

CHAPTER 2 - ORGANIZATION

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SUBCHAPTER 200 - ORGANIZATION OVERVIEW

A complete description of the FDA's organizational structure and its functional statement is found in various chapters of the Staff Manual Guides (SMG) which are available on FDA's Intranet Website see <http://intranet.fda.gov/oc/oms/oirm/manuals/smg/smg.htm>.

The FDA is a part of the Department of Health and Human Services (HHS). An appointed Commissioner who serves at the discretion of the President heads the agency.

There are approximately 9300 FDA employees.

The FDA is a team of dedicated professionals working to protect and promote the health of the American people.

FDA is responsible for ensuring:

Foods are safe, wholesome, and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.

Regulated products are honestly, accurately, and informatively represented.

These products are in compliance with the law and FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the marketplace.

201 - FDA PRINCIPLES

We strive to:

Enforce FDA laws and regulations, using all appropriate legal means.

Base regulatory decisions on a strong scientific and analytical base and the law; and understand, conduct, and apply excellent science and research.

Be a positive force in making safe and effective products available to the consumer, and focus special attention on rare and life-threatening diseases.

Provide clear standards of compliance to regulated industry, and advise industry on how to meet those standards.

Identify and effectively address critical public health problems arising from use of FDA-regulated products.

Increase FDA's effectiveness through collaboration and cooperation with state and local governments; domestic, foreign, and international agencies; industry; and academia.

Assist the media, consumer groups, and health professionals in providing accurate, current information about regulated products to the public.

Work consistently toward effective and efficient application of resources to our responsibilities,

Provide superior public service by developing, maintaining, and supporting a high-quality, diverse workforce.

Be honest, fair, and accountable in all our actions and decisions.

SUBCHAPTER 210 - OFFICE OF THE COMMISSIONER

210 - IMMEDIATE OFFICE (OC)(HF-1)

The Commissioner of the Food and Drug Administration is Mark B. McClellan, M.D., Ph.D.

The Deputy Commissioner of the Food and Drug Administration is Lester M. Crawford, D.V.M., Ph.D.

The immediate staff offices within the OC are:

1. Office of the Chief Council (GCF-1), Daniel Troy , Chief Counsel.
2. Administrative Law Judge (HF-3) Daniel J. Davidson, ALJ
3. Office of Equal Opportunity (HF-15) Anthony J. Kaminski, Acting Director
4. Senior Advisor for Science (HF-1) Bernard A. Schwetz, D.V.M., Ph.D.

The immediate OC has approximately 147 employees.

In addition, the four offices listed below will be discussed separately.

211 - OFFICE OF THE SENIOR ASSOCIATE COMMISSIONER (HF- 2)

The Office of the Senior Associate Commissioner is responsible for agency-level activities and decisions which affect agency-wide programs, projects, strategies and initiatives. Components under this office are:

1. Office of Executive Secretariat (HF-40) Catherine P. Beck, Director
2. Office of Public Affairs (HFI-1) Larry Bachorik , Interim Associate Commissioner
3. Office of the Ombudsman, Steve Unger, Acting Chief Mediator & Ombudsman
4. Office of Orphan Products Development (HF-35) Marlene E. Haffner, MD, Director
5. Office of Internal Affairs (HF-9) Tommy L. Hampton, Special Agent in Charge

212 - OFFICE OF POLICY, PLANNING, AND LEGISLATION (HF-22)

The Associate Commissioner for Policy, Planning and Legislation is William K. Hubbard.

The Acting Associate Commissioner for Policy is Margaret Dotzel.

This office is responsible for developing, coordinating, managing, and researching the policy of the agency and includes the following staffs:

1. Office of Policy
Regulations Policy and Management Staff, Edwin V. Dutra, Director
Policy Development and Coordination Staff, Catherine Lorraine, Director
2. Office of Planning
Planning Staff, Morris R. Bosin, Director
Evaluation Staff, Kathleen A. McEvoy, Director
Economics Staff, Lawrence Braslow, Director

3. Office of Legislation, Melinda Plaisier, Interim Associate Commissioner
Michael A. Eck, Director
Congressional Affairs Staff I,
Congressional Affairs Staff II,
Jarilyn Dupont, Director
Congressional Affairs Staff III, Vacant, Director
The OPP&L has approximately 37 employees.

213 - OFFICE OF MANAGEMENT (HF-20)

The Associate Commissioner for Management is Jeffrey M. Weber. This office is responsible for the planning and evaluation of agency activities and for the management of overall agency financial operations, human resources and management services, facilities, acquisitions and central services, plus information resources management.

The following offices are located in the Office of Management:

1. Office of Financial Management
2. Office of Chief Information Officer
components:
 - Office of Business Enterprise Solutions
 - Office of Information Technology Shared Services
3. Office of Shared Services (OSS)

OSS consists of the following components:

- Immediate Office, OSS
- Employee Resource & Information Center (ERIC)
- Office of Equal Opportunity & Diversity Management
- Office of Real Property Services
- Office of Acquisitions & Grants Services

4. Office of Human Resources
5. Office of Management Programs
6. Office of Executive Operations

The Office of Management has approximately 616 employees

214 - OFFICE OF INTERNATIONAL AND CONSTITUENT RELATIONS (HF-24)

The Deputy Commissioner for the Office of International and Constituent Relations (OICR) is Sharon Smith Holston. This office is responsible for special health issues, women's health, consumer affairs, and international programs.

