# Chapter 1
## REGULATORY ORGANIZATION

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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 and division may be found in various chapters of FDA’s Staff Manual Guide (SMG). This guide is available on FDA’s Intranet and Internet websites.

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)

As a result of the ORA reorganization efforts in 2012, new offices and divisions in ORA headquarters were established with new and combined functions to help support the rapid modernization and globalization of FDA’s regulated products and new legislative authorities provided by Congress.

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.

1-2-1 ACRA Organization

The following offices and senior officials report to the ACRA:

1. Deputy Associate Commissioner for Regulatory Affairs;
2. Executive Secretariat Staff;
3. Information Technology Staff;
4. External Relations Staff;
5. Senior Scientist;
6. Office of Resource Management;
7. Office of Operations; and,
8. Office of Criminal Investigations

1-2-2 The Immediate Office of the ACRA

The Immediate Office of the ACRA includes:

1. Executive Secretariat Staff;
2. Information Technology Staff;
3.  External Relations Staff; and,

4.  Senior Scientist.

The functional statements for the offices within the ACRA are found in Staff Manual Guides SMG 1121.1a (Office of the Associate Commissioner of Regulatory Affairs).

1-2-3 Deputy Associate Commissioner for Regulatory Affairs

The following offices report to the DACRA:

1.  Office of Policy and Risk Management

   The Office of Policy and Risk Management is comprised of risk, policy Staffs and a Division:
   a.  Risk Management Staff;
   b.  Food and Feed Policy Staff;
   c.  Medical Products and Tobacco Policy Staff; and,
   d.  Division of Planning Evaluation and Management.

2.  Office of Communications and Quality Program Management

   The Office of Communication and Quality Program Management includes the:
   a.  Quality Management Staff;
   b.  Internal Communications Staff; and
   c.  Project Coordination Staff.

3.  Office of Partnerships

   The Office of Partnerships includes the:
   a.  Contracts and Grants Staff; and
   b.  Standards Implementation Staff.

The functional statements for the aforementioned offices and division within these offices are found in the following Staff Manual Guides: SMG 1121.70 (Office of Policy and Risk Management); SMG 1121.71 (Division of Planning Evaluation and Management); SMG 1121.50 (Office of Communication and Quality Program Management); and SMG 1121.60 (Office of Partnerships).

1-2-4 Office of Resource Management:

   There are three Divisions within the Office of Resource Management:
1. Division of Human Resource Development;
2. Division of Management Operations; and
3. Division of Budget Formulation and Execution.

The functional statements for the Office of Resource Management and the three divisions within this office are found in the following Staff Manual Guides: SMG 1121.10 (Office of Resource Management); SMG 1121.13 (Division of Human Resource Development); SMG 1121.14 (Division of Management Operations); and SMG 1121.15a (Division of Budget Formulation and Execution).

1-2-5 Office of Operations:

The following offices and staff report to the Office of Operations:

1. Audit Staff
2. Office of Enforcement and Import Operations

There are three Divisions within the Office of Enforcement and Import Operations:
   a. Division of Enforcement;
   b. Division of Import Operations; and,
   c. Division of Compliance Systems.

3. Office of Food and Feed Operations

There are two Divisions within the Office of Food and Feed Operations:
   a. Division of Food Defense Targeting; and,
   b. Division of Food and Feed Operations and Inspections.

4. Office of Medical Products and Tobacco Operations

There are two Divisions within the Office of Medical Products and Tobacco Operations:
   a. Division of Medical Products and Tobacco Program Operations; and,
   b. Division of Medical Products and Tobacco Inspections.

5. Office of Regulatory Science

There are scientific and support staffs within the Office of Regulatory Science:
   a. Food and Feed Scientific Staff;
   b. Medical Products and Tobacco Scientific Staff; and,
c. Laboratory Operations and Support Staff.

6. ORA Regions

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

a. Regional Field Office, Northeast Region: Jamaica, NY;

b. Regional Field Office Central Region: Chicago, IL;

c. Regional Field Office, Southeast Region: Atlanta, GA;

d. Regional Field Office, Southwest Region: Dallas, TX; and

e. Regional Field Office, Pacific Region: Oakland, CA.

There are two to seven district offices within each region for a total of 20 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. Regional Laboratories, Winchester Engineering and Analytical Center, and Forensic Chemistry Center are also part of the ORA Field Offices.

The functional statements for the Office of Operations organizations can be found in the following Staff Manual Guides: SMG 1121.80 (Office of Operations), SMG 1121.81 (Office of Enforcement and Import Operations), SMG 1121.811 Division of Enforcement, SMG 1121.812 Division of Compliance Systems, SMG 1121.813 Division of Import Operations, SMG 1121.82 (Office of Food and Feed Operations), SMG 1121.821 Division of Food Defense Targeting, SMG 1121.822 Division of Food and Feed Program Operations and Inspections, SMG 1121.83 (Office of Medical Products and Tobacco Operations), SMG 1121.831 Division of Medical Products and Tobacco Inspections, SMG 1121.832 Division of Medical Products and Tobacco Program Operations, and SMG 1121.84 Office of Regulatory Science.

