Chapter 1
REGULATORY ORGANIZATION

This chapter includes the following sections:

1-1 INTRODUCTION

The purpose of this chapter is to provide an overview of the organizational structure of the offices involved in compliance related functions within FDA. It is not the intent to provide a complete description of FDA's organizational structure. FDA's functional statement for each office may be found in various chapters of FDA's Staff Manual Guide (SMG). This guide is available on FDA's Intranet Website.

This Regulatory Procedures Manual (RPM) chapter is divided into sections based on major organizational units, and includes a section for all centers and the Office of Regulatory Affairs (ORA).

1-2 OFFICE OF REGULATORY AFFAIRS (ORA)

1-2-1 Associate Commissioner For Regulatory Affairs (ACRA)

ORA is under the direction of the Associate Commissioner for Regulatory Affairs. The ACRA reports directly to the Commissioner of Food and Drugs.

1. **The Immediate Office Of The ACRA Includes The:**

    a. Deputy Associate Commissioner for Field Operations, who oversees the operation of the regional offices, district offices, and laboratories;

    b. Deputy Associate Commissioner for Compliance Policy, who ensures that ORA's programs and operations support the agency's public health and consumer protection missions, and leads efforts to develop and implement risk-based approaches to optimize, and maximize the impact of, ORA's programs and activities; and,

    c. Executive Operations Staff develops and maintains effective channels of internal and external communication of issues of significant visibility and importance on behalf of ORA; tracks, directs and controls development, coordination and, when appropriate, prepares important and sensitive ORA responses to executive and Congressional requests; and serves as ORA's liaison to the Office of Legislation, the FDA Office of the Executive Secretariat, and center counterparts.

2. **The Following Offices Report To The ACRA:**

    a. Office of Resource Management;

    b. Office of Criminal Investigations; and,

    c. Executive Operations Staff.

3. **The Following Offices Report To The Deputy Associate Commissioner for Field Operations:**

    a. Office of Regional Operations;

b. Regional Field Offices

   i. Central Region;

   ii. Northeast Region;

   iii. Pacific Region;

   iv. Southeast Region; and,

   v. Southwest Region.

4. **The Following Offices Report to the Deputy Associate Commissioner for Compliance Policy:**

   a. Office of Enforcement

5. **The Functional Statements For ORA Are:**

   a. Advises and assists the Commissioner and other key officials on regulations and compliance-oriented matters that have an impact on policy development and execution and long-range program goals;

   b. Coordinates, interprets, and evaluates the agency's overall compliance efforts; as necessary, establishes compliance policy or recommends policy to the Commissioner;

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

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

   e. Executes direct line authority over all agency field operations; develops, issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within the agency through which headquarters offices obtain field support services;

   f. Provides direction and counsel to Regional Food and Drug Directors (RFDDs) in the implementation of policies and operational guidelines that form the framework for management of agency field activities;

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

   h. Evaluates the overall management and capabilities of the agency's field organization; initiates action to improve the management of field activities and coordinates the formulation and management of career development plans;

i. Directs and coordinates the agency's emergency preparedness and civil defense programs; and,

j. Operates the Federal Medical Products Quality Assurance Program for the agency.

1-2-2 Office of Enforcement

There are three divisions within the Office of Enforcement :

1. Division of Compliance Management and Operations;
2. Division of Compliance Policy; and,
3. Division of Compliance Information and Quality Assurance.

The functional statements for the Office of Enforcement and the three divisions within this office are found in the following Staff Manual Guides: SMG 1121.20 (Office of Enforcement); SMG 1121.22 (Division of Compliance Management and Operations); SMG 1121.23 (Division of Compliance Policy); and SMG 1121.24 (Division of Compliance Information and Quality Assurance).

1-2-3 ORA Field Organization

The ORA field organization is divided into regional offices. The regional offices are under the direction of Regional Food and Drug Directors (RFDDs) who report to the ACRA. There are seven regional offices. They are located as follows:

1. Northeast Region: Jamaica, NY and Stoneham, MA;
2. Central Region: Chicago, IL and Philadelphia, PA;
3. Southeast Region: Atlanta, GA;
4. Southwest Region: Dallas, TX; and,
5. Pacific Region: Oakland, CA.

There are two to seven district offices within each region for a total of 19 districts. Each district office is usually comprised of three to four branches, including either a compliance branch or an enforcement branch, which is the primary regulatory contact within a district office.

1-3 CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

1-3-1 Office of Compliance And Biologics Quality (HFM-600)

The functional statements for the Office of Compliance and Biologics Quality are:

1. Monitors the quality of biological products, drugs, and devices regulated by CBER through surveillance, inspections, and compliance programs;
2. Reviews, evaluates and takes action on Investigational New Drug applications (INDs), biologics license applications (BLAs), supplements, and amendments, New Drug Applications (NDAs), Premarket Approval Applications (PMAs), and 510(k) premarket

notifications (510(k)s) submitted to CBER; performs Chemistry, Manufacturing and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews;

3. Advises the center director and other agency officials on emerging and significant compliance issues for biological products, drugs, and devices regulated by CBER; and serves as CBER's focal point for surveillance and enforcement policy;

4. Coordinates CBER's participation in the inspection of CBER-regulated manufacturing facilities;

5. Develops, with other CBER/agency components, compliance standards for biological products, drugs, and devices regulated by CBER, including Current Good Manufacturing Practice (CGMP) regulations, ensures their uniform interpretation and evaluates industry's conformance with CGMP in manufacturing biological products, drugs, and devices regulated by CBER;

6. Directs CBER's bioresearch monitoring program, enforcement, and recall programs for biological products, drugs, and devices regulated by CBER;

7. Develops compliance and surveillance programs for CBER-regulated products, coordinates and directs their field implementation, and advises other CBER components on these programs;

8. Provides guidance to headquarters and field personnel in the development of evidence to support enforcement actions;

9. Coordinates all CBER-field compliance activities, including planning and field assignments;

10. Coordinates CBER's import and export programs;

11. In coordination with other CBER components, responsible for lot release of biological products including testing products and review of protocols submitted for release by manufacturers also maintains a reference reagent program;

12. Reviews and evaluates all advisory action and administrative action recommendations including warning letters; suspension, revocation, denial of license; debarment; disqualification of clinical investigators; and recommended civil and criminal actions, including seizure, injunction, and prosecution based on findings of inspections and investigations;

13. Reviews and evaluates all recommendations for Orders of Retention, Recall, Destruction and Cessation of Manufacturing involving human cells, tissues, and cellular and tissue-based products (HCT/Ps);

14. Coordinates CBER's application integrity policy;

15. In coordination with other agency components, formulates policy in the areas of compliance and biologics quality including enforcement, good manufacturing practices, and labeling including advertising and promotion, and drafts guidance documents and regulations for other agency components and regulated industry on these subjects;

16. Enforces regulations pertaining to product labeling including proprietary names, labels, package inserts, and promotion and advertising material; formulates and establishes policy for the regulation of promotional activities including advertisements, promotional labeling, and promotional practices; and,

17. Plans and develops, in coordination with other agency and CBER components, information and education activities related to biological products, drugs, and devices regulated by CBER.

18. Manages CBER's product shortage program.

There are four divisions within the Office of Compliance and Biologics Quality:

1. Division of Case Management;

2. Division of Inspections and Surveillance; and,

3. Division of Manufacturing and Product Quality and,.

4. Division of Product Quality.

1-3-2 Division of Case Management (HFM-610)

The functional statements for the Division of Case Management are:

1. Reviews and evaluates administrative action recommendations including suspension, revocation, denial of license and debarment; reviews recommended civil and criminal actions, including seizure, injunction, and prosecution; prepares documents required for such enforcement actions and manages cases after actions are taken;

2. Reviews and evaluates all recommendations for Orders of Retention, Recall, Destruction and Cessation of Manufacturing involving human cells, tissues, and cellular and tissue-based products (HCT/Ps);

3. Coordinates support for ongoing litigation and contested cases with the Office of Chief Counsel and the Department of Justice, including the identification and preparation of expert witnesses;

4. In coordination with the Office of Communications, Outreach and Development, provides training for CBER and other agency personnel regarding evidence development in support of compliance actions;

5. Provides primary support within the Office of Compliance and Biologics Quality for agency ad hoc committee meetings relating to proposed enforcement action against products, manufacturers or other individuals associated with CBER regulated products;

6. Develops enforcement standards for direct reference authority to FDA district offices for issuance of Warning Letters and reviews and evaluates Team Biologics and district generated recommendations for the issuance of Warning Letters for which direct reference authority has not been granted;

7. Coordinates CBER's application integrity policy;

8. Directs and coordinates CBER's import and export programs, including the review of applications for export of unapproved biological products and requests for export certificates;

9. Provides assessment of the compliance status of regulated firms within CBER's purview (compliance status checks); and,

10. Reviews, evaluates, and monitors material associated with promotion, advertising, conferences, exhibits, and similar types of media for all biological products, new drugs, and medical devices approved by CBER; participates in actions to remedy violative promotion.

1-3-3 Division of Inspections And Surveillance (HFM-650)

The functional statements for the Division of Inspections and Surveillance are:

1. Coordinates and provides support and guidance to district offices for investigations and surveillance inspections;

2. Works with the Office of Regulatory Affairs (ORA) to prepare inspection work plans and allocate resources for the biological product inspection program;

3. Develops guidance and other training programs in conjunction with CBER components, to promote industry compliance and for use in training headquarters and field inspection staffs;

4. Develops and updates compliance programs on behalf of CBER;

5. Manages the biological compliance surveillance activities including review of transfusion-related fatality reports and biological product deviations;

6. Plans and directs investigation and surveillance assignments in response to reports regarding product defects, adverse events, biological product deviations, and allegations of violative activity; evaluates the related inspection and investigation reports;

7. Manages the Bioresearch Monitoring programs for CBER, including clinical investigator disqualifications; reviews, evaluates, and classifies establishment inspection reports and prepares Warning Letters;

8. Coordinates office follow-up and response to complaints related to investigational products and clinical trials;

9. Working with the Office of Communications, Outreach and Development, provides guidance to industry and government concerning bioresearch monitoring policies and regulations;

10. Promotes uniformity between CBER and ORA with regard to conducting inspections and the implementation of Current Good Manufacturing Practices (CGMPs) policy;

11. Serves as CBER's contact for Team Biologics issues during inspections;

12. Supports the CBER pre-approval inspection program; and,

13. Serves as the CBER contact for other federal agencies concerning enforcement matters, and coordinates review of these matters with other agency components as appropriate.