The following offices are located in OICR:

1. Office of International Programs (HFG-1)
Sharon Smith Holston, Acting Director
2. Office of Consumer Affairs (HFE-1)
Patricia M. Kuntze, Acting Associate Commissioner
3. Office of Women's Health
Audrey Sheppard, Acting Director
4. Office of Special Health Issues (HF-12)
Theresa Toigo, R.Ph., MBA, Associate Commissioner

The OICR has approximately 82 employees.

SUBCHAPTER 220 - CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

220 - OFFICE OF THE CENTER DIRECTOR

The CBER Director is Jesse Goodman, M.D., M.P.H. This center is responsible for administering the regulation of biological products under the biological product control provisions of the Public Health Services Act (PHS Act) and applicable provisions of the Federal Food Drug and Cosmetic Act (FD&C Act).

Establishes written and physical standards, conducts research, tests products submitted for release, approves licensing of biological manufacturers and biological products, and inspects licensed manufacturers' facilities for compliance with standards. Provides focus in FDA for coordination of the Acquired Immune Deficiency Syndrome (AIDS) program. Works to develop an AIDS vaccine, AIDS diagnostic tests and conducts other AIDS-related activities.

Plans and conducts research on the preparation, preservation, and safety of blood and blood products, the methods of testing safety, purity, potency and efficacy of such products of therapeutic use, and the immunological problems concerned with products, testing, and use of diagnostic reagents employed in grouping and typing blood.

In carrying out these functions, cooperates with other FDA components, other PHS organizations, governmental and international agencies, volunteer health organizations, universities, individual scientists, non-governmental laboratories and manufacturers of biological products.

Office of the Center Director is organized as follows:

1. Deputy Director (Operations), (HFM-2)
Mark A. Elengold
2. Deputy Director (Medicine), (HFM-6).
3. Associate Director for Quality Assurance (HFM-4),
Sheryl L. Lard-Whitford, Ph.D.
4. Associate Director for Policy (HFM-10),
Diane Maloney, JD.
5. Associate Director for Review Management (HFM-25), Robert A. Yetter, Ph.D.
6. Associate Director for Research (HFM-20),
Neil D. Goldman, Ph.D.
7. Associate Director for Medical and International Affairs, (HFM-30) Elaine C. Esber, M.D.
8. Senior Policy Advisor (HFM-1), Jill H. Warner, J.D.

The Center has seven Offices under the direction of the Center Director, which will be discussed below.

220.01 - Office of Biostatistics and Epidemiology (OBE) (HFM-210) Susan S. Ellengerg, Ph.D., Director

This office provides oversight and resources for the review of biological products and is responsible for statistical and epidemiological services to the Center, including responsibility for the adverse event reporting system.

The Office of Biostatistics and Epidemiology is organized as follows:

1. Division of Biostatistics (HFM-217)
Peter A. Lachenbruch, Ph.D, Director
2. Division of Epidemiology (HFM-220)
M. Miles Braun, MD, MPH, Acting Director

**221 - OFFICE OF COMMUNICATION,
TRAINING, AND MANUFACTURERS
ASSISTANCE (OCTMA) (HFM-40)
MARY T. MEYER, DIRECTOR**

This office manages the Center's professional and management training program, career and staff development program, employee orientation program, and related employee development policies. Directs the Center's consumer and professional informational activities in coordination with the other Agency components.

Serves as a liaison with Center components to provide advice and assistance to manufacturers and scientific associations to promote their understanding and compliance with FDA regulations. The Office is responsible for all activities relating to the administration of the Center's central documentation room.

The Office has the following Divisions:

1. Division of Manufacturers Assistance and Training (HFM-42) Gail H. Sherman, Director
2. Division of Disclosure and Oversight Management (HFM-44) JoAnne C. Binkley, Director

**222 - OFFICE OF MANAGEMENT (OM)
(HFM-100)
DON R. PETERSON, DIRECTOR**

This Office monitors the development and operation of planning systems for Center activities and resource allocations and advises the Center Director on Center administrative policies, guidelines, and information systems and services. Plans and directs Center operations for financial, personnel and administrative management services. Directs and counsels Center managers through program evaluation and technological forecasting.

Functions as an advisor on contract and grant proposals.

Office of Management is organized as follows:

1. Regulatory Information Management Staff (HFM-110) Roger D. Eastep, Director
2. Division of Management Services (HFM-115) Gerald L. Anderson, Director
3. Division of Planning, Evaluation and Budget (HFM-140) Nancy D. Williams, Director

**222.01 - Office of Information Technology
Management (OITM) (HFM-160)
Ron D. Connor, Director**

This office manages the Center's microcomputer resources and LAN/WAN network architecture, provides oversight and management of CBER's automated information systems and acts as the liaison with Center activities and contract Information Technology vendors.

Develops, implements, and monitors ADP standards and policies for all Center Information Resource activities and

maintains the Center-wide Information Resource security program for all legacy data and electronic access. Provides budget execution and contract monitoring of Information Technology resources.

The Office has the following Divisions:

1. Division of Information Technology Operations (HFM-165) Ginger Leo, Director
2. Division of Information Technology Development (HFM-170) John C. Chang, Director
3. Division of Information Technology Infrastructure (HFM-180) Vacant Director

**223 - OFFICE OF BLOOD RESEARCH AND
REVIEW (OBRR) (HFM-300)
JAY S. EPSTEIN, MD, DIRECTOR**

OBRR develops policy and procedures governing the pre-market approval review and evaluation of biological blood products in keeping with the provisions of the PHS Act and applicable provisions of the FD&C Act.