The function statements for the ORA Field Organizations are found at: SMG 1311.1 Regional Field Office, Northeast Region – Jamaica, NY, SMG 1311.2 District Office – New York, NY, SMG 1311.4 District Office – New England, SMG.1311.6 Northeast Regional Laboratory, SMG 1311.7 Winchester Engineering and Analytical Center, SMG 1312.1 Regional Field Office, Central Region – Chicago, IL, SMG 1312.2 District Office – Baltimore, MD, SMG 1312.3 District Office – Cincinnati, OH, SMG 1312.4 Forensic Chemistry Center, SMG 1312.5 District Office – New Jersey, SMG 1312.6 District Office – Philadelphia, PA, SMG 1312.7 District Office – Chicago, IL, SMG 1312.8 District Office – Detroit, MI, SMG 1312.9 District Office – Minneapolis, SMG 1313.1 Regional Field Office, Southeast Region – Atlanta, GA, SMG 1313.2 District Office – Atlanta, GA, SMG 1313.4 District Office – Florida, SMG 1313.5 District Office – New Orleans, LA, SMG 1313.6 District Office – San Juan, PR, SMG 1313.7 Southeast
Regional Laboratory – Atlanta, GA), SMG 1315.1 (Regional Field Office, Southwest Region – Dallas, TX), SMG 1315.2 (District Office – Dallas, TX), SMG 1315.3 (District Office – Kansas City, MO), SMG 1315.4 (District Office – Denver, CO), 1315.5 (Arkansas Regional Laboratory), SMG 1315.6 (Southwest Import District Office – Dallas, TX), SMG 1316.1 (Regional Field Office Pacific Regional – Oakland, CA), SMG 1316.2 (San Francisco District Office – Alameda, CA), SMG 1316.3 (Los Angeles District Office – Irvine, CA), SMG 1316.4 (Seattle District Office – Bothell, WA), SMG 1316.5 (Pacific Regional Laboratory Southwest – Irvine, CA), and SMG 1316.6 (Pacific Regional Laboratory Northwest – Bothell, WA).

1-2-6 Office of Criminal Investigations:

The Office of Criminal Investigations includes the:

1. Office of the Director;
2. Office of Internal Affairs;
3. Mid-Atlantic Area Office;
4. Northeast Area Office;
5. Southwest Area Office;
6. Southeast Area Office;
7. Midwest Area Office; and,
8. Pacific Area Office.

The functional statements for the Office of Criminal Investigations can be found in the following Staff Manual Guides: SMG 1121.40 (Office of Criminal Investigations).

1-2-7 The Functional Statements for ORA:

1. 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;

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

3. Stimulates 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;

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

5. 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;

6. 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;

7. 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;

8. 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;

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

10. Operates the Federal Medical Products Quality Assurance Program for the agency;

11. Advises the ACRA on all matters related to ORA’s information technology needs, systems development, and budgetary issues;

12. Coordinates with staff in ORA offices, regions, districts and laboratories as well as offices and staff external to ORA to develop and evaluate business needs in relation to current and planned information technology systems, and foster relations that facilitate ORA’s IT efforts;

13. Develops long-range strategic plans for ORA’s information technology infrastructure and systems;

14. Coordinates programs and procedures to solicit input from end-users throughout ORA to achieve efficiencies within IT systems and to ensure customer needs are met; and,

15. Evaluates new policies and regulations for impacts to ORA IT systems.

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. Ensures the quality of products regulated by CBER over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach, and compliance;

2. Monitors the quality of marketed biological products through surveillance, inspections, and compliance programs; reviews, evaluates and takes appropriate compliance action, in coordination with other Agency components;
3. Reviews, evaluates and takes action on manufacturing supplements submitted by manufacturers (except blood and plasma establishments), and leads pre-approval and pre-license inspections supporting Biologics License Application submissions and supplements as part of the CBER managed review process;

4. Advises the center director and other agency officials on emerging and significant compliance issues for biological products and serves as CBER’s focal point for surveillance and enforcement policy;

5. Coordinates CBER’s participation in the inspection of biological product manufacturing facilities;

6. Develops, with other CBER/agency components, policies and compliance standards for biological products including Current Good Manufacturing Practice (CGMP) regulations; ensures the uniform interpretation of standards and evaluates industry’s conformance with CGMP in manufacturing biological products;

7. Directs CBER’s bioresearch monitoring program, and takes appropriate compliance actions, in coordination with other Agency components;

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

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

10. Coordinates all CBER compliance activities with Office of Regulatory Affairs, including planning and field assignments;

11. Coordinates CBER’s import and export programs;

12. In coordination with other CBER components, responsible for lot release of biological products including review of protocols submitted for release by manufacturers;

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

14. 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);

15. Coordinates CBER’s application integrity policy;

16. Develops, reviews, and analyzes, in coordination with other agency components, policies that apply to products regulated by CBER, including procedures, instructions, guidance documents, regulations, and other written policy statements;

17. Reviews, evaluates, and takes appropriate compliance actions on advertising and promotional labeling materials for CBER-regulated products to ensure that the
information about the risks and benefits of regulated products are communicated in a truthful, accurate, science-based, non-misleading and balanced manner and is in compliance with pertinent federal laws and regulations;

18. Plans, develops, and implements, in coordination with other agency and CBER components, education programs for Agency staff, industry, health professionals, and consumers, concerning products regulated by CBER;

19. Manages CBER's product shortage program, and

20. In cooperation with other Center components, develops and maintains scientific programs dealing with the preparation and distribution of official U.S. reference preparations used in the control testing of biological products. Collaborates with national and international health agencies on evaluation studies of International Reference Preparations and functions as a World Health Organization/Pan American Health Organization (WHO/PAHO) Reference Laboratory.

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

1. Division of Case Management;
2. Division of Inspections and Surveillance;
3. Division of Manufacturing and Product Quality; and,
4. Division of Biological Standards and Quality Control

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, and denial of license. 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 other Agency and CBER components, plans and implements educational programs for Agency staff 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 the Office of Regulatory Affairs (ORA) for issuance of Warning Letters and reviews and evaluates
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 requests for export of unapproved biological products and requests for export certificates;

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

10. Reviews, evaluates, and takes appropriate compliance actions on advertising and promotional labeling materials for CBER-regulated products to ensure that the information about the risks and benefits of regulated products are communicated in a truthful, accurate, science-based, non-misleading and balanced manner, and is in compliance with pertinent laws and regulations.