1-3-4 Division of Manufacturing And Product Quality (HFM-670)

The functional statements for the Division of Manufacturing and Product Quality are:

1. Reviews, evaluates, and takes action on Investigational New Drugs applications (INDs), license applications, supplements, and amendments submitted to the Center for Biologics Evaluation and Research (CBER); performs Chemistry, Manufacturing and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews;

2. Develops and administers the biological products lot release program; reviews manufacturers' submissions for licensed biological product lots; receives, maintains, and distributes samples of biological products submitted for testing;

3. In coordination with the Office of Communications, Outreach and Development, provides expert technical and regulatory guidance and training to CBER and other agency components, government agencies, and representatives of domestic and foreign biological establishments regarding biological product manufacturing and quality;

4. Leads prelicense and preapproval inspections, and participates in routine GCMP inspections of establishments manufacturing biological products; participates in the preparation of inspection reports as part of an inspection team and evaluates the firm's corrective actions; and,

5. Supports enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by other CBER or field components.

1-3-5 Division of Product Quality (HFM-680)

The functional statements for the Division of Product Quality are:

1, Develops product testing programs for CBER regulated products in a secured and controlled environment using appropriately qualified and validated methods for generating data supportive of CBER regulatory activities.
2, Maintains CBER product testing programs in a manner accreditable to internationally recognized standards.
3, Participates in biological product lot release activities by performing testing of submitted samples of biological products and review of lot release protocols for these biological products.
4. Supports enforcement activities by contributing expertise to the evaluation of test methods, assessment of acceptability of assay method validation packages, and evaluation of appropriateness of product specifications.
5. In coordination with the Office of Communications, Outreach and Development, provides expert scientific and technical advice and assistance to CBER and other agency components, and international and academic organizations on issues (related to biologics product testing and methods validation.
6. Prepares, calibrates, holds and distributes official U.S. reference preparations used in the control testing of biological products.

7. Develops and maintains scientific programs for the evaluation and standardization of reagent test kits for CBER regulated biological products and related devices.

1-4 CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

1-4-1 Office of Compliance

The Office of Compliance ensures that safe and effective drugs are available to the American people.

The Division of Scientific Investigation was transferred to the office in May, 2006.

The functional statements for the Office of Compliance are:

1. Protects the American public from unsafe and ineffective drugs by addressing public health risks associated with legal violations;
2. Develops and oversees drug compliance programs designed to reduce consumer exposure to risks of unsafe and ineffective drugs;
3. Monitors the quality of human drugs through inspectional coverage, product testing, and other pre- and post-market surveillance activities;
4. Advises the center director and other agency officials on regulatory and enforcement issues involving human drugs;
5. Coordinates center-field relations and provides support and guidance to field offices on case development and regulatory actions; ensures uniform interpretation of standards;
6. Develops policies and compliance strategies to ensure that over-the-counter (OTC) and prescription (Rx) drugs are of high quality, properly labeled, safe, pure, and meet applicable drug approval requirements;
7. Develops policy and standards to achieve high product quality through application of current good manufacturing practice requirements; coordinates surveillance and preapproval inspections;
8. Coordinates evaluation and classification of drug recalls and provides center coordination with field offices for implementation of recalls; monitors resolution of drug shortage situations involving compliance issues; and,
9. Implements programs and projects to identify, assess, and prioritize the public health significance of legal violations and develops and utilizes innovative enforcement strategies to reduce public health risks associated with legal violations.

There are four divisions within the Office of Compliance:

1. Division of New Drugs and Labeling Compliance;
2. Division of Manufacturing and Product Quality;
3. Division of Compliance Risk Management and Surveillance; and,

4. Division of Scientific Investigation.

1-4-2 Division of New Drugs and Labeling Compliance

The division's primary responsibility is to protect the public health by ensuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic Act as it relates to over-the-counter (OTC) drugs, prescription (Rx) drugs, and drugs falling within the health fraud program area.

The division consists of five teams, the Over-The-Counter Drugs Team, the Internet and Health Fraud Team, the Pharmacy Compounding Team, the New Drugs and Labeling Team, and the Import-Export Team. The functional statements for the Division of New Drugs and Labeling Compliance are:

1. Protects the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug, and Cosmetic Act as it relates to over-the-counter (OTC) drugs, prescription (Rx) drugs, and drugs falling within the health fraud program area;

2. Develops compliance strategies, programs and policy guides to ensure that all OTC and Rx drugs marketed in the United States are properly labeled and meet applicable new drug requirements and to remove from the market fraudulent drug products that pose direct or indirect public health risks;

3. Maintains the integrity of imported drug products by assuring their compliance with applicable legal requirements;

4. Provides guidance and consults on export policies and procedures;

5. Directs field inspections and investigations and recommends, directs and/or coordinates case development and compliance actions regarding OTC, Rx, and health fraud drug products;

6. Provides enforcement and litigation support and guidance for OTC, Rx, and health fraud drugs, including support for State Attorney General and Office of Criminal Investigation cases;

7. Develops legislative proposals, implementing regulations, policy, and guidance documents; enforcement strategies; and outreach activities relating to pharmacy compounding;

8. Develops legislative proposals, implementing regulations, policy and guidance documents, enforcement strategies, and outreach activities relating to pharmacy compounding;

9. Monitors the Internet in support of division enforcement initiatives, actions and outreach programs; and,

10. Prioritizes unapproved drugs identified for regulatory action using risk based assessment and develops compliance strategies to address the most significant legal violations.

1-4-3 Division of Manufacturing and Product Quality

The division is the agency focal point for comprehensive regulatory oversight of the human drug manufacturing industry to ensure that drug products offered in the U.S. marketplace are not adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act.

The division consists of the Domestic Case Management Branch, the Manufacturing Assessment and Pre-Approval Compliance Branch, the International Compliance Branch, the Guidance and Policy Team, and the Recalls and Shortages Branch. The functional statements for the Division of Manufacturing and Product Quality are:

1. Serves as agency focal point regarding compliance of establishments and products with current good manufacturing practices (CGMP) and other adulteration provisions of the Federal Food, Drug and Cosmetic Act;

2. Ensures the quality and purity of marketed human drug products through enforcement of the CGMP regulations for the manufacture, testing and holding of human drugs; develops and directs the CDER drug product quality enforcement programs;

3. Provides clear and consistent guidance to FDA field personnel, industry and foreign governments on manufacturing quality requirements for human drug products;

4. Ensures rapid access to quality new human drugs by verifying new drug application commitments, CGMP compliance, and supporting data before and after application approval; develops and implements strategies for alleviation of drug shortages/drug supply problems;

5. Ensures that the appropriate corrective action is taken when human drug products are unsafe or adulterated; manages the CDER product recall program, coordination of Health Hazard Evaluations, coordination of CDER response to incidents involving possible drug quality problems, and potential drug shortages that are the result of product defects or enforcement actions.

6. Develops guidance materials and educational programs to promote compliance with drug current good manufacturing practice requirements;

7. Develops agency compliance policy for enforcement of the Federal Food, Drug, and Cosmetic Act regarding drug product quality;

8. Processes regulatory actions involving drug product quality requirements and supports litigation arising from regulatory actions;

9. Proposes and implements agreements with foreign governments for harmonization of requirements and program efficiencies for assuring human drug product quality;

10. Reviews chemistry manufacturing controls (CMC) submission for the approval of biological license applications (BLA) and supplements, focusing on areas relevant to manufacturing controls, microbiology product quality, and sterility assurance of biotech drugs;

11. Serves as the lead investigator for preapproval inspections for BLA applications; and,

12. Serves as the technical experts in biotech drug manufacturing and controls.

1-4-4 Division of Compliance Risk Management and Surveillance

The division's primary responsibility is to advance the office mission through implementation of programs and projects that identify, assess and prioritize legal violations based upon their public health significance. This approach requires qualitative and quantitative data analyses and the use of strategic problem solving to target compliance actions and develop innovative enforcement strategies for reducing public health risks associated with violative drug products.

The division is composed of the Surveillance and Data Analysis Branch which includes the Risk Management and Strategic Problem Solving Team, Surveillance Programs Team, Data Analysis and Information Management Team, and Drug Registration and Listing Team. The functional statements for the Division of Compliance Risk Management and Surveillance are:

1. Fosters the use of risk-based approaches to compliance and enforcement actions undertaken by the office;

2. Applies qualitative and quantitative analysis to identify, assess and prioritize legal violations for compliance action based upon their public health significance;

3. Utilizes strategic problem-solving to select projects for intervention and to develop and evaluate the effectiveness of such interventions in reducing the public health risks associated with violative drug products;

4. Works closely with other agency units in areas of strategic planning, identification of priorities, and development of risk-based compliance initiatives;

5. Monitors the quality of the nation's drug supply through post-market surveillance activities, including overseeing the sampling and analysis of drugs and directing compliance activities pertaining to the postmarketing adverse drug experience reporting requirements;

6. Develops expertise in working with office and agency databases, including drug surveys, Drug Quality Reporting and NDA Field Alert System, AERS, Drug Recalls and Shortages, Establishment Evaluation System, Drug Registration and Listing System, Prescription Drug Marketing Act, DESI Federal Register database, Turbo EIR and FACTS; and also establishes familiarity with relevant databases outside the office and agency; and,

7. Provides guidance and interpretation of drug establishment registration and drug product listing regulations involving domestic and imported drug products.

1-4-5 Division of Scientific Investigations

The division's primary responsibility is to verify the integrity of efficacy and safety data submitted to the FDA in support of new drug applications and to assure that the rights and welfare of human research subjects are protected.

The division is composed of two clinical review branches (Good Clinical Practices Branch I and Good Clinical Practices Branch II), the Human Subjects Protection Team (HSP Team), a Good Laboratory Practices/Bioequivalence Branch, and Teams for International Policy, Informatics and Infrastructure, and Enforcement Policy.

The functional statements for the Division of Scientific Investigations are:

a. Develops and implements the Agency's Bioresearch Monitoring Program for Human Drugs under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other Federal statutes, and applicable regulations.

b. Develops standards for the conduct of clinical and nonclinical investigations performed to demonstrate the safety and effectiveness of drug and biologic products.

c. Designs and operates surveillance and compliance programs in the areas of nonclinical and clinical drug product investigations, bioequivalence studies, and human subject protections. Assigns, directs and coordinates onsite inspections of sponsors and investigators of preclinical and clinical drug product studies; bioequivalence, biopharmacokinetics, and biopharmacodynamic studies and the laboratories used for these studies, institutional review boards, and commercial clinical testing facilities in collaboration with the Agency's field organization. Evaluates investigation reports, develops and issues correspondence to the inspected party, and initiates administrative and regulatory corrective measures as necessary.

d. Evaluates complaints related to the nonclinical and clinical drug investigations, initiates appropriate follow-up strategy including inspections, and, as necessary, generates regulatory or administrative actions.