Performs the investigational device exemption (IDE) review process for devices related to biological blood products and develops related policy of those products regulated by the Office. Reviews, evaluates and takes appropriate action on investigational new drug applications (INDs) related to biological blood products and amendments or supplements to these applications; product applications submitted by manufacturers of biological blood products, including labeling; and establishment license applications submitted by blood and plasma establishments.

Plans and conducts research related to the development, manufacture, and testing of biological blood products, including those related to AIDS and those prepared by genetic engineering and synthetic procedures. Develops and maintains a scientific base for establishing standards designed to ensure the continued safety, purity, potency, and effectiveness of biological blood products.

Plans and conducts research on the preparation, preservation, characteristics, action and safety of blood and blood products; the methods of evaluating safety, purity, potency and efficacy of such products; the therapeutic uses of such products; and the testing and use of diagnostic reagents employed in grouping and typing blood, and screening for markers of infectious diseases.

This office has the following Divisions

1. Division of Emerging and Transfusion Transmitted Diseases (HFM-310)
Hira L. Nakhasi, Ph.D., Director
2. Division of Hematology (HFM-330)
Mark J. Weinstein, Ph.D., Acting Director
3. Division of Blood Applications (HFM-370)
Vacant, Director, Director

**224 - OFFICE OF VACCINES RESEARCH AND
REVIEW (OVRR) (HFM-400)
KAREN MIDTHUN, DIRECTOR**

OVRR covers vaccines, allergenic products, antigen specific, immunomodulators, and diagnostic antigens.

Reviews, evaluates, and takes appropriate action on

INDs related to vaccines and regulated products and amendments or supplements to these applications, including approval or disapproval of research plans and protocols, modifications and restrictions. Performs the IDE review process for devices related to vaccines and related products regulated by CBER. Develops all related policy and procedures governing pre-market approval review and evaluation of vaccines and related products in keeping with the provisions of the PHS Act and applicable provisions of the FD&C Act.

Plans and conducts research related to the development, manufacture, and testing of vaccines and related products, including those related to AIDS and those prepared by genetic engineering and synthetic products. Develops and maintains a scientific base for establishing standards designed to ensure continued safety, purity, potency and effectiveness of vaccines and related products.

In cooperation with other CBER components, tests products submitted for release by manufacturers; evaluates clinical experience and reports of adverse events as necessary; participates in inspection of manufacturing facilities; and takes appropriate action on recommendations concerning denial of license applications for products.

The divisions in this office are:

1. Division of Bacterial, Parasitic, and Allergenic Products (HFM-410)
Richard I Walker, PhD., Director
2. Division of Viral Products (HFM-445)
Jerry P. Wier, PhD., Director
3. Division of Vaccines & Related Products Applications (HFM-475)
Karen L. Goldenthal, MD, Director

225 - OFFICE OF CELLULAR TISSUE AND GENE THERAPIES

Philip D. Noguchi, M.D., Director

In October 2002, FDA created the Office of Cellular, Tissue, and Gene Therapies (OCTGT) to consolidate regulatory and review activities for tissues, cellular and tissue-based products, gene therapies, and xenotransplantation products. This office includes experts in molecular and cell biology, viral and nonviral gene therapy vectors, nucleic acid chemistry and genomics, proteomics, developmental and reproductive biology, stem cell biology and physiology, tissue and organ regeneration and medical and pharmacology/toxicology. OCTGT evaluates potential shortages to help assure the continued safe supply of needed products. This office works with CDC, NIH and other appropriate organizations to develop standards and methods for cellular therapies and participates in inter-center focus groups for collaborative reviews. Through this centralization of activity and expertise, FDA is working more effectively with our agency partners, conducting outreach, and regulating tissue products to achieve a safe and adequate supply.

The divisions in this office are:

1. Division of Cellular and Gene Therapies (HFM-735)
Raj K. Puri, M.D., Ph.D., Acting Director

2. Division of Clinical Evaluation and Pharmacology/Toxicology (HFM-755)
Cynthia A. Rask, M.D., Director
3. Division of Human Tissues (HFM-770)
Ruth R. Solomon, M.D., Acting Director

226 - OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY (HFM-600) STEVEN A. MASIELLO, DIRECTOR

OCBQ monitors the quality of marketed biological products through surveillance, inspections, compliance activities, application review, and lot release programs. Advises the Center Director and other Agency officials on FDA's regulatory compliance responsibilities for biological products. Reviews license applications and supplements to determine if the facilities are appropriate for the manufacturing activities. Participates in prelicense and annual inspections and on license application review committees.

Serves as the focal point for all CBER enforcement activities. Provides guidance to Headquarters and field personnel in the development of evidence to support enforcement actions for deviations from the applicable standards. Coordinates Center/field compliance activities, including planning activities and field assignments, with the exception of consumer affairs activities.

Manages the CBER biological product inspection program. Coordinates with other Center Offices and Agency components. Directs the Center's bioresearch monitoring and recall programs for biological products.

Develops biological product compliance and surveillance programs, coordinates field implementation, and advises other Center components on these programs. Evaluates, in coordination with appropriate Agency officials, firms' conformance with CGMP in producing biological products for procurement by Federal and State agencies.

Coordinates the Center's export program and serves as the Center's focal point for import and export issues.

