reports, and invoices for commercial payments made by the Food and Drug Administration (FDA) headquarters, assuring compliance with accounts and the Prompt Pay Act.

6. Coordinates with vendor and center personnel in researching payment information.

7. Responds to all vendor inquiries as well as inquiries from center personnel.

8. Prepares various reconciliations to ensure that schedules are properly accounted for and entered into the accounting system.

9. Reviews and distributes monthly accounting reports and processes corrections, as necessary.

10. Liaison with the Department of Treasury to initiate check traces.

Division of Travel Services:

1. Oversees processing of vouchers, including audit, matching with obligations, and scheduling for direct deposit using Travel Manager Software.

2. Oversees post audit of travel vouchers.

3. Provides travel advice/guidance throughout the agency, including significant research on Comptroller General Decisions; participates in training on travel procedures.

4. Oversees contractor processing of all headquarters and field Permanent Change of Station travel vouchers, including complex tax calculations.

5. Coordinates with the General Services Administration (GSA) contractual travel agent to ensure the Food and Drug Administration (FDA) travel and transportation requirement are met.

6. Field activities perform travel services directly for ORA and NCTR to include NCTR travel, ORA international travel, FATA responsibilities, data calls, travel audits, 348 travel and conference reporting.

Office of Information Management:

1. Develops the architecture, standards, policies, governance, best practices and technology road map that support the business priorities of the agency, including managing information technology infrastructure, telecommunications, security, strategic planning, capital planning and investment control, enterprise architecture, and applications development and management. Provides advice and assistance to the Commissioner and senior management officials on information technology resources and programs.

2. Establishes and oversees implementation of the Food and Drug Administration (FDA) information technology policy and governance, procedures and processes to bring the agency in conformance with the Clinger/Cohen Act and the Paperwork Reduction Act. Provides leadership and direction regarding all aspects of the agency records management program.

3. Works in full partnership with FDA business areas, develops and communicates the overall vision for the agency's IT program.

4. Provides expert technical evaluation and recommendations for the new and emerging technologies to ensure the agency's IT program can proactively adjust to changing business needs and technology drivers.

5. Represents the agency IT program on internal and external meetings and workgroups on agency information technology programs and issues (e.g., Health and Human Services (HHS) Chief Information Officer (CIO) Council, FDA Leadership council, FDA level Review boards, etc.).

6. Establishes policies and procedures for system risk assessments and system business continuity and contingency planning.

Division of Business Partnership Support:

1. Advocates, communicates, provides, and manages liaison services and provides management and technical consultation resources regarding information technology to FDA offices, centers and other FDA stakeholders, including parties external to FDA (non-govt, e.g., PHRMA, BIO, DIA, ICH, etc) and PHS, Department, and other Federal government IRM and ADP operations.

2. Collaborates with BIB and the BRBs to prioritize new business requirements and establish projects which will require PM's and designs, develops and maintains the communication plan for all Enterprise agency projects the BIB, BRBs, and OIM.

3. Collaborates with other divisions within OIM to review request for each system; providing estimates for implementation and to assist in the establishment of priorities and schedules (overarching timeline of all projects/independencies), as well as ensure project/investment formulation, execution and actual information is reported.

4. Oversees and manages IT program and project management activities of major IT initiatives following project management best practices (Project Management, System Development, and Enterprise Program life cycles), in collaboration with the Division of CIO Support/Governance Branch, develops policies and procedures on all aspects of project planning, and interacts with and coordinates responses to the Department and OMB on all project management related activities.

5. Coordinates development of Center/Offices IT budget and provides support for budget execution and contract monitoring of information resources.

6. Oversees day-to-day operations of FDA web development, redesign, and web hosting environment.

7. Manages FDA Forms programs and is the lead for agency Section 508 implementation.

8. Receives user requests, orders, and issues desktop-related tools and equipment.

9. Manages and oversees help desk services and user support for infrastructure Center and/or FDA-wide applications (excludes field help desk which is part of the Division for Infrastructure Operations).

Division of Chief Information Officer Support:

1. Establishes and maintains an agency Enterprise Architecture (EA) governance structure that includes processes for systems, business, data, applications, technology, and security architectures.

2. Serves as a focal point within FDA and as a liaison between FDA and external public and private sector organizations regarding enterprise standards, IT architecture, investment management practices and related methodologies, data sharing and support services, and regarding all aspects of IT planning, development and management.

3. Develops, tracks and maintains the IT budget, operating plan, and acquisition plan. Manages and maintains an acquisition strategy policy and implements all aspects of contract administration and management for the Office of Information Management.

4. Plans, organizes and manages FDA's IT investment management process (CPIC) to ensure that IT resources are acquired and managed effectively, and to ensure effective ongoing control of IT investments. Additionally, architectural reviews of IT investments are conducted to ensure alignment with business functions, avoid duplication of effort, reduce costs, and improve the efficiency and effectiveness of IT initiatives and to ensure that the FDA IT enterprise employs appropriate standards.

5. Coordinates the agency IT risk management program, including identification, analysis, and mitigation and reporting of program and system level weaknesses. The division also maintains and audits compliance for system risk assessments and system business continuity and contingency planning.

6. Establishes administrative policies for OIM consistent with agency policies and manages all administrative activities including Administrative Support, Travel and Timekeeping.

7. Develops, maintains and manages the electronic records (e-records) policy within the Office of Information Management and coordinates as

necessary with other business entities within the FDA on records management activities.

8. Provides management of all aspects of human capital in the recruitment, hiring, deployment, development, management, training and evaluation of the OIM workforce to ensure that human capital programs are aligned with organizational goals and agency Human Resource requirements.

9. Develops and disseminates administrative internal communications and operational procedures for the OIM in coordination with the Communications Team. Keeps abreast of agency and office rules, regulations, procedures, policies and decisions

Division of Systems Management:

1. Designs, develops, implements, and maintains all agency software applications, IT systems, systems support and maintenance, and their integration with other Federal agencies, State and foreign governments and public and private entities.