1-5 CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

1-5-1 Office of Compliance

The Office of Compliance (OC) develops, directs, coordinates, evaluates, and monitors compliance programs covering regulated industry. OC conducts field tests and inspections when necessary for regulatory purposes, evaluates industry quality control and testing programs to ensure compliance with regulations, and provides advice to agency field offices on, and manages center activities relating to, legal actions, case development, and contested case assistance, and coordinates all field planning activities and issues all field assignments for the center.

There are four divisions in the Office of Compliance:

1. Division of Risk Management Operations;

2. Division of Bioresearch Monitoring;

3. Division of Enforcement A; and,

4. Division of Enforcement B.

1-5-2 Division of Risk Management Operations

The functional statements for the Division of Risk Management Operations are:

1. Advises and supports office officials and staff regarding all policies and procedures relating to administrative support activities;

2. Provides analysis activities for office, center and agency senior management in the development and implementation of risk-base regulatory and enforcement activities;

3. Advises office officials and staff regarding management information system initiatives and serves as the office liaison to other center and agency components on all such matters; plans, coordinates, and implements an Office Information Technology strategic plan;

4. Provides information for requests from external as well as internal sources; coordinates and processes Freedom of Information requests (FOI) and issues certificates for requests to export approved medical devices and non-approved medical devices under 801(e) of the Federal Food, Drug, and Cosmetic Act (the Act);

5. Coordinates the center's administrative activities with field offices as well as internal regulatory actions;

6. Develops, coordinates, and/or conducts medical device and electronic products training programs for field personnel and state and local agencies in coordination with other center and agency components; and,

7. Develops, processes information for, and maintains the medical device registration and product listing system; develops and monitors contracts for data processing; ensures industry compliance with reporting requirements through a certification program; and develops and maintains a document tracking system.

There are three branches within this division:

1. Field Operations Branch;

2. Risk Management and Analysis Branch; and,

3. Regulatory Policy and Systems Branch.

1-5-3 Division of Bioresearch Monitoring

The functional statements for the Division of Bioresearch Monitoring are:

1. Enforces the Medical Device Amendments of 1976 and 1992 and the Safe Medical Devices Act of 1990 as they relate to investigational devices;

2. Manages and coordinates the administrative and regulatory responsibilities of the agency's Bioresearch Monitoring Program for medical devices; prepares related warning letters and other correspondence; ensures corrective actions taken by firms inspected under the Bioresearch Monitoring Compliance Program are acceptable;

3. Assigns, directs, and coordinates on-site inspections of sponsors and investigators of preclinical and clinical device product studies, institutional review boards, commercial clinical testing facilities, and nonclinical toxicology laboratories in collaboration with the agency's field organization;

4. Provides regulatory guidance and interpretations of the informed consent, institutional review board, and the investigational device exemption regulations to the field and industry;

5. Designs, implements, and evaluates surveillance and compliance programs in the areas of preclinical and clinical investigational device product investigations. Manages the premarket approval data audit program to ensure the integrity of data submitted to the agency; and,

6. Coordinates and implements the agency's Application Integrity Policy for medical devices.

There are three branches within the Division of Bioresearch Monitoring:

1. Program Enforcement Branches A and B; and,

2. Special Investigations Branch.

1-5-4 Division of Enforcement A

Enforces medical device regulations as they relate to general surgical devices, dental; ear, nose, and throat (ENT); and ophthalmic devices; urology, gastroenterology; and obstetrics/gynecology (OB/GYN) devices; and general hospital devices.

There are four branches within this division:

1. Dental, ENT, and Ophthalmic Devices Branch;

2. General Hospital Devices Branch;

3. General Surgical Devices Branch; and,

4. OB/GYN, Gastroenterology, Urology Devices Branch.

1-5-5 Division of Enforcement B

Enforces medical device regulations as they relate to cardiovascular, radiologic, orthopedic, physical medicine, anesthesiology, and neurological devices.

There are four branches within this division:

1. Cardiac Rhythm and Electrophysiology Devices Branch;

2. Vascular and Circulatory Support Devices Branch

3. Orthopedic and Physical Medicine Devices Branch; and

4. Radiology, Anesthesiology and Neurology Devices Branch

The functional statements for the Divisions of Enforcement A and B, as they relate to each division's specialty areas, are:

1. Manages and coordinates activities associated with administrative and regulatory actions;

2. Develops, interprets, and issues policy guidance in response to specific requests from the medical device, trade associations, other federal agencies, other countries, state

agencies, and the general public; develops, reviews, and revises new and amended regulations including good manufacturing practices (GMP);

3. Plans, initiates, coordinates, and conducts medical device inspections and investigations of manufacturers and their products; and,

4. Identifies the need for and directs the development of compliance policy guides and programs to facilitate compliance by manufacturers; develops, coordinates, reviews, and revises medical device industry GMP regulations; develops and implements programs to ensure uniform interpretation and application of GMP and recommends regulatory action when appropriate.

1-5-6 Office Of Communication, Education And Radiation Programs

1. **Division Of Mammography Quality And Radiation Programs**
Enforces the Mammography Quality Standards Act and the electronic product radiation control provisions of the Federal Food, Drug, and Cosmetic Act as they relate to medical diagnostic and therapeutic and non-medical radiation-emitting electronic products.

    a. There are six branches within this division:

        i. Information Management Branch;

        ii. Accreditation and Certification Branch;

        iii. Radiation Programs Branch;

        iv. Inspection and Compliance Branch;

        v. Electronic Products Branch; and,

        vi. Diagnostic X-ray Devices Branch.

        The latter three have compliance functions.

    b. The functional statements for the Division of Mammography Quality and Radiation Programs are:

        i. Manages and coordinates activities associated with administrative and regulatory actions regarding radiation-emitting electronic products and mammography facilities;

        ii. Develops, interprets, and issues policy guidance in response to specific requests from the medical device and electronic product industries, mammography facilities, professional and trade associations, other federal agencies, other countries, state agencies, and the general public;

        iii. Develops, reviews, and revises new and amended regulations including good manufacturing practice (GMP) and performance standards for radiation-emitting electronic products and quality standards for mammography facilities;

iv. Plans, initiates, coordinates, and conducts inspections and investigations of manufacturers and certain specific users of radiation-emitting diagnostic, and therapeutic medical devices and non-medical electronic products; also includes inspections and investigations of mammography facilities;

v. Reviews and evaluates design, test, and production data and reports from manufacturers of radiation-emitting medical and non-medical diagnostic and therapeutic devices to ensure compliance with promulgated standards and regulations;

vi. Identifies the need for and directs the development of compliance policy guidance and programs to facilitate compliance by manufacturers of radiation-emitting medical and non-medical diagnostic and therapeutic devices, as well as mammography facilities;

vii. Develops, coordinates, reviews, and revises medical device industry GMP regulations as they pertain to radiation-emitting diagnostic and therapeutic devices; and,

viii. Develops and implements programs to ensure uniform interpretation and application of GMP and recommends regulatory action when appropriate.

1-5-7 Office Of In Vitro Diagnostic Device Evaluation And Safety

The Office of In Vitro Diagnostic Device Evaluation and Safety enforces medical device regulations as they relate to in vitro diagnostic devices. The functional statements for this office relating to compliance and enforcement activities involving in vitro diagnostic devices are:

1. Manages and coordinates activities associated with administrative and regulatory actions;

2. Develops, interprets, and issues policy guidance in response to specific requests from the in vitro diagnostic device industry, trade associations, other federal agencies, other countries, state agencies, and the general public; develops, reviews, and revises new and amended regulations and standards for in vitro diagnostic devices;

3. Plans, initiates, coordinates, and conducts inspections and investigations of in vitro diagnostic device manufacturers and their products; reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with regulations; and,

4. Identifies the need for and directs the development of compliance policy guides and programs to facilitate compliance by manufacturers. Develops and implements programs to ensure uniform interpretation and application of GMP and recommends regulatory action when appropriate.

1-6 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

1-6-1 Office Of Compliance (HFS-600)

1. **Office of the Director**

   a. Has primary responsibility within the Center for compliance and enforcement with respect to foods and cosmetics, including coordinating compliance and enforcement actions within the Center and with other FDA components. Oversees the development of compliance and enforcement strategies for emerging compliance challenges.

   b. Provides expert advice to the Center Director, Deputy Center Directors, and other key Agency and government officials, and serves as principal liaison to industry, international, and other organizations on issues related to compliance and enforcement and to the Interstate Travel Program (ITP).

   c. Serves as the primary contact between the Center and FDA's field organization, including the Field Food Committee.

   d. Has primary responsibility for management of compliance programs, field assignments, and work plans and maintains the center-wide compliance management and reference systems.

   e. Initiates or coordinates the planning, development, publication, and promotion of field guidance documents for CFSAN-regulated foods and cosmetics to implement sound public health practices, food safety/security interventions, compliance/enforcement strategies, and regulatory programs; provides information, training, and technical assistance to implement guidance and regulations.

   f. Reviews proposed regulatory actions and recalls for adequacy of evidence and consistency across programs and with established program priorities, policy, and guidance.

   g. Monitors information from internal and external sources to identify trends or emerging compliance and enforcement related issues that may influence the Center's area of regulatory responsibility. Provides data and other information on field accomplishments to support the Center's evaluation of programs and assignments, development of new assignments, assessment of the industry, or any other relevant Agency purpose.

   h. Oversees, monitors, and evaluates the food facility registration data base.

   i. Provides leadership, oversight, and technical assistance for the Agency's Interstate Travel Program (ITP), including developing regulations, guidance, policy, programs, position papers, and advisory opinions, and recommending research priorities for matters within the scope of the ITP.