Identifies and recommends appropriate action, in coordination with other FDA components, on the results of continuing surveillance and evaluation of advertising and clinical experience reports submitted by manufacturers and sponsors of products regulated by CBER.

Maintains a reference reagent program, and establishes written and reference standards for biological product establishments (except blood and plasma establishments). In coordination with other CBER components, tests products submitted for release by manufacturers.

This office has three Divisions:

1. Division of Case Management (HFM-610)
Mary A. Malarkey, Director
2. Division of Inspections and Surveillance (HFM-650)
Elaine Knowles Cole, Director
3. Division of Manufacturing and Product Quality (HFM-670) John A. Eltermann, Jr., Director

SUBCHAPTER 230 - CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

230 - OFFICE OF THE CENTER DIRECTOR (HFD-1)

Janet Woodcock, M.D. is the CDER Director.

Dr. Murray Lumpkin is the Deputy Center Director for Review Management and the Deputy Center Director for Pharmaceutical Science is currently vacant.

Warren Rumble (HFD-001) is CDER's Ombudsman.

CDER is responsible for developing FDA policy with regard to safety, effectiveness, and labeling of all drug products for human use; reviewing and evaluating new drug applications (NDAs) and investigational new drug applications (INDs); and developing and implementing standards for the safety and effectiveness of all over-the-counter (OTC) drugs. CDER is responsible for monitoring the quality of marketed drug products; developing and promulgating guidelines on Current Good Manufacturing Practices; conducting research and developing scientific standards on the composition, quality, safety, and effectiveness of human drugs. CDER is responsible for collecting and evaluating information on the effects and use trends of marketed drug products; monitoring prescription drug advertising and promotional labeling; and analyzing data on accidental poisonings and disseminating toxicity and treatment information on household products and medicines.

There are three staffs under the immediate office of the Center Director:

1. Regulatory Policy Staff (HFD-7)
Jane Axelrad, Acting Director
2. Executive Operations Staff (HFD-6)
Deborah Henderson, Director
3. EEO Staff (HFD-8)
Diane Smith, Director

The Office of Medical Policy, Robert Temple, MD, Director operates directly under the Center Director. There are two divisions under this office:

1. Div. Of Marketing, Advertising and Communications (HFD-40), Norm Drezin, Acting Director
2. Division of Scientific Investigations (HFD-340), Joanne Rhoads, MD, Director

231 - OFFICE OF MANAGEMENT (HFD-10) RUSSELL ABBOTT, DIRECTOR

The Office of Management monitors the development and operation of planning systems for resource allocations and information systems; manages studies designed to improve processes and resource allocations; advises the Center on contract and grant proposals; and provides coordination, receipt and distribution of initial drug applications.

There are two divisions and one staff under the Office of Management:

1. Strategic Planning Staff (HFD-10)
Charlene Cherry, Director

2. Division of Planning, Evaluation, and Resource
Division of Management Services (HFD-60)
Ruth Clements, Director

232 - OFFICE OF INFORMATION TECHNOLOGY (HFD-070) RALPH LILLIE, DIRECTOR

The Office of Information Technology oversees CDER's installation, maintenance and development of computer systems and databases. There are two staffs and three divisions:

1. Quality Assurance Staff (HFD-070)
Judy McIntyre, Director
2. Technology Support Services Staff (HFD-070)
David Moss, Director
3. Division of Infrastructure Management and Services (HFD-072), Patrick David, Director
4. Division of Applications Development Services (HFD-072), Melissa Chapman, Director
5. Division of Data Management and Services (HFD-090), Greg Warzala, Director

233 - OFFICE OF TRAINING AND COMMUNICATIONS (HFD-200) NANCY SMITH, Ph.D. DIRECTOR

The Office of Training and Communications prepares, develops, and coordinates Center and Agency responses to drug-related requests under the Freedom of Information Act, Privacy Act and other statues. The office provides leadership and direction for all Center internal and external communications; plans coordinates, and evaluates policies, procedures, and programs for the orientation and training of Center staff; and provides scientific and technical resources and other library services.

There is one staff and three divisions under the Office of Training and Communications:

1. Freedom of Information Staff (HFD-200)
Director - Vacant
2. Division of Training and Development (HFD-220)
Janice Newcomb, Director
3. Division of Communications Management (HFD-210), Ellen Shapiro, Director
4. Division of Medical Library (HFD-230)
Carol Assoud, Acting Director

234 - OFFICE OF COMPLIANCE (HFD-300), DIRECTOR - DAVID J. HOROWITZ

The Office of Compliance monitors the quality of marketed drugs through product testing, surveillance, and compliance programs; develops standards for drug industry practices, including Current Good Manufacturing Practice (CGMP) regulations, and ensures their uniform interpretation.

There are three divisions under the Office of Compliance as follows:

1. Division of New Drugs and Labeling Compliance (HFD-310), Director - Vacant

2. Division of Manufacturing and Product Quality (HFD-320, Director, Joseph C. Famulare
3. Division of Compliance Risk Management and Surveillance, (HFD-330), Director - Vacant

235 - OFFICE OF PHARMACEUTICAL SCIENCE, (HFD-3) DEPUTY CENTER DIRECTOR FOR PHARMACEUTICAL SCIENCE DIRECTOR - VACANT

The Office of Pharmaceutical Science provides advice and information on pharmaceutical programs and issues; and oversees the development of standards for the safety and effectiveness of generic drugs. OPS oversees the review and evaluation of Abbreviated New Drug Applications (ANDAs), Abbreviated Antibiotic Drug Applications (AADAs), and their amendments or supplements, and determines approvability.