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 direction 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 CBER inspection programs;

3. Develops guidance and other training programs in conjunction with CBER components, to promote industry compliance and for use in training Agency staff, industry, health professionals and consumers concerning products regulated by CBER;

4. Develops and updates CBER compliance programs;

5. Directs CBER’s program for biological product deviation reports (including HCT/P deviation reports and medical device reports), and reports of complications of blood collection or transfusion confirmed to be fatal. Coordinates case reviews, as appropriate, by a committee of medical officers;

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

7. Directs CBER’s Bioresearch Monitoring program with oversight of clinical investigators, institutional review boards, and sponsors of clinical research for biological products. Plans and directs inspection assignments, evaluates Establishment Inspection Reports, and takes appropriate compliance actions, in coordination with other Agency components, including Untitled Letters, Warning Letters, and the initiating the disqualification of clinical investigators;

8. Coordinates office follow-up and response to complaints related to investigational products and clinical trials;
9. Working with other Agency components, provides guidance to industry, consumers, and other government officials 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. Provides support for Team Biologics inspections and coordinates participation by qualified product specialists. 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 inspection, surveillance, and 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 CBER as part of the managed review process. Performs Chemistry, Manufacturing and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews for CBER-regulated products;

2. Develops and administers the biological products lot release program in coordination with other CBER components; reviews manufacturers’ submissions for licensed biological product lots; receives, maintains, and distributes samples of biological products submitted for testing;

3. Leads pre-license and pre-approval inspections supporting Biologics License Applications submissions and supplements, as part of the CBER managed review process. Prepares inspection reports as part of an inspection team and evaluates the firm’s corrective actions; and,

4. 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 Biological Standards and Quality Control (HFM-680)

The functional statements for the Division of Biological Standards and Quality Control are:

1. Develops product testing programs in a secured and controlled environment using appropriately qualified and validated methods for generating data supportive of CBER regulatory activities;

2. Maintains product testing programs in a manner that meets internationally recognized standards;

3. Participates in lot release activities by performing testing of submitted samples and review of lot release protocols according to approved testing programs;
4. Participates in regulatory review 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. Provides expert scientific and technical advice and assistance to industry, 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; and,

7. Develops and maintains scientific programs for the evaluation and standardization of reagent test kits and related devices in cooperation with other Center components.

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 functional statements for the Office of Compliance are:

1. Promotes and protects the public health through strategies and actions that minimize consumer exposure to unsafe, ineffective, and poor quality drugs;

2. Proactively advises the Center Director and other Agency officials on FDA’s regulatory and enforcement responsibilities and possible risks associated with human drugs, application integrity, and human subject protection;

3. Strategically implements programs and projects to identify, assess, and prioritize the public health significance of legal violations presented throughout the drug lifecycle;

4. Develops and utilizes innovative enforcement strategies and risk-based decision making to reduce public health risk by ensuring that marketed drugs are of high quality and integrity, properly labeled, safe, pure, and meet applicable drug approval requirements; and,

5. Coordinates Center-field relations and provides support and guidance to field offices on case development and regulatory actions, and ensures uniform interpretation of standards.

As a result of reorganization efforts in 2011, the following four Offices were created within the Office of Compliance:

1. Office of Unapproved Drugs and Labeling Compliance;

2. Office of Manufacturing and Product Quality;

3. Office of Drug Security, Integrity and Recalls; and,

4. Office of Scientific Investigation

1-4-2 Office of Unapproved Drugs and Labeling Compliance
The Office’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 Office consists of two Divisions, the Division of Prescription Drugs and the Division of Non-Prescription Drugs and Health Fraud. The functional statements for the Office of Unapproved Drugs and Labeling Compliance are:

1. Develops policies and compliance strategies for protecting the public health by assuring compliance with the new drug and misbranding requirements of the Federal Food, Drug and Cosmetic Act, and
2. Uses risk based assessments and strategic enforcement actions to identify and address products that pose the most significant risks to consumers associated with unapproved and misbranded drugs.

1-4-3 Office of Manufacturing and Product Quality

The Office 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 Office consists of the Division of Domestic Drug Quality, the Division of Good Manufacturing Practice Assessment, the Division of International Drug Quality, and the Division of Policy, Collaboration and Data Operations. The functional statements for the Office of Manufacturing and Product Quality are:

1. Develops policies, surveillance activities, and compliance strategies to protect public health by assuring compliance with Current Good Manufacturing Practices (CGMP) requirements of the Federal Food, Drug and Cosmetic Act (FD&C Act);
2. Uses risk-based assessments and strategic enforcement actions to identify and address the most significant legal violations associated with drug manufacturing or product quality;
3. Reviews field recommendations and findings, and initiates appropriate regulatory actions against violative manufacturers;
4. Develops, contributes and formalizes regulatory strategies, guidance, and policies including preparing regulations, industry guidance, Compliance Program Guidance Manuals, Compliance Policy Guides, CDER MaPPs, and Staff Guidance Manuals to promote compliance with CGMP, and
5. Provides technical and scientific assistance in the area of manufacturing and product quality.

1-4-4 Office of Drug Security, Integrity and Recalls
The Office’s primary responsibility is to promote and protect the integrity of the global supply chain throughout the drug lifecycle to minimize consumer exposure to unsafe, ineffective, and poor quality drugs.

The Office consists of the Division of Supply Chain Integrity and the Division of Import Operations and Recalls. The functional statements for the Office of Drug Security, Integrity and Recalls are:

1. Develops policies and compliance strategies for protecting the public health by assuring drug product integrity and supply chain security;

2. Coordinates evaluation and classification of drug recalls and provides Center coordination with field offices for implementation of recalls and monitors resolution of related compliance issues; and

3. Ensures integrity of imported drug products by assuring compliance with applicable legal requirements.

1-4-5 Office of Scientific Investigations

The Office’s primary responsibilities include verifying the integrity of efficacy and safety data submitted to the FDA in support of new drug applications, assuring that the rights and welfare of human research subjects are protected, assuring that responsible parties submit required postmarketing adverse events and reports, and assuring sponsor compliance with the Risk Evaluation and Mitigation Strategies (REMS) requirements.