      There are two divisions within the Office of Compliance:

      i. Division of Enforcement

      ii. Division of Field Programs and Guidance

2. **Division of Enforcement (HFS-605)**

a. Has primary responsibility for managing reviews of regulatory actions recommended by Agency field offices and for guiding field offices' activities, when necessary, in developing scientifically and legally supportable actions.

b. Reviews incoming investigational findings and recommendations to determine if a proposed enforcement action or alternative remedy is supported by the documented observations and other evidence, based on relevant statutes, regulations, policy, programs, precedents, and Agency and Center enforcement priorities; assesses the integrity and relevance of the evidence; and obtains necessary scientific verification from appropriate subject matter experts.

c. Serves as the Center's point of contact for policy and inquiries related to enforcement, including recalls, from other Agency units, industry, and other parties.

d. Provides expert compliance and enforcement guidance for CFSAN officials, other FDA components, Federal and State officials, and industry; participates in Agency discussions, decisions, and fact finding on compliance and enforcement issues related to CFSAN-regulated products and industries.

e. Works with other Center and FDA components to develop compliance and enforcement strategies to address cross-cutting regulatory issues or emerging compliance challenges. Develops innovative enforcement solutions to novel, complex, and precedent-setting regulatory problems.

f. Evaluates recall recommendations, obtains scientific and technical support to document health risks associated with recalled products, and ensures that recall actions are consistent with Agency and Center policies.

g. Assists the Office of General Counsel and field units and the Department of Justice in developing legal documents including declarations, obtaining experts, responding to interrogatories, and providing trial or other requested assistance. Represents the Center at enforcement negotiations.

There are two teams and two branches within the Division of Enforcement:

i. Recall Team

ii. Labeling Compliance Team

iii. Product Adulteration Branch

iv. Manufacturing and Storage Adulteration Branch

3. **Division of Field Programs and Guidance (HFS-615)**

a. Serves as the focal contact point within the Center for compliance programs, field assignments, and work plans; and plans and implements these activities working closely with the Agency field organization and Center offices to reflect a risk-based approach.

b. Actively manages compliance programs and field assignments and provides information, based on its monitoring and data reporting activities, to other Center offices to support Center evaluation of programs and assignments.

c. Provides Center leadership and coordination for Compliance Policy Guides and works closely with other Center offices and Agency headquarters and field offices in Compliance Policy Guide development and issuance.

d. Provides expert guidance for CFSAN officials and other Agency components, Federal and State officials, and industry concerning field programs, guidance, the context of mined data, and regulatory requirements and their implementation for the Interstate Travel Program (ITP).

e. Maintains the Center-wide compliance management and reference systems and works closely with Agency information technology offices and the field organization to provide effective compliance information management concerning foods and cosmetics. Implements and provides monitoring and evaluation of the food facility registration data base.

f. Plans and develops approaches to administer regulatory responsibilities in the Interstate Travel Program and provides information, problem-solving, and technical assistance to Agency and external organizations within this program to maintain an effective and consistent regulatory program in the interstate travel industry.

g. Reviews regulatory actions including information about proposed enforcement actions or alternative remedy to determine if ITP actions are supported by relevant science and established program priorities, policy, and guidance; determine, where policy or guidance do not exist, whether the Division can provide expert scientific testimony to defend the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

h. Monitors and mines information from internal and external sources to identify trends or emerging compliance and enforcement related issues that may influence the Center's area of regulatory responsibility and brings the information to the attention of other Center offices for consideration and action when necessary.

There are two branches within the Division of Field Programs and Guidance:

i. Field Programs Branch

ii. Compliance Information Branch

1-6-2 Office Of Cosmetics And Colors (OCAC) (HFS-100)

1. **Office of the Director**

a. Develops regulations, guidance, policy, programs, position papers, and advisory opinions, and recommends research priorities for matters within the scope of the responsibility of the Office.

b. Provides expert advice to the Center Director, Deputy Center Directors, and other key Center, agency and government officials, and serves as principal liaison to industry, international, and other organizations on cosmetic products and ingredients and color additive certification.

c. As necessary, reviews regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within OCAC's purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Office can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

d. Administers the Color Certification program including methodology research.

e. Administers the Voluntary Cosmetic Registration Program.

f. Provides leadership and works closely with other Agency units in the area of nanotechnology.

There is one staff and one division within the Office of Cosmetics and Colors:

i. Cosmetics Staff

ii. Division of Color Certification and Technology

2. **Cosmetics Staff (HFS-125)**

a. Develops regulations, guidance, policy, programs, position papers, and advisory opinions, and recommends research priorities for cosmetics and color additives.

b. Provides expert guidance for CFSAN officials and other Agency components, Federal and State officials, and industry concerning regulatory requirements and their implementation for cosmetics and color additive certification.

c. Reviews regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within OCAC's purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Office can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

d. Administers the Voluntary Cosmetic Registration Program.

e. Manages the Quality Assurance Program for the Color Certification Program.

There is one team within the Cosmetics Staff.

i. Cosmetics Activities Team

3. **Division of Color Certification and Technology (HFS-105)**

a. Develops regulations, guidance, policy, programs, position papers, and advisory opinions, and recommends research priorities for color additives.

b. Provides expert guidance for CFSAN officials and other Agency components, Federal and State officials, and industry concerning color additive methodology.

c. Reviews regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within OCAC's purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Office can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

d. Administers the Agency Color Certification Program.

e. Identifies substances and issues of safety concern for certifiable color additives and their raw materials.

There is one team and one branch within the Division of Color Certification and Technology:

i. Color Technology Team

ii. Color Certification Branch

1-6-3 Office Of Food Safety (HFS-300)

(Note: Replaces the Office of Plants and Dairy Foods and Office of Seafood both of which have been abolished.)

1. **Office of the Director**

a. Develops regulations, guidance, policy, programs, position papers, and advisory opinions, and recommends research priorities for issues related to food safety within the scope of the responsibility of the Office.

b. Conducts food safety research related to chemical or microbial contamination.

c. Administers the federal portion of the Federal/State cooperative programs.

d. Provides toxicological evaluations and quantitative risk assessments related to the presence of industrial chemicals, process-induced toxicants and toxic elements in food.

e. Provides expert advice to the Center Director, Deputy Center Directors, and other Center, Agency, and government officials, as well industry, international and other organizations on food safety programs and policies.

f. As necessary, reviews industry petitions and regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within OFS's purview are supported by relevant science and established program priorities, policy, and guidance;

determines, where policy or guidance do not exist, whether the Office can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

g. Provides expertise in acidified and low acid food technologies, including the registration and evaluation of filed processes.

There are two teams within the office of the Director, Office of Food Safety:

i. Food Processing Evaluation Team

ii. Chemical Hazard Assessment Team

There are two staffs and four divisions within the Office of Food Safety:

i. Retail Food & Cooperative Programs Coordination Staff

ii. Produce Safety Staff

iii. Division of Food Processing Science and Technology

iv. Division of Seafood Science and Technology

v. Division of Plant and Dairy Food Safety

vi. Division of Seafood Safety

2. **Retail Food & Cooperative Programs Coordination Staff (HFS-320)**

a. Supports interaction and collaboration among Federal and State partners in each of the three cooperative program areas.

b. Maintains the Interstate Certified Shellfish Shippers List and the Interstate Milk Shippers List.

c. Serves as Agency liaison with State partners in administering the federal portion of the federal/state cooperative retail food program.

d. Develops and promotes the adoption and implementation of the FDA Food Code, the National Retail Food Regulatory Program Standards, and related agency policy for sound public health practices.

e. Provides technical support and outreach to FDA staff and other Federal, State and local officials on the Food Code and other agency guidance on retail food protection.

3. **Produce Safety Staff (HFS-317)**

a. Develops, collects and interprets data regarding the microbial safety and defense of fresh and fresh-cut produce.

b. Develops policy, regulations, regulatory guidelines, advisory opinions, position papers, and compliance strategies and policy on the microbial safety of fresh and fresh-cut produce.

c. Reviews petitions on the microbial safety of fresh and fresh-cut produce related to this office.

d. Serves as the agency focal point for the development and evaluation of programs and the implementation of the laws and regulations related to this office regarding microbial safety of fresh and fresh-cut produce.

e. Serves as the principal Agency liaison on microbial fresh and fresh-cut produce safety programs and policies with industry, Federal, State, and foreign governments, and other organizations outside the Agency.

f. Provides expert program policy, scientific and technical advice, and assistance to the Center Director, other key officials, and the field on microbial fresh and fresh-cut produce safety and defense issues, field programs, initiatives, the conduct of international activities, including the development and implementation of bilateral agreements, and other related activities.

g. Reviews proposed regulatory actions referred by the Office of Compliance for program policy consideration and provides technical evaluation and necessary scientific support on cases related to the microbial safety of fresh and fresh-cut produce.

4. **Division of Food Processing Science and Technology (HFS-450)**

a. Conducts food safety, nutrition and defense research in food processing, food packaging and food technology; as it relates to food production and handling principles.

b. Participates, in conjunction with the Office of Food Defense, Communication and Emergency Response (OFDCER) and others, in educational and information programs on contemporary food safety and security issues.

c. Evaluates and accredits Grade “A” Milk laboratories and certifies state laboratory evaluation officers.

d. Conducts proficiency testing program for milk, shellfish, Food Emergency Response Network/Laboratory Response Network (FERN/LRN), and other food laboratories.

e. Provides consultation to FDA, and outside organizations on laboratory equipment, apparatus, methods, and facilities problems associated with laboratory examination of foods.

There are two branches and one team within the Division of Food Processing Science and Technology:

i. Process Engineering Branch

ii. Food Technology Branch

iii. Laboratory Proficiency and Evaluation Team

5. **Division of Seafood Science & Technology (HFS-400)**

The Division of Seafood Science & Technology, in conjunction with federal, state, academic, and public partners is responsible for providing the scientific basis for Agency policy, regulation and compliance programs which promote and protect the public's health by ensuring that the nation's seafood supply is safe, sanitary and secure.

The functional statements for the Division of Seafood Science and Technology are:

a. Identifies and characterizes existing, emerging and potential health hazards in seafood

b. Determines exposure thresholds, consumer health effects, and recommends guidance levels for health hazards in seafood

c. Develops, optimizes and validates surveillance/monitoring methods for detection of health hazards in seafood.

d. Promotes surveillance/monitoring method standardization and trains federal and state public health personnel in their applications and use

e. Evaluates strategies and technologies for mitigation of health hazards in seafood.

f. Provides scientific information and technical support for Center components and other federal, state and international public health agencies.

g. Responds to regional, national, and international seafood disease outbreaks and emergency/threat situations.

h. Maintains scientific capability and currency with emerging technologies and the scientific community at-large.