There are two staffs and four offices under the Office of Pharmaceutical Science:

1. Product Quality Support Staff
Vacant, Director
2. Operations Staff (HFD-358)
Helen Winkle, Acting Director

235.01 - Office of New Drug Chemistry (HFD-800) Yuan Yuan Chiu, Ph.D., Director

The Office of New Drug Chemistry manages the science issues of chemistry, microbiology, manufacturing and control reviews; and ensures consistency in new drug chemistry reviews; and manages the overall coordination for IND and NDA chemistry and microbiology review processes.

There are three divisions under the Office of New Drug Chemistry:

1. Division of New Drug Chemistry I (HFD-810)
Charles Hoiberg, Ph.D., Director
2. Division of New Drug Chemistry II (HFD-820)
John Gibbs, Ph.D., Director
3. Division of New Drug Chemistry III (HFD-830)
Chi-Wan Chen, Ph.D., Director

235.02 - Office of Generic Drugs (HFD-600), Gary Buehler, Acting Director

The Office of Generic Drugs oversees the development and implementation of standards for the safety and effectiveness of generic drugs; reviews and evaluates ANDAs and AADAs and the amendments or supplements, and determines approvability; and establishes bioequivalency specifications for drug products.

There are four divisions under the Office of Generic Drugs:

1. Division Of Labeling & Program Support (HFD-605) Jerry Philips, Director
2. Division of Chemistry I (HFD-620)
Rashmikant Patel, Ph.D., Director
3. Division of Chemistry II (HFD-640)
Frank Holcombe, Jr., Ph.D., Director

4. Division of Bioequivalence (HFD-650)
Nicholas Fleischer, Ph.D., Director

235.03 - Office of Testing and Research (HFD-900) James MacGregor, Ph.D., Director

The Office of Testing and Research conducts research and develops scientific standards on the composition, quality, safety, and effectiveness of human drug products.

There is one staff, one laboratory, and three divisions under the Office of Testing and Research:

1. Regulatory Research and Analysis Staff (HFD-901) Joseph Contrera, PhD, Director
2. Laboratory of Clinical Pharmacy (HFD-902)
Jerry Collins, Ph.D., Director
3. Division of Product Quality Research (HFD-940) Karl Flora, Ph.D., Director
4. Division of Applied Pharmacology Research (HFD-910) Frank Sistare, Ph.D., Director
5. Division of Testing and Applied Analytical Development (HFD-920) Moheb Nasr, Ph.D., Director

235.04 - Office of Clinical Pharmacology & Biopharmaceutics (HFD-850) Larry Lesko, PhD, Director

The Office of Clinical Pharmacology & Biopharmaceutics evaluates pharmacokinetic, pharmacodynamic, bioavailability, bioequivalence, and drug metabolism protocols and data in notices of claimed investigational exemption for INDs, NDAs, antibiotic applications, and their supplements and amendments.

There is one staff and three divisions under the Office of Clinical Pharmacology & Biopharmaceutics:

1. Pharmacometrics Staff (HFD-851)
William Gillespie, Ph.D., Acting Director
2. Division of Pharmaceutical Evaluation I (HFD-860)
Hank Malinowski, Ph.D., Director
3. Division of Pharmaceutical Evaluation II (HFD-870)
Mei Ling Chen, Ph.D., Director
4. Division of Pharmaceutical Evaluation III (HFD-870) John Lazor, Ph.D. Acting Director

236 - OFFICE OF REVIEW MANAGEMENT (HFD-20) MURRAY LUMPKIN, DEPUTY DIRECTOR

The Office of Review Management develops and implements the Center's review management and scientific policies, including user fee policies, pertaining to the drug review process.

There are three staffs and seven offices under the Office of Review Management:

1. Advisors and Consultants Staff (HFD-21)
John Treacy, Director
2. Program Management Team (HFD-022)
William Oswald, Team Leader

3. Reports and Data Management Team (HFD-023)
Ann Myers, Team Leader
4. Pharmacology/Technology Staff (HFD-024)
Joseph DeGeorge, Ph.D., Team Leader

236.01 - Office of Drug Evaluation I (HFD-101) Robert Temple, MD

This office reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials. Evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements proposing changes in the conditions upon which NDA approvals are based.

There are three divisions in this Office as follows:

1. Division of Neuropharmacological Drug Products (HFD-120) Russ Katz, MD, Director
2. Division of Oncologic Drug Products (HFD-150)
Robert Justice, MD, Director
3. Division of Cardio-Renal Drug Products (HFD-110)
Raymond Lipicky, MD, Director

236.02 - Office of Drug Evaluation II (HFD-102) John Jenkins, MD, Director

This office reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials. Evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements proposing changes in the conditions upon which NDA approvals are based.

There are three divisions in this Office as follows:

1. Division of Metabolic & Endocrine Drug Products (HFD-510) Solomon Sobel, MD, Director
2. Division of Pulmonary Drug Products (HFD-570)
Robert Meyer, MD, Acting Director
3. Division of Reproductive and Urologic Drug Products (HFD-580) Lisa Rarick, MD, Director

236.03 - Office of Drug Evaluation III (HFD-103) Florence Houn, MD, Director

The Office of Drug Evaluation III reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials. They evaluate for safety and effectiveness and approve new drug applications (NDAs) for products regulated by this Office, and evaluate supplements proposing changes in the conditions upon which NDA approvals are based.