2. Establishes and implements an Enterprise IT Common Component Framework containing modules/services to be shared across FDA information systems and maintains FDA enterprise applications through effective evaluation, streamlined application development, monitoring, testing, and control of agency-wide systems utilizing e-platform initiatives and interchangeable common components in order to support FDA business process needs and objectives efficiently and effectively.

3. Validates requirements for and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the agency, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.

4. Designs, develops, implements, and maintains standards-based electronic IT data systems and repositories that provide the FDA with an integrated and interoperable information environment to receive, track, analyze, and disseminate knowledge on FDA business/program activities and directs the development and implementation of FDA Data Administration policies standards and procedures to ensure design consistency, including review of work products for compliance with standards.

5. Assists in the development and implementation of technical specifications and plans for

procurement of IT equipment (HW/SW) and support resources required for the integrating of new system designs.

6. Develops and implements a program risk management plan to oversee and mitigate critical risks and vulnerabilities in the execution of the systems under its responsibility.

7. Assists CIO Support Division in development and maintenance of FDA's policies and procedures for independent verification and validation of IT systems. Develops, implements and provides problem management processes for the FDA systems, including trend analysis of problems. Develops standard IT reports.

Division of Infrastructure Operations:

1. Manages agency wide LAN/WAN computer environment, including desktop, laptop, and Personal Digital Assistants (PDAs), as well as utilizing the computer environment for the development, testing, validation and integration of information technology applications throughout the agency.

2. Oversees and manages day-to-day operations of all FDA telecommunications activities including VoIP and customer support, mailbox management and problem resolution related to FDA Email services.

3. Oversees day-to-day operations and performance of all FDA hardware, including IT resources such as electrical power, HVAC, etc.

4. Provides technical consultation to the Systems Division in identifying appropriate IT hardware, software and infrastructure requirements for new IT applications that support FDA business process needs.

5. Assists CIO Support's Procurement Team in development and implementation of technical specifications and plans for procurement of IT equipment, software and support services.

6. Manages and coordinates the integration of systems and business applications, including testing of the applications, and coordinates the execution of services acquired by FDA to implement new system design efforts and their underlying infrastructure into operations and maintenance.

7. Collaborates with the Systems Management Division on the development and implementation of technical standards, policies and procedures to ensure efficient operations and controls of FDA IT systems and that infrastructure services are developed and operated.

8. Conducts studies and analyses and performs capacity planning to determine appropriate IT hardware, software and infrastructure requirements. Ensures agency

infrastructure is kept up to date with FDA technology standards.

Division of Technology:

1. Reviews and evaluates the appropriateness of new and emerging information technologies, including those with potential science and laboratory benefits and enterprise architecture, for incorporation into existing systems and applications and for use in future agency supported initiatives.

2. Oversees the establishment and implementation of technology through an enterprise approach of common IT frameworks, connectivity and consistent practices, standards and policies to enable and support interoperability and consistency throughout the agency.

3. Establishes and manages, through an enterprise approach, the development of standards, including governance for reusable templates, services and common functions for application development.

4. Interacts with HHS, and other interagency groups to guide and align FDA to Government-wide initiatives regarding information technology.

5. Regularly attends industry and other technology meetings to stay abreast of emerging trends and technologies.

6. Directs and implements the FDA information security program to ensure that security controls for hardware, software and telecommunications solutions are: effective, facilitate the continuity of operations for FDA information systems, protect privacy, confidentiality and availability of FDA data; that they manage system security policies and standards for FDA information systems enterprise-wide in accordance with the agency, HHS, GSA, OMB and other Federal government security requirements.

7. Directs and responds to security audits and collaborates with assessment teams and other agency groups to develop and implement corrective action plans.

8. Establishes and communicates policies and procedures for system risk assessments and system business continuity and contingency planning.

9. Oversees disaster recovery planning for data center operations and coordinates with other divisions within OIM to plan, monitor, and test recovery plans for all applications throughout FDA.

10. Develops and monitors scientific workstation standards. Designs and implements new IT methods and applications for scientific computing for Bioinformatics Board activities.

Office of Management:

1. Advises and assists the Commissioner, Deputy Commissioner, Associate Commissioners and other key agency officials on various management and systems activities.

2. Assures that the conduct of agency administrative, personnel, organization, and similar support activities effectively support program operations.

3. Provides leadership and direction regarding all aspects of a variety of agency management programs, including ethics, dockets management, organization management, delegations of authority and special studies and projects for the Office of the Commissioner. Establishes agency-wide policy and provides overall direction and leadership for the Freedom of Information (FOI) program and Privacy Act program.

4. Integrates the agency's technical, programmatic and facilities requirements into the overall budgetary and development plan for the agency's consolidation. Implements relocation planning needed to successfully transition the agency into its new location.

5. Provides Food and Drug Administration's administrative services and facilities. Utilizes a call center to address all administrative and information technology management issues, and monitors and analyzes operational and customer satisfaction.

6. Provides leadership and direction regarding all aspects of agency-wide human resources management including employment, recruitment, training, career development, partnership activities, quality of work life issues, and executive services.

7. Provides program, technical and resources management for the FDA White Oak consolidation, logistics and facilities operations and maintenance services.

8. Provides leadership and guidance to the agency for all aspects of physical and personnel security including the suitability and National Security Information Program. Develops and implements agency wide security policy.

9. Manages and administers the suitability and security program as required by the Office of Personnel Management as set forth in "Suitability" (5 CFR, Part 731), and "National Security Positions" (5 CFR, Part 732). Monitors the appropriate security clearance levels for agency positions, employees, and contract employees.

10. Processes clearance requests, reviews investigative reports/findings and makes suitability determinations based on investigative findings.

11. Develops and directs the agency wide physical security programs and provides professional leadership and authoritative guidance.

12. Formulates policy and procedures necessary to maintain the integrity of privileged and trade secret information submitted by industry.

13. Develops and manages the agency's contractor security program when Automated Data Processing services or non-public information is released under contract agreement.

14. Serves as the single point of contact and focus for the Operating Division's management of more than 800 PHS commissioned officers assigned to approximately 150 duty stations in 47 states.