There are two branches within the Division of Seafood Science and Technology:

i. Chemical Hazards Science Branch

ii. Microbiological Hazards Science Branch

6. **Division of Plant and Dairy Food Safety (HFS-315)**

a. Develops regulations, guidance, policy, programs, position papers, and advisory opinions, and recommends research priorities for issues related to the safety, defense, composition, and quality of plantfoods, dairy foods, eggs, game meats, and beverages.

b. Provides expert advice to the Center Director, Deputy Center Directors, and other Center, FDA, and government officials, and serves as principal liaison to

industry, international and other organizations on issues related to plant foods, dairy foods, eggs, game meats, and beverages.

c. As necessary, reviews industry petitions and regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within the Division's purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Division can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

d. Reviews and accepts or rejects the sanitary design and construction standards for milk equipment.

e. Standardizes, certifies, and evaluates FDA, State staff, and others relevant to standardizing and certifying the evaluation of state and international milk programs.

f. Collaborates with other parts of the Agency to identify emerging needs, and to plan, develop, and coordinate compliance programs, field assignments, and work plans, as related to food safety.

There are two branches within the Division of Plant and Dairy Food Safety:

i. Dairy and Egg Branch

ii. Plant Products Branch

7. **Division of Seafood Safety (HFS-325)**

a. Develops regulations, guidance, policy, programs, position papers and advisory opinions, and recommends research priorities for issues related to the safety of seafood.

b. Examines and appraises the implementation of seafood regulations, domestic and foreign programs, and bilateral agreements.

c. As necessary, reviews industry petitions and regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within the Division's purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Division can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

d. Provides expert advice to the Center Director, Deputy Center Directors, and other key Agency and government officials, and serves as principal liaison to industry, international and other organizations on issues related to seafood safety.

e. Develops model regulations, and provides scientific/technical support, training, evaluation and certification for State and international shellfish programs.

There are two branches within the Division of Seafood Safety:

i. Shellfish and Aquaculture Policy Branch

ii. Seafood Processing and Technology Policy Branch

1-6-4 Office Of Nutritional, Labeling and Dietary Supplements (HFS-800)

1. **Office of the Director**

a. Has primary responsibility for policy development and management of food and nutrition labeling, dietary supplements, special nutritionals (including infant formula and medical foods) and, in conjunction with the Office of Food Defense, Communication and Emergency Response (OFDCER), associated educational initiatives.

b. Develops regulations, guidance, policy, programs, position papers, and advisory opinions, and recommends research priorities for matters within the scope of the responsibility of the Office.

c. Provides expert advice to the Center Director, Deputy Center Directors, and other key Agency and government officials on food and nutrition labeling, dietary supplements, and special nutritionals and serves as liaison for major Agency and Department nutrition and labeling initiatives.

d. As necessary, reviews regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within ONLDS' purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Office can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

There are three staffs and one division within the Office of Nutritional Labeling and Dietary Supplements.

i. Food Labeling and Standards Staff

ii. Nutrition Programs Staff

iii. Infant Formula and Medical Foods Staff

iv. Division of Dietary Supplement Programs

2. **Food Labeling and Standards Staff (HFS-820)**

a. Has primary responsibility for policy and regulatory development and management of the food labeling program (other than nutrition labeling).

b. Conducts scientific and technical review of and responds to petitions and notifications related to all aspects of food labeling.

c. Provides expert guidance for CFSAN officials and other Agency components, Federal and State officials, and industry concerning regulatory requirements and their implementation for food labeling including infant formula, medical foods and nutrition-related labeling.

d. Provides expert technical advice for participation in international forums.

e. Reviews food product labeling (including infant formula, medical foods, and nutrition labels) for adherence to regulations and appropriateness of claims and manages the Small Business Nutrition Labeling Exemption Notification Program.

There are two teams within the Food Labeling and Standards Staff:

i. Product Evaluation and Labeling Team

ii. Labeling Regulations Implementation Team

3. **Nutrition Programs Staff (HFS-830)**

a. Manages and conducts scientific review and analysis of issues related to nutrition and nutrition labeling, and dietary guidance recommendations, and related nutrition science issues and provides expert advice and assistance on these issues to key CFSAN and Agency components as well as international bodies.

b. Conducts scientific and regulatory review of health claim petitions, qualified health claim petitions, nutrient content claim petitions, and FDA Modernization Act notifications for health claims and nutrient content claims.

c. Identifies program priorities for, provides content design input to, and analysis of large-scale databases of food consumption, food composition, food ingredients, sales of processed packaged food products, and product label information. Develops methods for monitoring US populations and special subgroups relative to use and safety of conventional foods and dietary supplements.

There are two teams within the Nutrition Programs Staff:

i. Nutrition Assessment and Evaluation Team

ii. Nutrition Science Review Team

4. **Infant Formula and Medical Foods Staff (HFS-850)**

a. Manages and conducts scientific review and analysis of issues related to infant formula and medical foods including petitions and notifications, and provides expert advice and assistance on these issues to key CFSAN and Agency components as well as international bodies.

b. Provides clinical and scientific expertise on the design and conduct of clinical trials, risk assessment, adverse event reports, and educational initiatives related to infant formula and medical foods.

5. **Division of Dietary Supplement Programs (HFS-810)**

a. Has primary responsibility for the development of regulations, guidance, policy, programs, position papers and advisory opinions, and recommends research priorities for the management of the dietary supplement program, which includes safety assessments for the New Dietary Ingredient Notification Program, structure-function notifications, Certificates of Export, technical consultation on dietary supplement cGMP inspections, safety assessments for dietary supplement policy, responses to petitions and industry-related notifications, post-market adverse event evaluations, and issues related to dietary supplement safety and nutrition.

b. As necessary, reviews regulatory actions, including information about proposed enforcement actions that is provided by the Office of Compliance, to determine if those actions within the Division's purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance do not exist, whether the Office can provide expert scientific testimony to support the actions; and provides technical review of laboratory analyses supporting proposed enforcement actions.

c. Evaluates adverse event reports and other sources of signals related to the safety of dietary supplements.

d. Provides clinical/scientific expertise in the evaluation of safety information provided in New Dietary Ingredient Notifications, and provides responses to citizen petitions.

There are two teams and one staff within the Division of Dietary Supplement Programs:

i. Clinical Evaluation Team

ii. Dietary Supplement Regulations Implementation Team

iii. NDI Review Staff

1-6-5 Office of Regulatory Science (HFS-700)

(Note: This contains some functions from the Office of Plant and Dairy Foods which has been abolished).

1. **Office of the Director**

a. ORS, in coordination with the Office of Applied Research and Safety Assessment (OARSA), establishes (with input from other Center components), manages, and conducts a cohesive, CFSAN mission-relevant research program to provide the science for the Center's regulatory, policy, and compliance and enforcement programs. ORS' research focuses on: 1) regulatory methods

development and validation – i.e., the recovery, detection, identification and quantification of microbial pathogens and chemical contaminants from foods, including dietary supplements, and for nutrition labeling requirements; 2) the transfer of the technology to appropriate testing laboratories; and 3) the toxicology of cosmetic ingredients and contaminants and of dietary supplement contaminants.

b. In conjunction with OARSA, serves as one of the Center's research liaisons with other FDA Centers and other organizations outside the Agency. In conjunction with other Center Offices, initiates and coordinates collaborative studies with Center stakeholders and coordinates development of collaborative research planning with other Center, Agency, academic, and research components to achieve food safety and food defense.

c. In conjunction with OARSA, provides expert scientific direction, guidance, and support to the Center's regulatory and compliance programs and enforcement actions, and provides expertise in both food safety and food defense to ensure the safety of the U.S. food supply and the establishment of sound counterterrorism measures.

d. Originates, plans, and conducts research in the areas of food processing and packaging, food chemistry, food toxicants, food microbiology and cosmetics.

e. Reviews regulatory actions for adequacy of analytical and related evidence and accuracy of the science and technical procedures and findings.

f. In coordination with OARSA, recommends and develops the Center's research program goals and priorities on food safety threat agents, safety and health hazards to foods, dietary supplements, chemical contaminants, natural toxicants and metabolites, and conducts related research.

There are three divisions within the Office of Regulatory Science:

i. Division of Analytical Chemistry

ii. Division of Bioanalytical Chemistry

iii. Division of Microbiology

2. **Division of Analytical Chemistry (HFS-705)**

a. Performs laboratory analysis of samples and provides technical support and expert advice in cooperation with other Center and Agency components to support research and policy development and to assess sample compliance with laws and regulations enforced by the Agency.

b. Reviews regulatory actions for adequacy of analytical evidence in support of Agency compliance programs.

c. Develops, extends, refines, and validates analytical chemistry based methods for food defense threat agents, food additives, pesticides, dietary supplements, seafood toxins, and industrial chemicals that may be present in or contaminate

CFSAN-regulated food and cosmetic products; recommends analytical methods for field use in monitoring and enforcement programs for these chemicals.

d. Provides specialized infrared, nuclear magnetic resonance and electron spin resonance spectroscopy, and mass spectrometry support to Center and the Agency and conducts research to develop and refine the application of specialized instrumentation to Center and Agency problems.

e. Originates, plans and documents research to ascertain the nature and magnitude of chemical contamination of CFSAN-regulated food and cosmetic products via environmental and other routes for risk assessment and policy development purposes.

f. Develops analytical testing protocols for evaluating the migration of food packaging components to foods or food simulants in order to facilitate submission and safety evaluation of indirect food additive petitions and notifications.

g. Supports food defense measures through special research projects and scientific support during threat situations.

There are two branches within the Division of Analytical Chemistry:

i. Methods Development Branch

ii. Spectroscopy and Mass Spectrometry Branch

3. **Division of Bioanalytical Chemistry (HFS-715)**

a. Conducts laboratory investigations in the broad areas of elemental analysis, natural toxins, nutrients in food, ingredients in dietary supplements, and ingredients in cosmetics.

b. Develops analytical methods and provides technical support of regulations and related policy developments in areas of Division expertise.

c. As necessary, reviews regulatory actions for adequacy of analytical evidence in support of CFSAN and Agency compliance programs.

d. Serves as the focal point for expertise in the development and dissemination of methods of analysis for elements and radionuclides in foods, including dietary supplements.

e. Identifies substances and issues of safety concern for cosmetic products and their raw materials and contaminants; and develops and evaluates methods to identify and quantify potentially harmful ingredients and contaminants.

f. Provides expert scientific and technical advice and assistance to the Center Director, Deputy Center Directors and other Center components, as well as and other FDA officials on the conduct of international seafood activities, including the development and implementation of bilateral agreements; and develops

technical content for and participates in programs designed to improve compliance by industry through problem prevention.

g. Originates, plans, and conducts laboratory research related to the scope of responsibilities of the Office. Develops appropriate methods for analysis of nutrients in food and ingredients in dietary supplements; reviews and evaluates chemistry information and data provided in New Dietary Ingredient Notifications and Infant Formula Notifications; maintains the Center's analytical capability for food labeling compliance.