OSI is composed of three Divisions (Division of Good Clinical Practices Compliance; Division of Safety Compliance; and Division of Bioequivalence and Good Laboratory Practice Compliance).

The functional statements for the Office of Scientific Investigations are:

1. Develops policies, surveillance activities, and compliance strategies relating to nonclinical and clinical drug product studies, bioequivalence studies, human subject protections, post-market Adverse Drug Experience reporting requirements, Risk Evaluation and Mitigation Strategies, and commitments for Postmarketing Requirements and Safety Labeling;

2. 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, the Food and Drug Amendments Act, other Federal statutes, and applicable regulations; and

3. Develops, contributes and formalizes regulatory strategies and guidance including CDER MaPPs, Staff Guidance Manuals, and Compliance Program Guidance Manuals to promote compliance with Good Clinical Practice (GCP) in research, human subject protections, Good Laboratory Practices, Bioequivalence, Pharmacovigilance, Risk Evaluation and Mitigation Strategies, and Safety Labeling.

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,

1-5-3 Division of Bioresearch Monitoring

The functional statements for the Division of Bioresearch Monitoring are:


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


a. There are six Branches within this Division:

1. Information Management Branch;
2. Accreditation and Certification Branch;
3. Radiation Programs Branch;
4. Inspection and Compliance Branch;
5. Electronic Products Branch; and,

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

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

2. 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;

3. 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;

4. 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;

5. 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;

6. 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;

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

8. 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. Serves as the primary contact between the Center and FDA’s field organization, including the Field Food Committee;

   b. Has primary responsibility for management of compliance programs, field assignments, and work plans;

   c. Initiates and/or coordinates the planning, development, publication and promotion of field guidance documents for CFSAN-regulated food and cosmetic products 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;

   d. Reviews proposed regulatory actions and recalls for adequacy of evidence and consistency across programs. Oversees the development of compliance and enforcement strategies for emerging compliance challenges;

   e. 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. 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;

   f. Oversees, monitors, and evaluates the food facility registration database; and,

   g. 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.
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. Serves as the Center’s point of contact for enforcement policy and priority inquiries, including recalls, from other agency units, industry, and other parties;

b. Manages reviews of regulatory actions recommended by agency field offices and other Agency components. Guides field offices activities, when necessary, in developing scientifically and legally supportable actions. Participates in case development strategy calls with the field and other Agency components;

c. Works with other Center and Agency units 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;

d. Evaluates import and domestic inspectional, investigational, and analytical evidence and determines whether to pursue a regulatory action or alternative remedy;

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

f. Assists agency legal offices and field units and the Department of Justice developing legal documents including declarations, obtaining experts, responding to interrogatories, and providing trial or other requested assistance. Represents the Center at enforcement negotiations;

g. Serves as an expert resource on foreign product compliance and participants in agency discussions, decisions, and fact finding for import and international issues for foreign country, product, and industry assessments; and,

h. Serves as the Center focal point for consumer complaints and daily Reportable Food Registry (RFR)/Risk Control Review activities. Maintains the Center RFR database and guides field follow-up to RFR reports.

There are two teams and one branch within the Division of Enforcement:

i. Recall and Product Reconditioning Team

ii. Labeling and Dietary Supplement Compliance Team

iii. Food Adulteration Assessment 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. 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. Maintains the 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;

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

f. 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; and,

g. Plans and coordinates strategy for Foreign Food Inspections program. Manages firm selection and contact process and data mining procedures. Transfers and tracks submissions made to field organizations.

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 (HFS-100)

1. Office of the Director

a. Develops guidelines, regulations, and policies for cosmetics and color additives;

b. Provides expert scientific and technical support for cosmetics and color additives;

c. Communicates this information to the public, affected industry, and international regulatory bodies;
d. Provides expert scientific and technical advice and support on cosmetic products and ingredients and color additives;

e. Administers the Color Certification Program, including methodology research and quality control;
f. Administers the Voluntary Cosmetic Registration Program; and

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

   a. Administers the agency Color Certification Program, including methodology research and quality control;

   b. Provides expert scientific and technical advice and support on color additive methodology; and

   c. 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

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

   a. Develops guidelines, regulations, and policies for cosmetics and color additives;

   b. Provides expert scientific and technical support for cosmetics and color additives;

   c. Administers the Voluntary Cosmetic Registration Program; and

   d. Communicates policy, guidance, and information for cosmetics and color additive certification and supports other units in this area.

   There is one team within the Cosmetic Staff:
     i. Cosmetics Activities Team

1-6-3 **Office of Food Additive Safety (HFS-200)**

1. Office of Food Additive Safety

   a. Serves as the Center focal point for scientific and policy support for the development of Agency-initiated regulations on matters pertaining to the
provisions of the food and color additive sections of the Federal Food, Drug, and Cosmetic Act;

b. Manages the Center's petition review processes (both those conducted in-house and under extramural contract) for food additives and color additives, and consultation/notification processes for GRAS (Generally Recognized As Safe) substances, food contract substances, and foods and food ingredients derived from recombinant DNA biotechnology. Evaluates safety information, compiles the administrative record supporting actions on petitions and other agency actions, and prepares Federal Register documents relating to petitions;

c. Prepares and/or reviews documentation required by the Center to implement the National Environmental Policy Act (NEPA). Coordinates the Center review of documents prepared under NEPA by other Federal agencies;

d. Serves as the principal Agency liaison on safety testing methodologies and protocol standards needed to evaluate the safety of food ingredients and on other aspects of regulatory decisions;

e. Develops compliance policy, position papers, procedural regulations, regulatory guidelines, and advisory opinions on issues related to the safe uses of food additives, food contract substances, color additives, GRAS substances, biotechnology derived foods, and prior sanctioned substances. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely and efficient manner. Consults with FDA laboratories regarding research relevant to the regulation of food and color additives and food ingredients;

f. Manages the Agency's review and monitoring of identity, probable human exposure to, and toxicity information on food additives and color additives, food contract substances, and GRAS substances in current use. Recommends enforcement action or regulatory change as needed. Provides expert scientific and technical advice to other Office, Center, and Agency components as needed;

g. Provides evaluation and participates in bioresearch monitoring of non-clinical laboratory studies and facilities to assure quality and integrity of data submitted to the Agency in accordance with good laboratory practices.