15. Provides coordination between FDA management and the Assistant Secretary for Health's Commissioned Corps programs. Serves the FDA Centers, special assignments and details to other organizations and initiatives.

16. Develops and implements all policies for utilization of all PHS Commissioned Officers in FDA. Coordinates all orders, billets, Commissioned Officer Effectiveness Reports, promotions, and awards for commissioned officers.

Ethics and Integrity Staff:

1. Develops agency policy and procedures implementing the "Standards of Ethical Conduct for Employees of the Executive Branch" (5 CFR, Part 2635) including the Department of Health and Human Services (DHHS) supplemental regulations (5 CFR, Part 5501).

2. Monitors employee compliance with Federal regulations by reviewing employees' financial disclosure reports and outside activity requests. Reviews, prepares, evaluates and secures appropriate approvals for waivers and other determinations regarding financial interest, conflict of interest and other ethical issues. Counsels employees and provides authoritative advice on the statutory, regulatory, policy and procedural requirements regarding ethics and conflict-of-Interest issues. Develops and conducts training for supervisors, managers, administrative staff, special government employees and other agency employees. Provides oversight and direction to the agency's Advisory Committee program as it relates to special government employees. Assures that conflicts of interest waivers are consistent, legally supportable, well-documented and timely. Evaluates cooperative agreements developed by agency components under the Federal Technology Transfer Act and provides

technical advice on any related conflict of interest matters.

3. Provides advice to employees to ensure their compliance with applicable regulations and statutes on the following: (1) "Standards of Ethical Conduct for Employees of the Executive Branch" (5 CFR, Part 2635); (2) "Supplemental Standards of Conduct for Employees of the Department of Health and Human Services" (5 CFR, Part 5501); (3) "Executive Branch Financial Disclosure, Qualified Trusts, Certificates of Divestiture" (5 CFR, Part 2634); and (4) Criminal Conflict of Interest Statutes—Chapter 11—Bribery, Graft, and Conflicts of Interest (Chapter 11 of Title 18 U.S.C.)

4. Serves as liaison with other FDA components and the agency Office of General Counsel/Ethics Division to develop co-sponsorship agreements.

5. Provides executive and administrative support to the Conflict of Interest Review Board.

6. Coordinates Board activities, prepares background materials, analyzes recommendations and other correspondence for Board members and participates in Board decisions. Implements decisions including advising affected employees of Board determinations.

Office of Business Operations and Human Capital Programs:

1. The Office of Business Operations and Human Capital Programs is responsible for planning and directing agency management programs to include administering the FDA administrative policy programs. The following are specific functions within the Office:

Provides leadership and direction regarding all aspects of a variety of agency management programs, including strategic human capital, organization management, delegations of authority, competitive sourcing, executive resources management, performance management, rewards and recognition, workforce development and succession planning.

Provides executive leadership and direction to coordinate and operationalize the agency's business process improvement initiatives to increase quality, productivity, and transparency.

Oversees the development, prioritization and implementation of business process improvement recommendations to provide predictable, consistent and efficient application of decision-making standards, increase internal and external process transparency resulting in process clarity for internal and external stakeholders and improve the overall

operation and effectiveness of FDA resulting in productivity and efficiency gains.

Provides agency-wide leadership and guidance for all aspects of physical and personnel security including the Suitability and National Security Information program.

Develops and implements agency wide security policy.

Office of Management Programs:

1. Provides leadership and direction regarding all aspects of a variety of agency management programs, including strategic human capital, organization management, delegations of authority, competitive sourcing, executive resources management, performance management, rewards and recognition, workforce development and succession planning, and special studies and projects for the Office of the Commissioner. The following are specific functions within the Office:

Provides management analysis support and advisory services to the Office of the Commissioner and other agency components.

Serves as the agency focal point for FDA's organizational management and delegations of authority program, including monitoring of the establishment, abolishment, modification, transfer or consolidation of agency organizational components and their functional statements, and administering the Standard Administrative Code (SAC) system.

Provides direction and oversight for the agency's Competitive Sourcing Program, including the development of the FAIR Act Inventory, evaluating the efficiencies of the Most Efficient Organization, establishing policies, and advising senior leadership.

Manages the agency's human capital program, ensuring that human capital management programs are merit-based, effective, efficient and supportive of mission goals; alignment of human capital strategies with agency mission/goals; assessing workforce staffing needs; ensuring continuity of effective leadership to manage programs and achieve goals; and identification of mission-critical competency gaps and strategies to close the gaps and hire/retain necessary talent.

Provides leadership, direction, policy development, and oversees the performance management programs covering the Senior Executive Performance Management Program and the Performance Management Appraisal Program.

Provides leadership, direction, policy development and program management for agency workforce and succession planning activities.

Provides leadership, direction, policy development and program management for a variety of incentive programs, including recruitment, retention and relocation incentives, annual leave service credit, student loan program, Telework, etc.

Provides leadership, direction, policy development, program management, and training for special appointment authorities, including the Intergovernmental Personnel Act (IPA), Senior Executive Service (SES), Title 38, and Title 42, (including Service Fellowship, Senior Science Managers, and Senior Biomedical Research Service (SBRSS)).

Provides leadership, direction, policy development and program management for compensation programs including the hiring and advancement within the Senior Executive Service (SES), SBRSS, Title 38, Title 42, Service Fellowships, as well as waiver of overpayments, etc.

Assists the Office of the Chief Scientist in the management of peer review processes for scientific positions by: (1) Providing classification services for peer reviewed positions, and (2) providing staff support and advisory services for the SBRSS.

Manages the agency reward and recognition programs, including the agency Honor Awards Program.

Provides leadership and direction to the agency for meeting the government's competitive sourcing program outlined by OMB Circular A-76, Performance of Commercial Activities.

Provides strategic management of human capital in the recruitment, deployment, development and evaluation of the FDA workforce to ensure human capital programs and policies are aligned with organizational goals.

Provides leadership and direction on agency workforce planning and succession planning activities.