There are two branches within the Division of Bioanalytical Chemistry

i. Chemical Contaminants Branch

ii. Bioanalytical Methods Branch

4. **Division of Microbiology (HFS-710)**

a. Develops, optimizes and validates methods for recovery, detection, identification, and quantitation of pathogens and/or toxins from foods and cosmetics, and the processing environment.

b. Provides technical support of regulations and related policy developments in areas of Division expertise.

c. As necessary, reviews regulatory actions for adequacy of analytical evidence in support of CFSAN and Agency compliance programs.

d. Accomplishes the standardization and general acceptance of FDA-developed methodology by field personnel in their use and application, and supports compliance where questions of microbial methodology arise.

e. Maintains FDA's food-related gateway to the PulseNet System. Develops and applies subtyping methods to further enhance data generated for PulseNet, strain identification, and molecular epidemiological investigations.

f. Supports food security measures through special research projects and scientific support during threat situations.

There are two branches within the Division of Microbiology.

i. Microbial Methods Development Branch

ii. Molecular Methods and Subtyping Branch

1-7 CENTER FOR VETERINARY MEDICINE (CVM)

1-7-1 Office of Surveillance and Compliance (HFV-200)

The functional statements for the Office of Surveillance and Compliance are:

1. Advises the center director on surveillance and compliance policy concerning FDA regulatory responsibility with respect to animal drugs, feeds, food additives, veterinary medical devices, and other veterinary medical products;

2. Develops and evaluates surveillance and monitoring programs to ensure the safety and effectiveness of animal drugs and animal feeds;

3. Plans, develops, monitors, and evaluates center surveillance and compliance programs and coordinates their field implementation to ensure the safety and effectiveness of marketed animal drugs, feeds, food additives, veterinary medical devices, and other veterinary medical products;

4. Directs and coordinates the development of scientific evidence supporting formal evidentiary hearings requested by the center;

5. Recommends to the center director the amendment or withdrawal of approved new animal drug applications;

6. Develops, coordinates, and directs the center's bioresearch monitoring program to ensure reliability of information on which to base new animal drug application and food additive petition; and,

7. Provides scientific and regulatory expertise to the center as needed.

The four divisions in this office are:

1. Division of Surveillance;

2. Division of Animal Feeds;

3. Division of Compliance, and

4. Division of Veterinary Product Safety.

Note: The Division of Epidemiology (HFV-250) no longer exists. Its functions have been distributed throughout CVM. For information contact: 240-453-6830.

1-7-2 Division Of Surveillance (HFV-210)

The functional statements for the Division of Surveillance are:

1. Evaluates the safety and effectiveness of marketed animal drugs, special dietary feeds, veterinary medical devices, and other veterinary medical products and recommends action to correct deficiencies resulting from inadequate directions for use, warnings, and cautionary information;

2. Evaluates drug product labels and other information to determine new animal drug status, regulatory priority, acceptable conditions of use, and need for regulatory activity; maintains and makes available inventory listing of all marketed animal drugs to ensure adequate information is available for regulatory activity and customer support; coordinates with field to develop enforcement activity, obtains expert witnesses and performs other scientific and regulatory case development activities;

3. Reviews marketed product labeling and makes recommendations concerning label revisions, regulatory supplements, suspension of manufacturing, and withdrawal of approval of new animal drugs to ensure marketed products are safe and effective;

4. Monitors and evaluates promotion of marketed veterinary drugs to ensure promoted claims are consistent with approved claims;

5. Manages compliance programs covering regulated industries in animal drugs, veterinary medical devices, and other veterinary medical products to ensure the effectiveness of the programs. Reviews establishment inspection reports, labeling, and other findings to determine whether regulated products are being marketed in accordance with the act and agency regulations and policy.

6. Evaluates the safety and effectiveness of marketed unapproved animal drugs, special dietary feeds, veterinary medical devices, and other veterinary medical products to establish medical risk as related to animal and public health. Coordinates with the Division of Compliance and other CVM Divisions to determine enforcement priorities and risk mitigation strategies.

There are three teams in this division:

1 Marketed Product Information Team;

2. Post-Approval Review Team; and

3. Unapproved Drugs and Hazard Review Team.

1-7-3 Division Of Animal Feeds (HFV-220)

The functional statements for the Division of Animal Feeds are:

1. Evaluates food additive petitions, generally recognized as safe notifications and investigational food additive applications for adequacy of : (1) data on animal safety, utility, and stability; (2) labeling; and; (3) manufacturing facilities and controls; coordinates the review of the human food safety and environmental impact information; recommends approval of food additives to the center director;

2. Evaluates the safety of complete feeds, feed supplements, and feed ingredients for animals, including pets, and provides risk assessments on hazardous contaminants in animal feeds;

3. Evaluates safety data, manufacturing and use information, and labeling for complete animal feeds and for non-drug substances added to animal feeds to determine their legal status;

4. Provides technical and scientific evaluations of new feed ingredients defined in the Official Publication of the Association of American Feed Control Officials (AAFCO), coordinates feed regulatory activities with state feed control offices, and participates in the activities of AAFCO committees and task forces and the AAFCO Board of Directors;

5. Coordinates scientific reviews and develops policy recommendations for animal feed issues (e.g., contaminants, biotech plants, unapproved feed ingredients);

6. Evaluates Biotech Plant Notifications for adequacy of the composition and animal safety data; collaborates on Note to Files with the Center for Food Safety and Applied Nutrition (CFSAN), and recommends sign-off by the OSC Director on letters to the firms concluding FDA consultations relating to feed issues; develops policy recommendations on feed issues involving biotech plants, and participates in developing policy recommendations on general issues involving biotech plants with CFSAN, other centers and offices in FDA, and other federal agencies;

7. Approves feed mill licenses after being assured that the licensee can manufacture and label medicated feed in compliance with agency regulations;

8. Maintains inventory of distributors of veterinary feed directives drugs;

9. Ensures that licensed facilities comply with the medicated feed license regulations by implementing and evaluating the results of an inspectional compliance program for these facilities;

10. Provides consulting reviews to ONADE for medicated feed labels, including medicated pet food labels;

11. Develops, monitors and evaluates CVM compliance programs or field assignments for medicated feeds, Type A medicated articles, and feed contaminants (e.g., BSE, microbial pathogens, mycotoxins, pesticides, heavy metals, industrial chemicals); reports the findings from the programs to the states, FDA field, and other interested parties;

12. Provides scientific support for regulatory actions for animal feeds and medicated animal feeds; and,

13. Recommends and may participate in intramural and extramural research projects conducted or coordinated by the Office of Research to gain further information on contaminants, drugs, and food additives.

There are four teams within this division:

1. Animal Feed Safety Team;

2. Ingredient Safety Team;

3. Medicated Feeds Team; and,

4. Nutrition and Labeling Team.

1-7-4 Division Of Compliance (HFV-230)

The functional statements for the Division of Compliance are:

1. Coordinates the preparation of evidence concerning withdrawal/refusal to approve animal drugs and the documentation for a formal evidentiary hearing; coordinates the preparation of administrative and evidentiary records for a hearing;

2. Develops, monitors, and evaluates the center's bioresearch monitoring programs and their investigative and regulatory follow-up; manages the application integrity policy;

3. Develops, monitors, and evaluates the center's compliance and surveillance programs pertaining to tissue residues and national drug residue milk monitoring;

4. Monitors and handles many emerging issues involving food, drugs, and zoonotic diseases that require immediate CVM response and coordination.

5. Evaluates regulatory approaches to human food safety concerns including monitoring the prevalence of violative levels of harmful drugs and chemicals in meat and poultry based on findings reported to FDA/CVM by USDA/FSIS and developing strategies designed to prevent food safety problems associated with pathogens and residues;

6. Coordinates and prepares compliance and enforcement oriented replies to inquiries from consumers, state and federal governments, Congress, industry, etc.;

7. Advises on regulatory and administrative policy issues and develops enforcement strategies involving animal drugs, feeds, feed additives, veterinary medical devices, and other veterinary medical products; prepares and issues guidance to the field offices; and,

8. Preliminarily reviews establishment inspection reports, investigations, complaints and other information on regulated products; coordinates investigative and regulatory follow-up through consultation with management, legal and scientific advisors; reviews proposed regulatory actions submitted by the field offices and recommends whether such actions should be pursued further by the agency.

There are five teams within this division:

1. Complaint/Emergency/Recall Team;

2. Post-Market Compliance Team;

3. Drug Residue Compliance Team;

4. Pre-Market Compliance and Administrative Actions Team; and

5. Programs and Operations Support Team.

1-7-5 Division of Veterinary Product Safety (HFV-240)

The functional statements for the Division of Veterinary Product Safety are:

1. Monitors adverse drug event database to identify safety signals and effectiveness issues of concern;

2. Evaluates adverse event reports to ensure labeling contains a current accurate safety profile, identifies unsafe products, and unsafe product uses;

3. Maintains liaison with other agencies and organizations engaged in similar activities to identify product interactions and coordinate activities;

4. Provides surveillance for adverse events involving consumption of pet food. Performs scientific and epidemiologic assessment of data as part of the pet food early warning system to assist the Division of Compliance in recognizing potential safety issues and establishing the need for product recalls;

5. Coordinates with FDA District Offices to receive and evaluate product defect reports for the identification of product safety issues. Interacts with other FDA centers to ensure appropriate investigatory and risk mitigation measures are taken by the Agency. Analyzes data and relevant information to assess the need for product recall(s);

6. Provides pre-market and post-market surveillance of drug product medication errors to CVM review Divisions; and,

7. Participates in outreach programs to encourage veterinarians to participate in the pharmacovigilance program and to educate veterinarians, animal owners, and the public regarding the medical risks and benefits of veterinary products.

There are three teams in this division:

1. Adverse Drug Event Review Team

2. Adverse Event Review Team; and,

3. Data Management and Analysis Team.

1-8 CENTER FOR TOBACCO PRODUCTS (CTP)

1-8-1 Office of Compliance and Enforcement

There are currently three groups:

1. Enforcement and Manufacturing

2. Promotion, Advertising and Labeling

3. State Programs

1-9 ENFORCEMENT POLICY DIRECTORY

The most current version of this directory is available on FDA's Intranet website.