There are three divisions in this office as follows:

1. Division of Gastrointestinal & Coagulation Drug Products (HFD-180) Lilia Talarico, MD, Director
2. Division of Anesthetic, Critical Care, & Addiction Drug Products (HFD-170) Cynthia McCormick,

MD, Acting Director

3. Division of Medical Imaging & Radiopharmaceutical Drug Products (HFD-160)
Patricia Love, MD, Director

236.04 - Office of Drug Evaluation IV (HFD-104) Sandra Kweder, MD, Acting Director

The Office of Drug Evaluation IV reviews notices of claimed investigational exemptions for new drugs for (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials. The office evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements proposing changes in the conditions upon which NDA approvals are based.

There are three divisions in this office as follows:

1. Division of Anti-Infective Drug Products (HFD-520)
Gary Chikami, MD, Director
2. Division of Anti-Viral Drug Products (HFD-530)
Heidi Jolson, MD, Acting Director
3. Division of Special Pathogen and Immunologic Drug Products (HFD-590) Mark Goldberg, MD, Director

236.05 - Office of Drug Evaluation V (HFD-105) Robert DeLap, MD, Director

This office reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials. This office evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements proposing changes in the conditions upon which NDA approvals are based.

There are three divisions in this Office as follows:

1. Division of Anti-Inflammatory, Analgesic & Ophthalmologic Drug Products (HFD-550)
Director Vacant
Division of Dermatologic & Dental Drug Products (HFD- 540) Jonathan Wilkin, MD, Director
3. Division of Over-the-Counter Drug Evaluation (HFD-560) Charles Ganley, MD, Director

236.06 - Office of Biostatistics (HFD-700) Robert O'Neill, Ph.D., Director

The Office of Biostatistics conducts programs to collect and evaluate epidemiological and non-epidemiological information on drug and biological product usage, adverse reactions, poisonings, safety, quality, and effectiveness.

There is one staff and three divisions under the Office of Biostatistics:

1. Quantitative Methods Research Staff (HFD-705)
Stella Machado, Ph.D., Director
2. Division of Biometrics I (HFD-710)
George Chi, Ph.D., Director

3. Division of Biometrics II (HFD-715)
S. Edward Nevius, Ph.D., Director
4. Division of Biometrics III (HFD-720)
Mohammed Huque, Ph.D., Director

236.07 - Office of Post Marketing Drug Risk Assessment (HFD-730) Murray Lumpkin, Acting Director

This office is responsible for obtaining and evaluating post-market information on approved NDAs, ANDAs, INDs, etc.

There are two staffs and two divisions under the Office of Post Marketing Drug Risk Assessment:

1. Extramural Program Staff (HFD-730)
Tom Conrad
2. Information Technology Staff (HFD-730)
William Calvert
3. Division of Drug Risk Evaluation I (HFD-730)
Peter Honig, MD, Director
4. Division of Drug Risk Evaluation II (HFD-730)
Evelyn Rodriguez

SUBCHAPTER 240 - CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

240 - OFFICE OF THE CENTER DIRECTOR

David Feigal, MD is the Center Director of CDRH. Linda Kahan is the Deputy Center Director of CDRH. Lillian J. Gill is the Senior Associate Director of CDRH.

The Center for Devices and Radiological Health (CDRH) develops and carries out a national program to assure the safety, effectiveness, and labeling of medical devices for human use. It reviews and evaluates medical device pre-market approval applications (PMA's), product development protocols (PDP's), exemption requests for investigational devices (IDE's), and premarket notifications [510(k)'s].

The Center provides technical and other nonfinancial assistance to small manufacturers of medical devices.

CDRH develops and carries out a national program designed to control unnecessary exposures of humans to, and assure the safe and efficacious use of, ionizing and non-ionizing radiation-emitting electronic products.

CDRH has about 1000 employees.

The Office of the Center Director, in addition to providing overall leadership and direction for the Center, provides advice and consultation to the Commissioner and other Agency officials on policy matters concerning radiological health and medical device activities. The office recommends changes in legislative authority to the Commissioner, establishes policy in the areas of education and communications, and formulates strategies for developing and disseminating educational and programmatic information to health professionals, consumers, and other government agencies. The office plans and coordinates the Center's equal employment opportunity programs.

241 - OFFICE OF SYSTEMS AND MANAGEMENT (HFZ-2) RUTH CLEMENTS, DIRECTOR

The Office of Systems and Management (OSM) advises the Center Director on all administrative and management matters, and plans, develops and implements Center management policies and programs concerning such areas as manpower and financial management, personnel management, contracts and grants. OSM also develops and applies evaluation techniques to measure the effectiveness of Center programs, and provides general information and technical publications support to the Center. Other functions include planning and coordinating all of the Center's scientific advisory committee management activities.

OSM also determines and implements Center strategy and utilization of information management resources. OSM designs administrative and scientific technical information systems in support of Center programs, designs and conducts educational programs for Center employees in data processing and management, and provides assistance to Center staff in accessing information necessary to carry out the Center's mission.

OSM is also responsible for carrying out the Center's FOI activities.