Develops and coordinates the implementation of policies, procedures, and review activities for the agency's peer review program. Provides classification services for research scientists, medical officers, consumer safety officers, and related positions. Provides leadership and direction in the effective and efficient use of resources by conducting management and policy studies and providing management consulting services to the Office of the Commissioner. Employs a variety of data gathering and quantitative analytical techniques to determine the merit of current and proposed management policies and procedures and to assess the impact of new policies and legislation.

Provides management analysis services to the Office of the Commissioner to assess program and management concerns, which may include management studies, option papers, reports, and working group facilitation.

Provides organizational expertise and policy advice, consultation, and support to agency components and monitors the establishment, abolishment, modification, transfer, and/or consolidation of the agency organizational components and their functional statements; controls the assignment of standard administrative codes for implementation of approved organization proposals in the agency and serves as the agency liaison with the Department on SAC activities.

Plans, develops, modifies, and coordinates the delegations of authority program for the agency. Provides advice and consultation on matters related to delegations of authority.

Office of Security Operations:

1. Provides leadership and guidance to Food and Drug Administration (FDA) for all aspects of physical and personnel security including the suitability and National Security Information program.

2. Develops and implements agency wide security policy.

3. Manages and administers the Suitability and Security Program as required by the Office of Personnel Management as set forth in "Suitability" (5 CFR, Part 731), and "National Security Positions" (5 CFR, Part 732). Monitors the appropriate security clearance levels for agency positions, employees, and contract employees.

4. Processes clearance requests, reviews investigative reports/findings and makes suitability determinations based on investigative findings.

5. Serves as liaison with the Department's drug testing officials and coordinates the agency's drug testing program.

6. Carries out duties as outlined in the Department of Health and Human Services and the National Security Information Manual. Serves as liaison and coordinates with the Department regarding the classified document program.

7. Coordinates other agency checks for all non-citizen personnel who work in the agency's facilities.

8. Develops and directs the agency-wide physical security programs and provides professional leadership and authoritative guidance.

9. Provides physical, documentary, and preventative security consultation to FDA components.

10. Formulates policy and procedures necessary to maintain the integrity of

privileged and trade secret information submitted by industry.

11. Develops and manages the agency's contractor security program when Automated Data Processing services or non-public information is released under contract agreement.

Office of White Oak Services:

1. Provides program, technical and resources management for the Food and Drug Administration (FDA) White Oak consolidation, logistics and facilities operations and maintenance services.

2. Provides leadership and guidance to FDA Headquarters' staff offices and Headquarters operating activities for White Oak services.

3. Directs building operations functions for all FDA facilities at the White Oak Campus.

4. Provides direct interface with the General Services Administration (GSA) for White Oak services.

5. Serves as liaison with the Department of Health and Human Services (DHHS) and GSA for the efficient management and operation of facilities occupied by FDA programs at White Oak.

6. Directs and manages over a \$70 million appropriation for the operation, construction, relocation, and maintenance for the White Oak Campus.

7. Provides leadership and direction to assure the efficient and effective utilization of FDA's resources dedicated to engineering design, facility improvements, and new construction of FDA facilities at White Oak.

8. Furnishes project management services including project planning, cost estimating and design, and oversight of construction until completion.

9. Ensures meaningful and continuous communication with community leaders and associations, other Federal officials, State and local governments, and business leaders and customers at White Oak.

10. Develops multiple strategies for addressing FDA's long and short-range facility plans at White Oak.

11. Develops agency plans, policy and procedures consistent with new regulatory requirements and agency needs for White Oak.

Division of Logistics Services and Facilities Operations:

1. Manages shared use conference and training facilities at the White Oak Campus.

2. Oversees transportation management programs and services, serves as the inter-governmental liaison on transportation issues, manages parking, ridesharing program, shuttle services, fleet management and motor pool management.

3. Oversees and directs a variety of commercial contracts to ensure smooth and efficient delivery of services.

4. Participates in the development of agency policy involving logistics programs and services.

5. Provides guidance and assistance to the agency operating activities on a variety of logistics management issues.

6. Manages the warehousing program for the White Oak facility to include material receiving and distribution, loading dock management, storage, collection and processing excess personal property, and labor services for movement of personal property.

7. Manages the Food and Drug Administration (FDA) mail room program for FDA headquarters and field organizations including mail room management, locator services, courier services, off-site mail screening and the nationwide meter contract.

8. Actively participates in and supports the continued development of the White Oak Campus.

Division of White Oak Consolidation:

1. Evaluates and implements strategies that enable the agency to maximize efficiency through the consolidation of specific and shared functions.

2. Coordinates budget and schedule in order to successfully implement project phases.

3. Establishes management structure and dialog with GSA, architectural and engineering design and construction contractors to ensure the FDA needs and concerns are fully addressed.

4. Monitors construction progress as individual projects proceed and coordinates necessary changes.

5. Provides technical direction interaction with design architects that ensure engineering, architectural and programmatic requirements are met in new facilities.

6. Coordinates the various activities required to successfully relocate the agency to its new location including the move, Information Technology (IT), security, safety and building operations.

7. Participates in the development of agency policy involving the consolidation program.

Office of Shared Services:

1. Provides FDA's administrative services including communications, facilities, library services, FDA historical activities, Freedom of Information (FOI) and Privacy Act programs, and dockets management.

Utilizes a call center to address all administrative and information technology management issues, and monitors and analyzes operational and customer satisfaction.

Employee Resource and Information Center:

1. Provides information and services through a call center environment to all Food and Drug Administration (FDA) employees for administrative and information technology management issues. Maintains and populates key technology tools and monitors and analyzes operational and customer satisfaction.

2. Provides call center support to the general public via the FDA Employee Locator phone line.

3. Provides leadership policy development, and coordination for programs with a financial impact on FDA employees including transit subsidy and childcare subsidy programs, fleet management and motor pool management, Presidential Management Fellows Program, Emerging Leaders Program and new employee orientation.

Office of Public Information and Library Services:

1. The Office of Public Information and Library Services (OPILS) is responsible for planning and directing agency information programs to set the direction, coordinate, determine policy, and provide oversight for the provision of information services and information, in a variety of formats and for a variety of purposes, to FDA and the public. OPILS includes the following divisions and sections: Division of Dockets Management (DDM), Division of Freedom of Information (DFOI), FDA Biosciences Library (FBSL), and the FDA History Office. The following are specific functions within the Office:

Provides leadership and direction for the operations of all of the agency information centers, including the FDA Biosciences Library and the DFOI and DDM public reading rooms.