1-9-1 Office of Regulatory Affairs - Headquarters

1. Associate Commissioner for Regulatory Affairs (ACRA)

   ACRA 301-796-8800

   i. Deputy for Field Operations..... 301-796-8800

   ii. Deputy for Compliance Policy..... 301-796-8810

2. Office of Enforcement (OE)

   a. Director, OE..... 301-796-8314
   Compliance Policy Council
   Internet Regulatory Policy and Enforcement

      i. Director of Compliance, OE..... 301-796-8314

      ii. Director, Division of Compliance Management and Operations …… 301-796-8200

      iii. Director, Division of Compliance Policy..... 301-796-3820

      iv. Director, Division of Compliance Information and Quality Assurance…… 301-796-5300

   b. Division of Compliance Management and Operations 301-796-8200
   Case Review and Management
   Civil Money Penalties (Compliance)
   Inspection Warrants
   Recalls
   Team Biologics (Compliance)
   Warning Letter Database

   c. Division of Compliance Policy……. 301-796-3820
   Bioresearch Misconduct and Monitoring
   Good Guidance Practices (GGPs)
   Good Laboratory Practices (GLPs)/Non-Clinical
   Information Disclosure (including FOI)
   Policy (Biologics, Civil Money Penalties, Cosmetics, Drugs, Foods, Medical Devices, Veterinary Medicine, and Radiation Emitting Electronic Products)
   Publications (Compliance Policy Guides Manual, Enforcement Notes, Information Disclosure Manual, Regulatory Procedures Manual), Testimony

   d. Division of Compliance Information and Quality Assurance……..... 301-796-5300
   Electronic Regulatory Information Assurance
   FACTS Firm Profiles (COMSTAT)

Government-Wide Quality Assurance Program (GWQAP)
Compliance Management System
Turbo EIR

Health Communications

3. Office of Regional Operations (ORO)

   a. Director, ORO..... 301-796-5753

   b. Director, Division of Domestic Field Investigations..... 301-796-5403

   c. Director, Division of Foreign Field Investigations..... 301-796-5521

   d. Director, Division of Field Science 301-796-5955

   e. Director, Division of Federal/State Relations..... 301-796-5810

   f. Director, Division of Import Operations & Policy..... 301-796-0356

      i. ...Director, Operations & Policy Branch. 301-796-6677

      ii. Director, Systems Branch……..... 301-796-8997
      (As of October 18, 2002 Emergency Operations has been organized structurally as Office of Emergency Operations, Office of Crisis Management, Office of the Commissioner)

4. Office of Resource Management (ORM)

   a. Director, ORM…… 301-796-4300

   b. Deputy Director, ORM..... 301-796-4300

5. Office of Criminal Investigations (OCI)

   a. Acting Director, OCI..... 240-276-9441

1-9-2 Office of Regional Affairs - Field

1. Northeast Region

   a. Regional Food and Drug Director, HFR-NE1..... ... 781-587-7533
   FAX..... ... 781-587-7556
   Deputy Regional Food and Drug Director, HFR-NE2..... 718-662-5610
   FAX..... 718-662-5434

   b. New York District Office……..718-340-7000

      i. District Director, HFR-100..... 718-662-5447
      FAX..... .. 781-662-5665

- Director Compliance Branch
  HFR-NE340.....716-551-4461 Ext 3116
  FAX.....716-551-4499

c. New England District Office..... 781-587-7500

i. District Director, HFR-NE200..... 781-587-7490
FAX..... 781-587-7556

- Director Compliance Branch, HFR-NE240..... .. 781-587-7488
  FAX..... .. 781-587-7556

d. Winchester Engineering & Analytical Center…….. 781-756-9700

i. Director, HFR-NE400..... 781-756-9701
FAX..... 781-756-9757

e. Northeast Regional Laboratory

i. Director, HFR-NE500..... 718-662-5450
FAX..... 718-662-5439

2. Central Region

a. Regional Food and Drug Director, CHI-FO, HFR-CE1..... 312-596-6501
FAX..... 312-886-1682

b. Deputy Regional Food and Drug Director, PHI-FO
HFR-CE2..... .. 215-717-3701
FAX..... 215-597-5798

c. Baltimore District Office

i. District Director, HFR-CE200..... .. 410-779-5424

- Director Compliance Branch, HFR-CE240..... 410-779-5417
  FAX..... .. 410-779-5707

d. Chicago District Office

i. District Director, HFR-CE600..... .. 312-596-4200

- Director Compliance Branch, HFR-CE640..... .. 312-596-4220
  FAX..... .. 312-596-4187

e. Cincinnati District Office

i. District Director, HFR-CE400.....513-679-2700 Ext 116

- Director Compliance Branch HFR-CE440.....513-679-2700 Ext 160
  FAX..... 513-679-2775

f. Detroit District Office

i. District Director, HFR-CE700..... 313-393-8106

- Director Compliance Branch, HFR-CE740..... 313-393-8110
  FAX.....313-393-8139

g. Forensic Chemistry Center

i. Director, HFR-CE500..... 513-679-2700 Ext 180
FAX..... 513-679-2761

h. Minneapolis District Office

i. District Director, HFR-CE800..... 612-334-4100

- Director Compliance Branch, HFR-CE840..... .. 612-758-7112
  FAX.....612-334-4134

i. New Jersey District Office

i. District Director, HFR-CE300..... 973-331-4901

- Director Compliance Branch, HFR-CE340..... .. 973-331-4902
  FAX.....973-331-4969

j. Philadelphia District Office

i. District Director, HFR-CE100..... .. 215-717-3001

- Director Compliance Branch, HFR-CE140..... 215-717-3071
  FAX..... .. 215-597-8212

3. Southeast Region

a. Regional Food and Drug Director, HFR-SE1..... 404-253-1171
FAX..... 404-253-1207

b. Atlanta District Office

i. District Director, HFR-SE100.....404-253-1161

- Director Compliance Branch, HFR-SE140.....404-253-1163
  FAX..... .. 404-253-1201

c. Florida District Office

i. District Director, HFR-SE200..... 407-475-4701

- Director Compliance Branch, HFR-SE240..... 407-475-4734
  FAX.....407-475-4769

d. New Orleans District Office

i. District Director, HFR-SE400..... .. 615-366-7803

- Director Compliance Branch, HFR-SE440.....504-219-8818 Ext 101
  FAX.....504-219-8813

e. San Juan District Office

i. District Director, HFR-SE500..... 787-474-9565

- Director Compliance Branch, HFR-SE540..... 787-474-9565
  FAX.....787-729-6658

f. Southeast Regional Laboratory

i. Director, HFR-SE600..... 404-253-1176
FAX..... 404-253-1208

4. Southwest Region

a. Regional Food and Drug Director, HFR-SW1..... 214-253-4904
FAX..... 214-253-4965

b. Arkansas Regional Laboratory

i. Director, HFR-SW500 870-543-4099
FAX..... 870-543-4002

c. Dallas District Office

i. District Director, HFR-SW100..... 214-253-5201

ii. Director Compliance Branch, HFR-SW140..... 214-253-5215
FAX..... 214-253-5314

d. Denver District Office

i. District Director, HFR-SW200..... 303-236-3016

ii. Director Compliance Branch, HFR-SW240..... 303-236-3019
FAX..... 303-236-3551

e. Kansas City District Office

i. District Director, HFR-SW300..... 913-752-2144

ii. Director Compliance Branch, HFR-SW340..... 913-752-2101
FAX..... 913-752-2111

f. Southwest Import District Office

i. Director, HFR-SW600..... 214-253-5283

ii. Director Compliance Branch, HFR-SW640..... 214-253-5284
FAX..... 214-253-5316

5. Pacific Region

a. Regional Food and Drug Director, HFR-PA1.....510-637-3960 Ext 118
FAX..... 510-637-3976

b. Los Angeles District Office

i. District Director, HFR-PA200..... 949-608-4414

ii. Director Compliance Branch, HFR-PA240..... 949-608-4426
FAX..... 949-608-4415

c. San Francisco District Office

i. District Director, HFR-PA100..... 510-337-6783

ii. Director Compliance Branch, HFR-PA140..... 510-337-6769
FAX..... 510-337-6703

d. Seattle District Office

i. District Director, HFR-PA300..... 425-483-4950

FAX..... 425-483-4989

Director Compliance Branch, HFR-PA340..... 425-483-4912
FAX..... 425-483-4760

e. Pacific Regional Laboratory Northwest

i. Director, HFR-PA360..... 425-486-8788
FAX..... 425-483-4996

f. Pacific Regional Laboratory Southwest

i. Director, HFR-PA260..... 949-608-2907
FAX..... 949-608-3567

1-9-3 FDA Centers

1. Center For Biologics Evaluation And Research (CBER)

a. Director, Office of Compliance and Biologics Quality,
HFM-600…….. 301-827-6190

b. Deputy Director, Office of Compliance and Biologics Quality,
HFM-600 301-827-6190

i. Director, Division of Case Management, HFM-610..... 301-827-6201

ii. Director, Division of Inspections and Surveillance,
HFM-650 301-827-6220

iii. Director, Division of Manufacturing and
Product Quality, HFM-670 301-827-3031

iv. .Director, Division of Product Quality, HFM-680 301-594-0847

2. Center For Drug Evaluation And Research (CDER)

a. Director, Office of Compliance,..... 301-796-3100

i. Associate Director of Scientific & Medical Affairs..... 301-796-3100

ii. Deputy Director, Office of Compliance..... 301-796-3100

iii. Assistant Director..... 301-796-3100

iv. Director, Division of New Drugs and Labeling Compliance..... 301-796-3110

- Deputy Director..... 301-796-3110
- Associate Director..... 301-796-3110
- OTC Drugs Team..... 301-796-3110
- Internet and Health Fraud Team..... 301-796-3110
- Compounding Team..... 301-796-3110
- New Drugs and Labeling Team..... 301-796-3110
- Imports and Exports Team..... 301-796-3110

v. Director, Division of Manufacturing and Product Quality..... 301-796-3120

- Deputy Director..... 301-796-3120
- Recalls and Shortages Branch 301-796-3120
- Manufacturing Assessment & Pre-Approval Compliance Branch..... 301-796-3120
- New & Generic Drug Manufacturing Team, ... 301-796-3120
- International Compliance Team..... 301-796-3120
- Biotech Manufacturing Team..... 301-796-3120
- Domestic Case Management & Guidance Branch... 301-796-3120
- Domestic Case Management Team..... 301-796-3120
- International Compliance Branch..... 301-796-3120
- Guidance and Policy Development Team 301-796-3120

vi. Director, Division of Compliance Risk Management & Surveillance..... 301-796-3130