The Office of Systems and Management is comprised of the following:

1. Integrity, Committee and Conference Management Staff - Communicates and coordinates ethics issues, FMFIA, committee management activities, serves as the Center's Intramural Research Integrity Officer, conference management program.
2. Division of Management Operations - Provides advice and guidance to Center management on personnel, procurement, property, facilities, occupational health and safety. Implements Center management policies and/or programs.
3. Division of Planning, Analysis and Finance - Develops and justifies budget, manages budget, develops and implements long-range and strategic planning, conducts evaluations, impact studies and research studies, and implements administrative policies for extramural research programs.
4. Division of Information Dissemination - Provides information dissemination services to Center and the public, develops and manages library science strategies and systems, provides advice, guidance and technical support to program officials on FOIA.
5. Division of Information Technology Management - Develops and implements information management strategies and policies, maintains ADP security plan, trains Center personnel and provides user assistance.
6. Program Management Staff - Provides administrative functions and computer support to the Office of Systems and Management.

242 - OFFICE OF SCIENCE AND TECHNOLOGY (HFZ-100) LARRY KESSLER, Sc.D., DIRECTOR

The Office of Science and Technology (OST) provides scientific and laboratory support in response to program needs of other Center and Agency components. OST plans, develops, and implements Center research and testing programs, and protocols in the areas of physical science, life science, and engineering. OST develops, modifies, and calibrates scientific instruments and equipment for use in testing programs; plans, conducts or stimulates research on the human health effects of radiation and medical devices and provides scientific and engineering support for the review of medical devices and radiological product submissions. OST conducts research related to existing and emerging health technologies.

OST provides leadership and technical expertise to other Departmental components in applying health physics procedures and radiation protection principles to radiological emergencies and other public radiation instances, and provides technical services and health physics advice to the Center.

OST also conducts studies to assess or advance the practical application of radiation protection principles, and maintains liaison with national and international radiation protection organizations.

There are 5 divisions in the OST as follows:

1. Division of Management, Information and Support Services - Provides the following services for the office: administrative support, fabrication and engineering support, technical information and reading room information.
2. Division of Electronics & Computer Science - Provides electronics, engineering and imaging and computer science support for Center programs.
3. Division of Mechanics and Material Science - Develops and provides technical support for measurement methods and analytical procedures, conducts and/or supports research studies for safety thresholds, provides support to the device evaluation process.
4. Division of Physical Sciences - Plans and conducts laboratory and program activities in the physical science and general engineering disciplines.
5. Division of Life Sciences - Plans, conducts, supports and evaluates research on the health effects of radiation and medical devices.

243 - OFFICE OF HEALTH AND INDUSTRY PROGRAMS, (HFZ-200) LIREKA P. JOSEPH, Ph.D., DIRECTOR

The Office of Health and Industry Programs (OHIP) conducts and evaluates nationwide programs to prevent injuries and deaths resulting from misuse of medical devices. It applies Special Controls authorities specified in the Safe Medical Devices Act of 1990, as a means of assuring safe and effective use of medical devices. OHIP performs in-depth analyses of medical device adverse incident reports, often with the assistance of representatives of relevant health professional, manufacturer and consumer organizations. OHIP conducts and coordinates information-

al and training activities for these groups; provides training services to the Agency, and other federal, state and foreign government agencies and health-related missions; and participates in the development of national and international consensus standards and voluntary guidelines. In addition, OHIP establishes and maintains liaison with consumer and professional organizations, industry associations and groups, and foreign and domestic governmental organizations to promote Center program goals.

Other functions include coordinating the Center's cooperative activities with foreign government counterparts and international health organizations.

OHIP is the focal point for liaison with the Office of General Counsel and appropriate Agency components on FDA regulation development responsibilities relating to medical device and radiological health activities.

Provides expertise in communications technology in support of Center & FDA programs and the Staff College functions.

Staff College - Develops training courses for Center, sponsors seminars and lectures, performs needs assessments and develops training objectives.

Regulations Staff - Advises Center and Agency officials on FDA regulation development responsibilities.

Program Operations Staff - Provides administrative and computer support to the office, serves as the Center Consumer Affairs representative.

Division of Small Manufacturers, International and Consumer Assistance (DSMICA) - Provides technical and other non-financial assistance to small manufacturers.

Division of Device User Programs and Systems Analysis - Participates in the postmarket problem analysis and solution strategy activities, such as labeling and human factors guidance, to ensure user-related issues are addressed.

Division of Communication Media - Provides and maintains expertise in communications technology services and coordinates media and graphic arts services to the Center, FDA, and other Government agencies.

Division of Mammography Quality and Radiation Programs - Responsible for implementing the Mammography Quality Standards Act of 1992 and provides program planning and support activities for cooperative programs with other agencies which have radiological health responsibilities. Provides education and communication to mammography facilities and parties interested in mammography quality.

244 - OFFICE OF COMPLIANCE (HFZ-300) TIM ULATOWSKI, DIRECTOR

The Office of Compliance (OC) develops, directs, coordinates, evaluates, and monitors compliance programs covering regulated industry. OC conducts electronic product field tests and inspections when necessary for regulatory purposes, and evaluates industry quality control and testing programs to assure compliance with regulations. OC provides advice to Agency field offices on, and manages Center activities relating to, legal actions, case development, and contested case assistance. OC coordinates

field planning activities and issues all field assignments for the Center.

The Office of Compliance has five divisions as follows:

1. Division of Program Operations - Administrative functions for the office; clearinghouse for all assignments issued by the Center to the field; processing of Compliance Programs, Compliance Policy Guides; registration and listing program; certificates for export products.