Provides executive perspective on current policy objectives and increases public understanding of the agency's purpose and function.

Establishes agency-wide policy and provides overall direction and leadership for the Freedom of Information (FOI) and Privacy Act programs.

Provides information, information services and research support to FDA through access to information in various formats, via information consulting and advisory services.

Provides leadership and direction regarding all aspects of the agency's regulated dockets program.

Division of Dockets Management and Freedom of Information:

1. The Division of Dockets Management and Freedom of Information is responsible for planning and directing agency information programs to set the direction,

coordinate, determine policy, and provide oversight for the provision of services and information, in a variety of formats and for a variety of purposes, to FDA and the public for the services provided by the Dockets Management Branch (DMB) and the Freedom of Information Branch (FOIB).

The following are specific functions within the Office:

Provides leadership and direction for the operations of the agency information centers, including the FOIB and DMB public reading rooms.

Provides executive perspective on current policy objectives and increases public understanding of the agency's purpose and function.

Establishes agency-wide policy and provides overall direction and leadership for the Freedom of information (FOI) and Privacy Act programs.

Provides information and support to FDA through access to various documents via consulting and advisory services, and through proactive posting to the FDA internet.

Provides leadership and direction regarding all aspects of the agency's regulated dockets program.

Dockets Management Branch:

1. Receives, examines and processes submissions required or permitted in agency administrative proceedings; establishes and maintains docket files containing agency official records relating to an administrative proceeding. Disseminates submissions to appropriate offices for action. Routinely coordinates activities of the branch with other appropriate components.

2. Serves as the agency expert on requirements for submissions required or permitted in agency administrative proceedings. Participates in the development of regulations and policy impacting on agency administrative proceedings and the release of information under the Freedom of Information Act (FOIA).

3. Provides staff support for agency rulemaking activities. Determines compliance of petitions, comments, request for hearings, motions, briefs, and objections with agency regulations.

4. Establishes agency-wide policy and provides overall direction and leadership for the Freedom of information (FOI) and Privacy Act programs.

5. Maintains and operates a public reading room to make agency official records available to any interested party, and provides copies upon request, under the provisions of the FOIA.

6. Provides electronic access to these records, via the Internet, and other means, as required by the EFOIA.

7. Provides information access via the Intranet and other means to FDA personnel for Dockets Management Branch materials and to copyrighted documents.

8. Plans and conducts agency-wide analytical reviews and studies to assess and management information and address concerns. Makes recommendations and assists in the implementation of the recommendations.

Freedom of Information Branch:

1. Serves as the agency expert and focal point for headquarters and field personnel in the development and implementation of effective policies and procedures in accordance with the FOIA, the Privacy Act, FDA regulations, and other relevant statutes.

2. Receives, reviews, controls, coordinates and routes all FOI requests to the proper action office; designs and implements control mechanisms to assure FOI and Privacy Act inquiries are processed and responded to within established timeframes.

3. Establishes agency-wide policy and provides overall direction and leadership for the Freedom of information (FOI) and Privacy Act programs.

4. Reviews all recommendations for denials submitted by headquarters and field FOI officers. 5. Determines the need for supplemental information and/or changes in the denial recommendation and coordinates required action with the submitting office.

6. Analyzes, compiles, and prepares reports on privacy and FOI activities in the agency for the annual reports to the Department and for other reporting requirements.

7. Maintains copies of agency manuals, indexes, and other records required to be on public display in the public reading room.

Division of FDA Biosciences Library:

1. The Division of the FDA Biosciences Library is responsible for planning and directing agency library programs to set the direction, coordinate, determine policy, and provide oversight for the provision of library services and information, in a variety of formats and for a variety of purposes to FDA and the public. The following are specific functions within the Office:

Provides research support to FDA through delivery of information consulting and advisory services, literature searches, and document delivery services in order for FDA to carry out its public health mission.

Collaborates with FDA researchers on research projects, bibliographies,

internal publication databases, copyright issues, digitization and more, so FDA has the information it needs to meet its scientific and regulatory mission.

Plans, develops and conducts training sessions to teach customers how to access and best utilize the online resources available to them to enhance their research efforts.

Stewards of a unique, valuable, extensive and specialized collection of materials essential to FDA's scientific, legal, administrative and regulatory staff. Collects, organizes, maintains and preserves information resources, in multiple formats, in all areas of FDA's research and products FDA regulates, including: biologics, blood products, cosmetics, devices, drugs, food processing and safety, nutrition, pharmacy, pharmacology, radiology, tobacco, toxicology, and veterinary medicine.

Promotes and markets services and resources to customers. Leverages FDA's resources and increases awareness of the library services, staff expertise, and its valuable research collection. Provides services and resources to agency customers, other Federal employees and the public on a limited basis.

Selects, evaluates, acquires and/or develops, and provides electronic access to scientific and technical databases, publications and other media mechanisms in support of agency-wide research needs.

Partners with libraries and information centers, publishers, consortia across the Federal government, health related associations, and other organizations, to enhance resource sharing opportunities that provide for cost savings, resource sharing, sharing of skills and knowledge, benchmarking best practices, and collaboration on projects that have a beneficial impact on the library and FDA's work.

Public Services Branch:

1. Maintains library operations and staffs the public information desk, responding to requests for information from FDA and members of the public.

2. Provides information, information services and research support to FDA through access to information in various formats.

3. Provides training to FDA on the library's subscribed electronic research resources and tools.

4. Provides consulting and advisory services to FDA staff, through briefings and participation in scientific and regulatory meetings.

5. Provides research support through preparation of extensive literature

searches and delivery of customized information packages.

6. Provides articles and documents to researchers via document delivery and inter-library loan services.

7. Monitors and administers the document delivery system, *ILLiad*, and the customer relationship management system, *Ask a Librarian*.