h. Serves as the Center's focal point for scientific and policy support for the development of Agency-initiated regulations on matters pertaining to the provisions of the food additive and color additive sections of the Federal Food, Drug, and Cosmetic Act;

i. Ensures the scientific integrity and consistency of the Center's petition review processes (both those conducted in house and under extramural contract) for food additives and color additives, and consultation/notification processes for generally recognized as safe (GRAS) substances, food contract substances, and foods and food ingredients derived from recombinant DNA
biotechnology;

j. Consults with FDA laboratories regarding research relevant to the regulation of food and color additives and food ingredients;

k. Ensures that the Agency’s compliance policy, position papers, procedural regulations, regulatory guidelines, and advisory opinions on issues related to the safe uses of food additives, food contract substances, color additives, GRAS substances, biotechnology derived foods, and prior sanctioned substances are consistent and based on sound science;

l. Ensures the Agency's review and monitoring of identity, probable human exposure to, and toxicity information on, food additives and color additives, food contract substances, and GRAS substances in current use. Recommends enforcement or regulatory change as needed. Provides expert scientific and technical advice to other Office, Center, and Agency components as needed;

m. Provides toxicology, chemistry, and pathology expertise to the Center, develops guidelines for toxicological studies and establishing specifications of identity and purity of food additives and estimating dietary exposure, and monitors newly developed testing methodologies that may prove useful in toxicological assessments of novel food additives and other food ingredients and contributes to the Agency’s overall safety assessment of food ingredients; and

n. Provides evaluation and participates in bioresearch monitoring of non-clinical laboratory studies and facilities to assure quality and integrity of data submitted in accordance with good laboratory practices.

There is one policy staff, one support team, and three divisions within the Office of Food Additive Safety:

i) Senior Science & Policy Staff
ii) Stakeholder Support Team
iii) Division of Biotechnology and GRAS Notice Review
ii) Division of Petition Review
iii) Division of Food Contact Notifications

2. **Senior Science & Policy Staff (HFS-205)**

a. Develops regulations, guidance, policy, programs, position papers, and advisory opinions, and recommends research priorities for food and color additives, food contact substances, generally recognized as safe (GRAS) ingredients and bioengineered food;

b. Provides expert guidance for CFSAN officials and other Agency components, Federal and State officials, and industry concerning regulatory requirements and their implementation for food and color additives, food contact substances, generally recognized as safe (GRAS) ingredients and bioengineered food;
c. Reviews regulatory actions, including information about proposed enforcement actions that are provided by the Office of Compliance, to determine if those actions within OFAS’s purview are supported by relevant science and established program priorities, policy, and guidance; determines, where policy or guidance does 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. Develops and maintains OFAS knowledge management systems (e.g., information technology, bioinformatics, and computational toxicology); and

e. Provides animal pathology services to the Center for Food Safety and Applied Nutrition.

3. **Stakeholder Support Team (HFS-206)**

   a. Provides administrative support to OFAS;

   b. Prepares Certificates of Free Sale;

   c. Tracks and finalizes Freedom of Information Act requests and controlled correspondence;

   d. Maintains OFAS internet and intranet sites; and,

   e. Administers and maintains the CFSAN Thesaurus for the Center for Food Safety and Applied Nutrition.

4. **Division of Biotechnology and GRAS Notice Review (HFS-255)**

   a. Provides Center guidance and coordinates the technical evaluation of regulatory and scientific issues regarding food additives, GRAS (Generally Recognized as Safe) substances, other food ingredients, and bioengineered food, including industry actions;

   b. Evaluates toxicological, nutritional and microbiological data and information, and chemical data (including data on probable human exposure) and information, submitted to the Agency that pertain to the safety of food ingredients, GRAS substances and bioengineered food. Develops guidelines and monitors newly developed techniques pertaining to the safety assessment of food additives, GRAS substances, and bioengineered food;

   c. Consults with prospective notifiers prior to submission, concerning proposed uses of food additives, GRAS substances, other food ingredients, and bioengineered food, advising on content of submissions and approaches to meet statutory standards. Advises notifiers and other interested parties of any inadequacies that may preclude requested action for submissions reviewed by this Division;
d. Writes and amends, as needed, procedural regulations, food ingredient regulations, and guidelines to implement relevant provisions of the Federal Food, Drug, and Cosmetic Act;

e. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with GRAS substances and bioengineered food matters;

f. Develops and maintains information for assessment and monitoring of food additives, GRAS substances, other food ingredients, and bioengineered food. Responds to stakeholder inquires and processes Freedom of Information requests in a timely and efficient manner;

5. **Division of Petition Review (HFS-265)**

a. Provides Center guidance and coordinates the technical evaluation of regulatory and scientific issues regarding direct food additives, food irradiation, and color additives, including industry actions;

b. Evaluates toxicological, nutritional, and microbiological data and information, and chemical data (including data on probable human exposure) submitted to the agency by petitioners or from other sources, that pertain to the safety of direct food additives, irradiated food, and of color additives in foods, drugs, medical devices, or cosmetics;

c. Consults with prospective petitioners prior to filing, concerning proposed new uses of direct food additives and color additives, advising on petition content and approaches to meet statutory standards. Advises petitioners and other interested parties of any inadequacies that may preclude requested action on petitions reviewed by this Division;

d. Writes and amends, as needed, direct food additive and color additive regulations, procedural regulations, and guidelines to implement the provisions of the Federal Food, Drug, and Cosmetic Act specific to direct food additives and color additives;

e. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with direct food additive and color additive issues; and,

f. Develops and maintains information on the safety and use of direct food additives and color additives. Responds to stakeholder inquires and processes Freedom of Information requests in a timely and efficient manner.