- Deputy Director..... 301-796-3130
- Risk Management and Strategic Problem Solving Team, ... 301-796-3130
- Surveillance and Data Analysis Branch, ... 301-796-3130
- Surveillance Programs Team..... 301-796-3130
- Data Analysis & Information Management Team, ... 301-796-3130
- Drug Registration & Listing Team..... 301-796-3130

vii. Director, Division of Scientific Investigations..... 301-796-3150

- Deputy Director..... 301-796-3150
- Good Clinical Practice Branch 1..... 301-796-3150
- Good Clinical Practice Branch 2..... 301-796-3150
- Human Subjects Protections Team 301-796-3150
- Good Laboratory Practices Bioequivalence Branch..... 301-796-3150
- .. Informatics and Infrastructure Team..... 301-796-3150
- .. International Policy Team 301-796-3150
- .. Enforcement Policy Team 301-796-3150

3. Center For Devices And Radiological Health (CDRH)

a. Director, Office of Compliance, WO66, 3521..... 301-796-5500

i. Deputy Director for Regulatory Affairs, Office of Compliance..... 301-796-5500

ii. Deputy Director for Medical Affairs, Office of Compliance..... 301-796-5800

iii. Director, Division of Risk Management Operations WO66, 3521..... 301-796-5530

iv. Deputy Director, Division of Risk Management Operations..... 301-796-5530

- Chief, Recall Branch..... 301-796-5792
- ... Chief, Field Operations Branch..... 301-796-5812
- Chief, Regulatory Policy and Systems Branch, ... 301-796-5615

v. Director, Division of Bioresearch Monitoring, WO66, 3446..... 301-796-5490

- Chief, Program Enforcement Branch A, ... 301-796-5654
- .. Chief, Program Enforcement Branch B 301-796-6054
- Chief, Special Investigations Branch, ... 301-796-6561

vi. Director, Division of Enforcement A, WO66, 3512 301-796-5770

- Deputy Director, Division of Enforcement A, ... 301-796-5770
- Lead CSO..... 301-796-5770
- Chief, General Surgical Devices Branch, ... 301-796-5462
- Chief, Dental, ENT and Ophthalmic Devices Branch, ... 301-796-5770
- .. Chief, OB/GYN, Gastroenterology and Urology Devices Branch..... 301-796-5484
- Chief, General Hospital Devices Branch, ... 301-796-5770

vii. Director, Division of Enforcement B, WO66, 3656..... 301-796-5540

- Deputy Director, Division of Enforcement B, ... 301-796-5540
- Lead CSO..... 301-796-5593
- Software Expert..... 301-796-5543
- Chief, Cardiac Rhythm and Electrophysiology Devices Branch..... 301-796-5540
- Chief, Vascular and Circulatory Support Devices Branch 301-796-5540
- Chief, Orthopedic and Physical Medicine Devices Branch

..... 301-796-5588

- Radiology, Anesthesiology, and Neurology Devices Branch..... 301-796-5540

b. Director, Office of In Vitro Diagnostic Device Evaluation and Safety, WO66, 5680..... 301-796-5453

i. Deputy Director, Patient Safety and Product Quality, ... 301-796-6225

ii. Deputy Director, New Product Evaluation 301-796-5454

c. Director, Office of Communication, Education and Radiation Programs, WO66 4312..... 301-796-5716

i. Director, Division of Mammography Quality and Radiation Programs, WO66 4680..... 301-796-5713

- Chief, Electronic Products Branch..... 301-796-5863
- Chief, Diagnostic X-Ray Devices Branch..... 301-796-5895
- Chief, Inspection and Compliance Branch..... 301-796-5911

4. Center For Food Safety And Applied Nutrition (CFSAN)

a. Director, Office of Compliance (OC), HFS-600 240-402-2359

i. Special Advisor (OC), HFS-600..... 240-402-2030

ii. Deputy Director (OC), HFS-600..... Vacant

iii. Division of Enforcement, HFS-605..... 240-402-1750

- Recall Team, HFS-605..... 240-402-1742
- Manufacturing and Storage Adulteration Branch, HFS-607..... 240-402-1611
- Labeling Compliance Team, HFS-608..... 240-402-2148
- Product Adulteration Branch, HFS-606..... 240-402-2349

iv. Division of Field Programs and Guidance, HFS-615..... 240-402-1988

- Field Programs Branch..... 240-402-2774
- Compliance Information Branch..... 240-402-1910

b. Director, Office of Cosmetics and Colors (OCAC), HFS-100.....240-402-1130

i. Deputy Director (OCAC)..... 240-402-1130

ii. Cosmetics Staff, HFS-125..... 240-402-1124

- Cosmetics Activities Team, HFS-320..... Vacant

iii. Division of Color Certification and Technology, HFS-105.... 240-402-1108

- Color Technology Team, HFS-106 240-402-1136
- Color Certification Branch, HFS-107..... 240-402-1119

c. Director, Office of Nutrition, Labeling and Dietary Supplements, HFS-800..... 240-402-2373

i. Deputy Director (ONLDS), HFS-800..... 240-402-1761

ii. Food Labeling and Standards Staff, HFS-820..... 240-402-2371

- Product Evaluation and Labeling Team, HFS-820..... 240-402-1802
- Labeling Regulations Implementation Team, HFS-820..... 240-402-1690

iii. Nutrition Programs Staff, HFS-830.....240-402-1450

- Nutrition Assessment and Evaluation Team, HFS-830..... 240-402-1788
- Nutrition Science Review Team, HFS-830.....240-402-2579

iv. Division of Dietary Supplement Programs, HFS-810.....240-402-1850

- Clinical Evaluation Team.....Vacant
- Dietary Supplement Regulations Implementation Team, HFS-810.....240-402-1441
- NDI Review Staff, HFS-810.....240-402-2851

v. Infant Formula and Medical Foods Staff, HFS-850..... 240-402-1459

d. Director, Office of Food Safety (OFS), HFS-300..... 240-402-1700

i. Deputy Director (OFS), HFS-300..... 240-402-2300

ii. Chemical Hazard Assessment Team, HFS-301..... 240-402-1941

iii. Food Processing Evaluation Team, HFS-302..... 240-402-1781

iv. Division of Seafood Science and Technology, HFS-400..... 251-690-3368

- Chemical Hazards Science Branch, HFS-400.....215-690-3403
- Microbiological Hazards Science Branch, HFS-400 251-690-3361

v. Division of Food Processing Science and Technology, HFS-450..... 708-728-4154

- Process Engineering Branch, HFS-450..... 708-728-4131
- Food Technology Branch, HFS-450..... 708-728-4146
- Laboratory Proficiency and Evaluation Team, HFS-450..... 708-728-4114

vi. Division of Plant and Dairy Food Safety, HFS-315.....240-402-1488

- Dairy and Egg Branch, HFS-316..... 240-402-2041
- Plant Products Branch, HFS-317..... 240-402-2023

vii. Retail Food & Cooperative Programs Coordination Staff, HFS-320

..... 240-402-2149

- Retail Food Protection Team, HFS-320..... 240-402-2150

viii. Produce Safety Staff, HFS-317 240-402-1636

ix. Division of Seafood Safety, HFS-325.....240-402-1422

- Shellfish & Aquaculture Policy Branch, HFS-325.... 240-402-1401
- .. Seafood Processing and Technology Policy Branch,

.... HFS-325 240-402-1420

e. Director, Office of Regulatory Science (ORS), HFS-700..... 240-402-1990

i. Deputy Director (ORS), HFS-700..... 240-402-1908

ii. Division of Analytical Chemistry, HFS-705..... 240-402-1898

- Methods Development Branch..... 240-402-1893
- Spectroscopy & Mass Spectrometry Branch..... 240-402-2039

iii. Division of Microbiology, HFS-710..... Vacant

- Microbial Methods Development Branch, HFS-711…240-402-2009
- Molecular Methods and Subtyping Branch..... 240-402-2020

iv. Division of Bioanalytical Chemistry, HFS-715..... 240-402-1786

- Chemical Contaminants Branch, HFS-716..... 240-402-2003
- Bioanalytical Methods Branch.....240-402-2098

5. Center For Veterinary Medicine (CVM)

a. Director, Office of Surveillance and Compliance (OS &C), .HFV-200..... 240-453-6830

b. Deputy Director, OS&C, HFV-200..... 240-453-6830

i. Director, Division of Surveillance, HFV-210..... 240-276-9062

- Team Leader, Marketed Product Information Team, HFV-212..... 240-276-9075
- Team Leader, Unapproved Hazard and Jurisdictional Review Team, HFV-214..... 240-276-9063
- Team Leader, Post-Approval Review Team, HFV-216..... 240-453-6802

ii. Director, Division of Animal Feeds, HFV-220..... 240-453-6864

- Team Leader, Feed Safety Team, HFV-222..... 240-453-6851
- .. Team Leader, Ingredient Safety Team, HFV-224..... 240-453-6879
- Team Leader, Medicated Feeds Team, HFV-226..... 240-453-6858
- Team Leader, Nutrition and Labeling Team, HFV-228..... 240-453-6866

iii. Director, Division of Compliance, HFV-230..... 240-276-9200

- .. Team Leader, Complaint/Emergency/Recall Team HFV-231 240-276-9237
- Team Leader, Post-Market Compliance Team, HFV-232 240-276-9204
- Team Leader, Drug Residue Compliance Team, HFV-233 240-276-9209
- Team Leader, Pre-Market Compliance and Administrative Actions Team, HFV-234..... 240-276-9238
- Team Leader, Programs and Operations Support Team, HFV-235..... 240-276-9209

iv. Director, Division of Veterinary Product Safety HFV-240 240-453-6844

- Team Leader, Adverse Drug Event Review Team, HFV-241..... ... 240-276-9068

- Team Leader, Adverse Event Review Team, HFV-242 240-276-9056
- Team Leader, Data Management and Analysis Team, HFV-243..... 240-276-9071

6. Center For Tobacco Products (CTP)

a. . Director, Office of Compliance and Enforcement..... 301-796-5503

i. Deputy Director 301-796-8725

ii. ORA Liaison, General Inquiries..... 301-796-9296

iii. Group Leader, Enforcement and Manufacturing 301-796-9220

iv. Group Leader, Promotion, Advertising and Labeling Compliance 301-796-9235

v. Group Leader, State Programs 301-796-9220