8. Interprets library and information policy and copyright guidance for FDA customers.

9. Manages and coordinates access to bibliographic citation management systems, Reference Manager and EndNote, and consultants with researchers to assist with preparation of bibliographies and citations.

10. Delivers presentations and briefings at New Employee Orientations, Awareness Days, Open Houses, and FDA center events to promote the library resources and services.

Technical Services Branch:

1. Ensures the library collections, both online and in print formats, are responsive to customer research and information needs.

2. Manages portfolio of the library's research resources.

3. Develops and implements the library's collection development policy and interprets policy to customers to justify purchase decisions, collection scope and other criteria.

4. Collects usage data, customer recommendations and feedback to determine information resources to maintain and to cancel; administers acquisition of print and online resources.

5. Establishes site licenses beneficial to FDA research for all library subscribed electronic resources.

6. Establishes pilot tests to evaluate new electronic information resources; analyzes feedback and makes determinations for purchase decisions.

7. Administers the integrated library system and its modules, including the online public access catalog, the federated search engine, and the electronic resource management system.

8. Provides news pushes including the **Federal Register**, and manages listservs to provide daily email updates to online newsletters of interest.

FDA History Office:

1. Provides expertise on the history of FDA and its predecessors; is a key resource for historical records and resources used for agency commemoratives, anniversaries and milestones.

2. Responds to information requests from FDA centers, scholars, the press, consumers, government agencies, industry, trade organizations, health professionals, associations, and foreign

sources. Presents information in workshops, briefings, and seminars.

3. Conducts research and produces publications, briefing reports, and presentations interpretive of FDA. Maintains an extensive office research file.

4. Provides expertise and assesses the historical value of agency resources, i.e., records, photographs, films, audio-visual records, and rare or out-of-print monographs. Leverages FDA resources through consultative partnerships with FDA offices. Collaborates on preservation of historical materials with experts at the National Archives and Records Administration, the National Library of Medicine, the Smithsonian Institution, and other government, academic, and private institutions.

5. Collects, processes, and preserves artifacts that capture the history of FDA's work, represent the commodities it regulates, and document the breadth of its responsibilities. Mounts a variety of exhibits in collaboration with other public and private institutions to educate agency employees and the public about the history and work of the FDA.

6. Partners with the National Library of Medicine, History of Medicine Division, to create and make available transcripts and recordings of an oral history program that documents FDA's institutional history, through personal interviews with key exiting FDA employees.

Office of Real Property Services:

1. Provides leadership and guidance to agency components for all aspects of real property management functions.

2. Directs the management of programs and systems leading to the acquisition, alteration, maintenance, and utilization of leased and owned facilities nationwide, except for the acquisition of buildings for the White Oak Headquarters Consolidation.

3. Directs building operations functions for all Food and Drug Administration (FDA) facilities nationwide.

4. Manages the program and provides direct interface with General Services Administration (GSA) for lease acquisition and lease management for all agency facilities nationwide.

5. Serves as liaison with the Department of Health and Human Services (DHHS) and GSA for general facilities management issues and specifically for the efficient management and operation of facilities occupied by FDA programs nationwide.

6. Directs and manages an excess of \$221 million dollar appropriation for the acquisition, operation, construction,

maintenance for the agency's nationwide real property portfolio.

7. Provides leadership and direction to assure the efficient and effective utilization of FDA's resources dedicated to engineering design, facility improvements, and new construction of FDA facilities nationwide.

8. Establishes management structure and dialog with GSA and the architectural engineering design and construction contractors to ensure FDA program needs and concerns are fully addressed.

9. Ensures meaningful and continuous communication with community leaders and associations, State and local governments, and business leaders in areas where FDA proposes new facilities.

10. Develops and implements program plans, policies and procedures designed to create and maintain a safe and healthful environment for FDA employees, visitors, and guest workers, and to protect the environment.

11. Develops agency plans, policy and procedures consistent with new environmental health and safety regulatory requirements and agency needs. Provides fire protection, safety engineering, and environmental health consultation to the agency's program managers and engineering offices.

12. Leads the agency's decommissioning efforts to close FDA laboratories and offices from an environmental, safety and health perspective.

13. Consults with program officials on safety matters pertaining to changing and emerging research programs.

14. Recommends special technical studies to increase the knowledge of the relationship between occupational safety and environmental health and laboratory programs of FDA.

15. Provides support to the FDA Safety Advisory Board and conducts the FDA Safety and Health Council meetings.

16. Develops and implements a safety management quality assurance program for the agency's multiple work sites nationwide. Develops and implements a similar headquarters program consistent with the FDA Safety Advisory Board recommendations and approval.

Jefferson Laboratories Complex Staff:

1. Provides leadership and direction regarding all aspects of facilities management.

2. Manages and coordinates all aspects of the Jefferson Laboratories long range facilities planning.

3. Develops renovation and improvement project definitions and priorities for inclusion in the agency's Annual Facilities Plan and budget.

4. Provides leadership and direction to assure the efficient and effective utilization of Jefferson Laboratories resources dedicated to engineering design, facility improvements, maintenance and new construction projects.

Division of Engineering Services:

1. Manages and directs design and construction requirements for facility acquisitions within the agency. These requirements may encompass the following activities singularly or in combination; preparation of proposals, preparation of functional requirements, program of requirements and criteria, architect and engineering liaison, space design and planning, functional and technical reviews, preliminary site selections, and project management for facilities construction, renovation and improvement projects.

2. Provides engineering guidance and support for all activities related to maintenance, alterations, and repairs for agency facilities nationwide.

3. Directs and coordinates all agency facilities programs concerned with equipment specifications and installation associated with facility acquisitions. Assists the programs' staffs in developing compatible facilities and equipment systems for the agency.

4. Provides overall engineering services including: feasibility studies, design criteria, concept, analysis, and estimates. Schedules and tracks building and facilities projects and manages project design.

5. Manages the FDA energy management program; develops agency policy relating to the program; develops and enforces supporting agency standards that comply with stated goals of the Department.

6. Oversight of structural, architectural or mechanical modifications to accommodate specific requirements in the existing FDA portfolio.