6. **Division of Food Contact Notifications (HFS-275)**

a. Provides Center guidance and coordinates the technical evaluation of regulatory and scientific issues regarding food contact substances including industry actions;

b. Evaluates toxicological data and information and chemical data and information (including data on probable human exposure), submitted to the agency by
notifiers, petitioners, or from other sources, that pertain to the safety of food contact substances;

c. Consults with prospective notifiers and petitioners prior to submission concerning proposed uses of food contact substances, advising on notification or petition content and approaches to meet statutory standards. Advises notifiers, petitioners and other interested parties of any inadequacies that may preclude requested action for submissions reviewed by this Division;

d. Writes and amends, as needed, procedural regulations and guidelines to implement the provisions of food contact substance sections of the Federal Food, Drug, and Cosmetic Act;

e. Develops and redirects, as necessary, current policies, compliance efforts, and research dealing with food contact substances; and,

f. Develops and maintains information for assessment and monitoring the safety of food contact substances. Responds to stakeholder inquiries and processes Freedom of Information requests in a timely and efficient manner.

1-6-4 Office of Food Safety (HFS-300)

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 assessments of chemical or microbial contamination;

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

d. 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;

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

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 does 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 is one team within the Office of the Director, Office of Food Safety:

i. Food Processing Evaluation Team

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There are two Staffs and four Divisions within the Office of Food Safety:

i. Produce Safety Staff

ii. Retail Food & Cooperative Programs Coordination Staff

iii. Division of Plant and Dairy Food Safety

iv. Division of Seafood Safety

v. Division of Seafood Science & Technology

vi. Division of Food Processing Science and Technology

2. 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 Center 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, FDA senior officials, FDA field and external stakeholders on microbial fresh and fresh-cut produce safety and defense issues, field programs, produce initiatives, the conduct of international activities including the development and implementation of bilateral agreements, and other related activities; and,

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

3. 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 which are shellfish safety, milk safety and retail food protection, and coordinates activities in support of the Partnership for Food Protection;
b. Maintains the Interstate Certified Shellfish Shippers List, the Interstate Milk Shippers List, and the list of jurisdictions enrolled in the Voluntary National Retail Food Regulatory Program Standards;

c. Serves as Agency liaison with State partners, other Federal agencies, and industry associations in administering the federal portion of the federal/state cooperative retail food protection 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. Identifies and characterizes existing emerging and potential health hazards associated with preparation and service of food at the retail level; and

f. Provides technical support, geographic information systems capacity, and outreach to FDA staff and other Federal, State, and Local officials on the Food Code and other agency guidance related to retail food protection.

4. 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 plant foods, dairy foods, eggs, game meats, and beverages;

b. Provides expert advice to the Center Director, other Centers, FDA, and government officials. Serves as principal Center 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, and State staff, i.e. ORA regional milk specialists, state regulatory agencies and international third parties relevant to standardizing and certifying the evaluation of state and international milk programs; and,

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

5. **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 key stakeholders and serves as principal Center liaison to industry, international and other organizations on issues related to seafood safety; and,

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

6. **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.

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; and,

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

7. 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 Analytics and Outreach (OAO) and others, in educational and informational 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 (FERN/LRN); and,

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

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

1. Office of the Director

a. Conducts laboratory science and research that supports the FDA regulatory agenda;
b. Develops laboratory based methods to support regulations and related policy developments;

c. Provides technical support and expert advice on scientific issues related to policy and regulations;

d. Originates, plans, and conducts research in the areas of food processing and packaging, food chemistry, food toxicants, dietary supplement ingredient analysis, food nutrient analysis, food microbiology, and cosmetic component studies; and

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

There are three Divisions within the Office of Regulatory Science:

i. Division of Analytical Chemistry
ii. Division of Microbiology
iii. Division of Bioanalytical Chemistry

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. 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;

c. Provides specialized infrared, near-infrared, Raman, surface Plasmon resonance, nuclear magnetic resonance and electron spin resonance spectroscopy, and mass spectrometry support to the Agency;

d. Provides specialized protein analysis and proteomics support to the Agency;

e. Conducts research to develop and refine the application of specialized and field portable instrumentation to Agency problems;

f. 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;

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

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

i. Supports food safety through the development of DNA-based methods for plant and animal species identification.

There are two branches within the Division of Analytical Chemistry:

i. Methods Development Branch
ii. Spectroscopy and Mass Spectrometry Branch
3. **Division of Microbiology (HFS-710)**

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

   b. 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;

   c. 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; and,

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

   There are two branches within the Division of Microbiology.

   i. Microbial Methods and Development Branch

   ii. Molecular Methods and Subtyping Branch

4. **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. Reviews regulatory actions for adequacy of evidence in support of 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; 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; and,

   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

1-6-6 Office of Nutrition, Labeling and Dietary Supplements (HFS-800)

1. Office of the Director
   a. Primary responsibility for policy development and management of food and nutrition labeling, conventional foods, dietary supplements, special nutritionals (include infant formula and medical foods) and associated educational initiatives;
   b. Develops, regulations, compliance policy, position papers, regulatory guidelines and advisory opinions for matters within the scope of the responsibility of the Office;
   c. Provides expert advice to the Center Director, other key officials, and directs major agency and Department nutrition labeling and dietary supplements initiatives and is the Delegate to national and international forums and conferences;
   d. Manages and provides scientific review on issues related to infant formula and medical foods including petitions and notifications, and provides advice to key agency components as well as international bodies;
   e. 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.