7. Prepares computer-aided design (CAD) drawings for the agency and maintains file of master drawings for FDA portfolio.

8. Administers agency contract for renovations/alterations of office space.

9. Provides space and alterations project management for existing FDA space to program components.

10. Develops, implements and manages integration of facilities technologies.

Environment, Safety and Strategic Initiatives Staff:

1. Manages the agency's Environment, Safety and Health (EH&S) Program;

2. Oversees strategic management initiatives and programs initiated at

Government-wide, Departmental, agency and Office levels.

3. Oversees and directs a variety of commercial contracts or interagency agreements to ensure smooth and efficient delivery of services.

4. Participates in the development of agency policy involving EH&S programs and services.

5. Provides guidance and assistance to the agency operating activities on a variety of EH&S and Strategic management issues.

6. Actively participates in and supports the agency Facility Management System used to manage FDA's Real Property Asset inventory.

7. Receives and implements new initiatives for Real Property Services (e.g. President Management Agenda initiatives; Office of Management and Budget Scorecards; Department Objectives and agency initiatives)

Division of Facilities Operations:

1. Coordinates building operations and facilities management functions for all Food and Drug Administration (FDA) owned facilities within the Washington metropolitan area which includes: Module 1 (MOD 1), and the Beltsville Research Facility (BRF). Through special delegations of authority from the General Services Administration (GSA), maintains responsibility for the total management, operation, and maintenance of Federal Building 8 (FB-8) and Module 2 (MOD 2).

2. Oversees and directs a variety of commercial contracts to ensure smooth and efficient delivery of services.

3. Participates in the development of agency policy involving building management and operations.

4. Provides guidance and assistance to the agency operating activities on a variety of facilities operations issues.

5. Coordinates office and laboratory relocations and provides technical assistance to programs regarding effective space utilization.

6. Provides guidance to program personnel in identifying or developing alternatives or emergency procedures during scheduled and unscheduled maintenance interruptions.

7. Administers agency contracts for moving services and preventive maintenance for government owned property.

8. Manages and coordinates the General Services Administration Delegations of Authority program for FDA nationwide. Responds, reviews, and analyzes existing and proposed Delegation Agreements, Interagency Agreements, Memorandum of Understandings regarding the agency's nationwide property holdings for

operational planning processes and improvement.

Portfolio Development Staff:

1. Plans and develops the agency Annual Facilities Plan that includes forecasts for long term, short term and immediate space needs as well as annual facilities budgets for rent, operations and maintenance and building and facilities.

2. Develops multiple strategies for addressing FDA's long and short range facility plans.

3. Develops agency standards and enforcement of occupied and vacant space utilization. 4. 4. Prepares reports and space management analysis of the agency's real property holdings. 5. 5. Analyzes agency housing plans and performs real property occupied and vacant space 5. customer analysis.

6. Provides cost analysis support to agency components concerned with leasing, construction, and finance costs.

7. Manages the policy, acquisition, management and administration of the agency's leased real property portfolio.

8. Provides guidance and assistance to the agency operating activities on a variety of nationwide real estate management issues.

9. Serves as liaison with the Department of Health and Human Services (DHHS) and the General Services Administration (GSA) for all lease acquisition and lease management of FDA nationwide facilities.

10. Conducts agency facility studies and develops specific long-range facility plans for both headquarters and field operations.

11. Directs or participates in, the preparation of the Program of Requirements for new construction projects.

Center for Tobacco Products:

1. The Center for Tobacco Products will be established to address the enactment of the Family Smoking and Tobacco Control Act. This Office will consist of an Office of Management, an Office of Policy, an Office of Regulations and an Office of Science.

Office of the Center Director:

1. Provides leadership and direction for all Center activities and coordinates programs within the agency, Department and government agencies.

2. Plans, administers, coordinates, evaluates and implements overall Center scientific, regulatory, compliance, enforcement and management programs, policies and plans.

3. Provides leadership and direction for Center management, planning, and evaluation systems to ensure optimum utilization of personnel, financial resources, and facilities.

4. Establishes and manages a program to maintain the highest level of quality and integrity for all Center laboratory studies and the processing of regulatory samples, and ensures that all laboratories are in compliance with Good Laboratory Practice Regulations.

5. Coordinates and monitors the Center's overall research portfolio, including all research-related activities and inquiries and the development of strategic research program plans.

6. Serves as the primary representational role for relationships with the department, OMB, the White House, the Congress and the media.

Office of Management:

1. Provides support to the Center Director and Deputy Directors, including the coordination and preparation of briefing materials and background information for meetings, responses to outside inquires, and maintenance and control of the Center Director's working files.

2. Manages the Center's Freedom of Information Act activities, coordinating responses with other Center technical, regulatory, and policy units as well as developing direct responses.

3. Provides correspondence control for the Center and controls and processes all agency public correspondence directed to the Center Director. Develops and operates tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.

4. Coordinates the Center's communications with the agency, Department, and the other Federal government agencies.

5. Provides authoritative advice and guidance to the Center Director on management policies, guidelines, issues and concerns that directly impact Center programs and initiatives.

6. Provides leadership, guidance and directs the development of long-range strategic and operational plans and systems for Center activities and directs technical support staff in providing essential management services and other critical support functions.

7. Provides leadership and guidance as primary interface working with the FDA Office of Shared Services to ensure provision of a broad range of essential technical support services.

8. Provides leadership and effective coordination as the primary Center liaison and expert with the Office of Information Management for provision and continuous improvement of information and technology services for the Center to include networking, scientific computing software engineering, systems, and telecommunications.

9. Administers and executes Center program planning and performance activities, budget formulation and execution, payroll, accounting, fleet and property management functions.

10. Analyzes, formulates and develops annual budget for the Center in accordance with FDA, DHHS, OMB and Congressional guidelines. Provides oversight and ensures compliance with all regulations governing financial processes as outlined in OMB, GAO, DHHS and FDA policies.

11. Manages and maintains a management system for center wide research and support functions.

12. Develops, maintains, monitors, analyzes and reports data to Center management and program officials on the Center's budget/planning resource monitoring and evaluations systems.

13. Manages, conducts, and analyzes studies designed to improve Center processes and resource utilization and support requirements.

14. Provides leadership, guidance, technical support and assistance to Center managers, employees and shared services staff on services including timekeeping, payroll, fleet management, personal property management, travel, acquisitions and financial services.

15. Provides leadership within the Center to assure compliance with statutes, executive orders and administrative directives, such as the Chief Financial Officer Act (CFO) and the Federal Financial Manager's Financial Integrity Act (FMFIA).

Office of Policy:

1. Advises the Center Director and other key agency officials on matters relating to agency policy, regulations and guidance, legislative issues, and planning and evaluation activities.

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

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

4. Advises and assists the Center Director and other key agency officials concerning legislative needs, pending legislation and oversight activities that affect FDA.

5. Serves as the focal point for overall legislative liaison activities within Center, FDA and between FDA, the Department, PHS and other agencies related to Tobacco; analyzes the legislative needs of the Center and drafts or develops legislative proposals, position papers, and departmental

reports on proposed legislation for approval by the Center Director and Commissioner.

6. Advises and assists members of Congress and congressional committees and staffs in consultation with the Office of the Secretary, on agency actions, policies, and issues related to legislation which may affect the Center.

Office of Regulations:

1. Provides Center oversight and leadership in the development of regulations, policies, procedures and guidance for the review and regulation of tobacco products, their labels, and marketing, and in the development of new legislation.

2. Provides Center oversight and leadership in the administration of the user fee billing and waiver program, and registration and listing.

3. Coordinates, interprets, and evaluates the Center's overall compliance efforts. As necessary, establishes compliance policy or recommends policy to the Center Director.

4. Oversees and directs the agency's rulemaking activities and regulation and guidance development system.

5. Serves as the agency focal point for developing and maintaining communications, policies, and programs with regard to regulations development.

6. Stimulates awareness within the agency of the need for prompt and positive action to assure compliance by regulated industries; works to assure an effective and uniform balance between voluntary and regulatory compliance and agency responsiveness to consumer needs.

7. Evaluates and coordinates all proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.

8. Develops and/or recommends to the Center Director policy, programs, and plans for activities between the agency and State and local agencies; administers the Center's overall Federal-State program and policy; coordinates the program aspects of agency contracts with State and local counterpart agencies.

Office of Science:

1. Serves as principal authority and provides leadership for the Center's participation in the National Toxicology Program (NTP).

2. Organizes, plans, and directs Center research programs in accordance with Center-wide strategic direction. Implements Center-wide strategies for achieving annual and long-range plans for research.

3. Provides leadership and direction for communications among scientific and administrative staffs.

4. Organizes, plans, and directs the Center for research support in the areas of Tobacco.

Directs the development methods used to extrapolate test results from animals to humans.

5. Coordinates research in Center program areas with leading scientists in other segments of FDA and the scientific community at large and promotes and coordinates the Center's technology transfer under the provisions of the Federal Technology Transfer Act.

6. Coordinates with other Center and agency components and top level officials of other agencies to provide input for long-term research planning in responsible program areas.

7. Insures that programs implemented are responsive to the Center's portion of the agency's integrated research plan.

8. Provides scientific oversight of Center research contracts and agreements.

9. Advises and assists the Center Director, Deputy Director, and other key officials on scientific issues that have an impact on policy, direction, and long-range goals.

10. Coordinates and provides guidance on special and overall science policy in program areas that cross major agency component lines and scientific aspects that are critical or controversial, including agency risk assessment policies.

11. Represents the Center with other government agencies, state and local governments, industry, academia, consumer organizations, Congress, national and international organizations, and the scientific community on tobacco science policy and tobacco science issues.

12. Serves as the focal point for overall management of Center activities related to science priorities, resources, and leveraging efforts, as well as peer review of scientists and scientific programs.

13. Advises the Commissioner, Deputy Commissioner, and other key officials on scientific facilities and participates with other agency components in planning such facilities.

14. Administers the Tobacco Advisory Committee that advises the Center Director, Deputy Director, and other key officials regarding the quality and direction of tobacco science and scientific issues.

II. Delegation 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.

Dated: August 7, 2009.

Kathleen Sebelius,

Secretary of Health and Human Services.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Development of Antiviral Products for Treatment of Smallpox and Related Poxvirus Infections; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding scientific issues in clinical development of antiviral drug products for treatment of smallpox and related poxvirus infections. This public workshop is intended to provide information for and gain perspective from health care providers, academia, and industry on various aspects of antiviral product development for smallpox and related poxvirus infections, including the status of clinical understanding of smallpox from pre-eradication experience, current epidemiology of naturally occurring poxvirus infections, potential effect of antiviral treatment for smallpox and related poxvirus infections, and issues pertaining to animal models for smallpox and related poxvirus infections. The input from this public workshop will help in developing topics for further discussion.

Dates and Times: The public workshop will be held on September 1, 2009, from 8:30 a.m. to 5:30 p.m. and on September 2, 2009, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Crowne Plaza Silver Spring, 8777 Georgia Ave., Silver Spring, MD 20910.

Contact Person: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993-0002, 301-796-1300.

Registration: To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to SmallpoxWkshp@fda.hhs.gov by August

24, 2009. Persons without access to the Internet can call 301-796-1300 to register. Registration is free for the public workshop, but interested parties are encouraged to register early because spaced is limited. Seating will be available on a first-come, first-served basis. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding antiviral drug development for smallpox and related poxvirus infections. This public workshop will focus on scientific considerations in the clinical development of products for treatment of smallpox and related poxvirus infections. This public workshop is intended to provide information regarding historical perspectives on smallpox and current perspectives on related poxvirus infections in humans. The workshop will explore approaches to assessing the potential effect of antiviral treatment for smallpox and related poxvirus infections. Issues pertaining to animal models for smallpox and related poxvirus infection and their relationship to disease in humans will be discussed at the workshop. In addition, the workshop will include perspectives of public health organizations on possible uses of an antiviral product for poxvirus infections.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 20 working days after the public workshop, at a cost of 10 cents per page. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm169065.htm> approximately 45 days after the workshop.

Dated: August 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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