There are two Staffs and one Division within the Office of Nutritional Labeling and Dietary Supplements:
   i. Division of Dietary Supplement Programs
   ii. Food Labeling and Standards Staff
   iii. Nutrition Programs Staff

2. Division of Dietary Supplement Programs (HFS-810)
   a. Has primary responsibility for policy development and strategic management of the dietary supplement program, which includes safety assessment and compliance strategy for the New Dietary Ingredient Notification Program, implementation and execution of Dietary Supplement Good Manufacturing Practices, structure-function notifications, Certificates of Export 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. Enforcement of the dietary supplement requirement of the DSHEA Act of 1994 and other relevant statutes to ensure the safe and truthful labeling of dietary supplements;

c. Provides expert advice for officials and other agency units on good manufacturing practices (GMP), field programs, compliance and enforcement issues and related activities, and provides assistance to Federal and State agencies and industry concerning regulatory requirements and compliance policies;

d. Provides guidance to the Field in cooperation with agency units in handling regulatory actions and assistance in the development, management, and coordination of enforcement/compliance cases;

e. Evaluates adverse events and other sources of signals related to the safety of dietary supplements;

f. Provides clinical/scientific/regulatory expertise in the assessment of risk of dietary supplements for related compliance activities, clinical responses to petitions, and in the evaluation of safety information provided in New Dietary Ingredient Notifications; and,

g. Provides guidance to agency scientific units and affiliated scientific units on activities related to compliance and regulatory activities and strategies.

There is one branch and one team within the Division of Dietary Supplement Programs:

i. Dietary Supplement Regulations Implementation Branch (divided into a labeling team and a cGMP team)

ii. NDI Review Team

3. Food Labeling and Standards Staff (HFS-820)

a. Has primary responsibility for policy and regulatory development and management of the conventional food labeling program (other than nutrition labeling), including NLEA, FALCPA and other FD&C and FPLA labeling requirements. Also manages the Standards of Identity program;

b. Provides scientific and technical review of and response to petitions and notifications related to all aspects of conventional food labeling. Determines compliance with existing food standards and common or usual name, regulations, and issuance of temporary marketing permits to allow manufacturers to test market new foods. In addition, provides scientific and technical review of enforcement and compliance materials for all conventional foods (including infant formula and medical foods), such as inspection reports, analytical reports and other pertinent records and provides policy and enforcement decisions for misbranding charges on for all domestic and import actions, including infant formula and medical food manufacturers;
c. Provides expert guidance for officials and other agency units, Federal and State officials, industry and consumers concerning regulatory requirements and compliance policies on conventional food labeling (including infant formula, medical foods and nutrition-related labeling) and reviews proposed enforcement/compliance actions referred by other agency units;

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; and,

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

i. Product Evaluation and Labeling Review Team

ii. Labeling Regulations Implementation Team

3. Nutrition Programs Staff (HFS-830)

a. Conducts scientific review and analysis of relevant information for making science-based decisions for policies, regulations, research priorities, position papers, and advisory opinions on issues related to nutrition and nutrition labeling, dietary guidance recommendations, and other nutrition science issues;

b. Conducts scientific and regulatory review of health claim petitions, qualified health claim petitions, nutrient content claim petitions, FDA Modernization Act notifications for health claims and nutrient content claims, and for providing regulations for the Nutrition and Supplements Facts labels;

c. Provides expert advice and assistance to key officials and coordinates with other domestic and international government agencies and scientific bodies on efforts related to nutrition and health;

d. 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; and,

e. Develops methods for monitoring U.S. 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

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, food for animals, 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 food for animals;

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, food for animals, 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 to make 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. Review 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. Medical 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 petitions 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 and GRAS substances 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 food 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 Office of Surveillance and Compliance (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 Office of New Animal Drug Evaluation (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 food for animals 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


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. Collaborates with CORE, monitors and handles many emerging issues involving animal 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 the FDA/CVM by the 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, food for animals, food 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. Imports/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

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

1. Advises the Center Director and other Agency officials on legal, administrative, and regulatory programs and policies concerning Agency compliance and enforcement responsibilities relating to tobacco products;

2. Coordinates, interprets, and evaluates the Center's overall compliance and enforcement efforts;

3. Provides technical support and guidance in the development and review of standards, regulations, and guidance related to compliance and enforcement;

4. Develops, directs, coordinates, evaluates, and monitors compliance and enforcement programs covering regulated industry;
5. Coordinates, develops, and directs State compliance and enforcement programs;

6. Provides training of Federal, State and Territorial compliance personnel;

7. Conducts field tests and inspections when necessary for regulatory purposes and evaluates regulated industry activities to assure compliance with regulations;

8. Provides advice to Agency field offices and commissioned officials, and manages Center activities relating to legal actions, case development, and contested case assistance;

9. Designs, develops, and implements Center programs to register Tobacco establishments, and product lists;

10. Coordinates all field planning activities and issues all field assignments for the Center;

11. Provides technical support and guidance in the development and review of standards, regulations, and guidance related to compliance and enforcement; and,

12. Advises actual or potential manufacturers, distributors, retailers, and importers concerning the requirements of the law and regulations related to compliance and enforcement.

**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 Associate Commissioner for Regulatory Affairs (DACRA) .. 301-796-8310

2. Office of Enforcement and Import Operations (OEIO)............. 301-796-5270
   
   i. Office Director ...................................................... .................                      vacant
   ii. Deputy Director.................................................................................. 301-796-5723

a. Director, Division of Import Operations (DIO) ................. 301-796-0356
   
   i. Chief, Import Operations and Maintenance Branch...............................vacant
   ii. Chief, Import Program Development and Implementation Branch.... 301-796-6677

b. Division of Compliance Systems (DCS)/Enforcement Systems Branch (ESB)
   
   i. Director........................................................................................................vacant
   ii. Chief, Enforcement Systems Branch....................................................... 301-796-3240
   iii. Chief, Import Compliance Systems Branch........................................... 301-796-8997

c. Division of Enforcement (DE)
   
   i. Director........................................................................................................301-796-8203
   ii. Deputy Director.................................................................................. 301-796-8206

d. Division of Import Operations
Import Alerts and bulletins
Import filer evaluation
program
Foreign Supplier Verification
program

e. Division of Compliance Systems/Enforcement Systems Branch
Electronic Regulatory Information Quality Assurance
Government-wide Quality Assurance Program
Federal Medical Products Quality Assurance Program
ORA systems (CMS, MARCS, Citations database, COMSTAT)
Compliance Information & Reporting
Turbo EIR
Health Communications

f. Division of Enforcement
Case Review and Management
Civil Money Penalties (Compliance)
Inspection Warrants
Recalls
Team Biologics (Compliance)
Warning Letter Database
Health fraud
Debarment …..

3. Office of Operations (OO)
a. Assistant Commissioner for Operations…………………………………….. vacant
i. Audit Staff Director……………………………………………………………………. vacant

4. Office of Policy and Risk Management (OPRM)
Compliance Policy Council
Compliance Policy Guides
Regulatory Procedures Manual
Testimony
Federal Register Regulations
Intra-agency Enforcement Policy
Program Planning and Evaluation
Policy (Food and Feed)
Policy (Medical Products and Tobacco)
Risk Management

i. Assistant Commissioner for Policy…………………………………………………301-796-8211
ii. Deputy Director…………………………………………………………………………301-796-8805

5. Office of Criminal Investigations (OCI)
a. Director, OCI………………………………………………………………………. 240-276-9460
1-9-2 Office of Regulatory 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.................................................. 781-662-5450
         FAX................................................................. 781-662-5439

   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.................615-366-7988
        FAX......................................................615-366-7805

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.................................................. 404-253-1170
      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
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,
2. Center for Drug Evaluation And Research (CDER)
   a. Director, Office of Compliance............................................. 301-796-3100
      i. Deputy Directors.......................................................... 301-796-3100
      ii. Associate Directors .................................................... 301-796-3100
      iii. Director, Office of Unapproved Drugs and Labeling
           Compliance ...................................................................... 301-796-3100
             • Deputy Director.................................................. 301-796-3100
             • Assistant Directors................................................. 301-796-3100
             • Division of Prescription Drugs................................. 301-796-3110
             • Division of Non-Prescription Drugs........................... 301-796-3110
      iv. Director, Office of Manufacturing and Product Quality ...... 301-796-3120
          • Deputy Director..................................................... 301-796-3120
          • Regulatory Policy and Collaboration Branch .............. 301-796-3120
          • Division of Good Manufacturing Practice
            Assessment................................................................... 301-796-3120
            • New Drug Manufacturing Assessment Branch .......... 301-796-3120
            • Division of International Drug Quality ...................... 301-796-3120
            • Biotech Manufacturing Assessment Branch .............. 301-796-3120
            • Division of Domestic Drug Quality ......................... 301-796-3120
            • Drug Surveillance and Data Reporting Branch .......... 301-796-3120
            • Generic Drug Manufacturing Assessment Branch....... 301-796-3120
• Division of Policy, Collaboration and Data Operations...301-796-3120

v. Director, Office of Drug Security, Integrity and Recalls ...... .... .... .... .... .... .... .... 301-796-3130
• Deputy Director................................................................. 301-796-3130
• Associate Directors ....................................................... 301-796-3130
• Division of Import Operations and Recalls ...... .... .... .... .... 301-796-3130
• Division of Supply Chain Integrity ...... .... .... .... .... 301-796-3130

vi. Director, Office of Scientific Investigations .................... 301-796-3150
• Deputy Director................................................................. 301-796-3150
• Division of Good Clinical Practice Compliance ... .... .... 301-796-3150
• Division of Safety Compliance ........................................... 301-796-3150
• Division of Bioequivalence and Good Laboratory Practice............ .... .... .... .... .... 301-796-3150
• Program Management and Organization Strategy 301-796-3150
• Risk Science, Intelligence and Prioritization............... 301-796-3150
• Outreach and Collaboration 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,
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. Deputy Director (OC), HFS-600......................... 240-402-1364
      ii. Division of Enforcement, HFS-605...................... 240-402-1750
         • Recall and Product Reconditioning Team, HFS-605 ..................................................... 240-402-1742
         • Food Adulteration Assessment Branch, HFS-607 .......... 240-402-1611
         • Labeling and Dietary Supplement Compliance Team, HFS-608 .................. 240-402-2148
      iii. 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. Cosmetics Staff, HFS-125..................................... 240-402-1124
      ii. Division of Color Certification and Technology, HFS-105 240-402-1108
   c. Director, Office of Nutrition, Labeling and Dietary Supplements, HFS-800................................................. vacant
      i. Deputy Director (ONLDS), HFS-800............................. 240-402-1761
      ii. Food Labeling and Standards Staff, HFS-820.............. 240-402-2371
iii. Nutrition Programs Staff, HFS-830.................................240-402-1450

iv. Division of Dietary Supplement Programs, HFS-810...

................................................................. 240-402-1850

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................................. vacant

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

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

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

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

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

................................................................. 240-402-2149

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

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

e. Director, Office of Regulatory Science (ORS), HFS-700..... vacant

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

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

iii. Division of Microbiology, HFS-710......................... 240-402-2020

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

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 (OCE) .... 301-796-9295
   i. Deputy Director ............................................................... 301-796-8569
   ii. ORA Liaison, General Inquiries ........................................... 301-796-9338
iii. Director, Division of Enforcement and Manufacturing ............... 301-796-5533

iv. Director, Division of Promotion, Advertising and Labeling Compliance ...................................................... 301-796-9235

v. Director, Division of State Programs ........................................... 301-796-9297