2. Division Bioresearch Monitoring - Manages and coordinates the administrative and regulatory responsibilities of the Agency's Bioresearch Monitoring Program for medical devices.

The Enforcement divisions were created along product lines as follows:

3. Division of Enforcement I - in vitro diagnostics, diagnostics devices and general surgery devices

4. Division of Enforcement II - dental, ear, nose and throat; ophthalmic; urology, gastroenterology, general hospital, and obstetrics/gynecology.

5. Division of Enforcement III - cardiovascular and neurology devices; orthopedic, physical medicine, and anesthesiology devices; therapeutic radiographic devices and electronic products.

245 - OFFICE OF DEVICE EVALUATION (HFZ-400) DANIEL SCHULTZ, M.D., Ph.D. , DIRECTOR

The Office of Device Evaluation (ODE) plans, conducts, and coordinates appropriate Center actions regarding approval, denial, and withdrawal of approval of pre-market approval applications (PMA's), product development protocols (PDP's), and investigational device exemptions (IDE's). ODE makes substantially equivalent determinations for pre-market notification submissions [510(k)'s]; and monitors sponsors' conformance with requirements of all programs. ODE also coordinates Center Classification activities, reviews petitions for or initiates reclassification of medical devices, provides executive secretariat and other technical support to medical device advisory panels, and conducts continuing review, surveillance, and medical evaluation of the labeling clinical experience, and required reports submitted by sponsors of approved applications.

The Office of Device Evaluation is organized as follows:

1. Program Management Office - Provides administrative functions for the office.

2. Program Operations Staff - Advises Office officials on premarket approval application, investigational device exemptions, premarket notification activities and classification/reclassification activities.

The Divisions serve as the primary source for scientific and medical device expertise with regard to safety and effectiveness.

3. Division of General, Restorative and Neurological Devices - general and restorative devices and neurological devices.

4. Division of Clinical Laboratory Devices-clinical laboratory devices.

5. Division of Cardiovascular Devices - cardiovascular and respiratory.

6. Division of Ophthalmic and Ear, Nose and Throat Devices - ophthalmic devices and ear, nose, and throat.

7. Division of Reproductive, Abdominal, & Radiological Devices; radiology; obstetrics/gynecology; and gastroenterology/urology medical devices.

8. Division of Anesthesiology, General Hospital, Infection Control and Dental Devices - dental, infection control and general hospital devices.

246 - OFFICE OF SURVEILLANCE AND BIOMETRICS (HFZ-500) SUSAN N. GARDNER, Ph.D., DIRECTOR

The Office of Surveillance and Biometrics (OSB) manages Center programs to collect, evaluate and disseminate medical device data, including information on injuries and other device related experiences. OSB also provides statistical, epidemiological, and biometrics services in support of the operating and administrative programs of the Center.

This office has a staff and three Divisions as follows:

1. Issues Management Staff - Directs and monitors the analysis, resolution and development and solution implementation of postmarket issues.

2. Division of Surveillance Systems - Serves as the office focal point in planning, developing, implementing, and maintaining databases and information systems.

3. Division of Postmarket Surveillance - Plans, evaluates, and coordinates all postmarket surveillance activities.

4. Division of Biostatistics - Provides statistical computational support activities for internal and external Center programs.

247 - OFFICE OF IN VITRO DIAGNOSTICS (HFZ-440) STEVE GUTMAN, M.D., DIRECTOR

SUBCHAPTER 250 - CENTER FOR VETERINARY MEDICINE (CVM)

250 - OFFICE OF THE CENTER DIRECTOR (HFV-1)

Stephen F. Sundlof, DVM, Ph.D., is the Center Director.

George A. Mitchell, DVM, is the Associate Director for Policy and Regulations. The Deputy Center Director is Linda K. Tollefson, DVM, Ph.D.

The Office of the Director is located at: MPN IV, 7519 Standish Place, Rockville, MD 20855 (301-827-2950).

CVM develops and recommends the veterinary medical policy of the Agency with respect to the safety and effectiveness of animal drugs, feeds, feed additives, veterinary medical devices (medical devices for animal use), and other veterinary medical products. CVM also ensures the food from these animals is safe before drugs are approved for marketing.

The Center evaluates, for animal safety and effectiveness, proposed and marketed animal drugs and feed additives and marketed veterinary medical devices. It coordi-

nates, evaluates, and plans Agency inspectional, investigational and surveillance programs.

Additional information on CVM can be found on their website at: www.fda.gov/cvm.

There are four offices within CVM that help to accomplish the mission of the Center. Those offices are as follows:

251 - OFFICE OF MANAGEMENT AND COMMUNICATION (HFV-10)

Robert W. Sauer is the Office Director. The Office is located at MPN IV. A contact phone number is 301-827-4410.

This office provides management oversight, administrative program and systems support for CVM. It is the CVM Freedom of Information focal point and provides educational information and material to both the consumer and industry. It also serves as liaison within FDA as well as with other government agencies.

The four staffs within this office are:

1. Administrative Staff (HFV-15)
Barbara E. Leach, Director
2. Communications Staff (HFV-12)
Jon W. Scheid, Director
3. Program Planning and Evaluation Staff (HFV-11)
David L. Lynch, Acting Director
4. Information Resources Management Staff (HFV-16):
 - Information Resources Support: Michele Koff
 - Data Applications: Dr. Jerome J. McDonald

252 - OFFICE OF NEW ANIMAL DRUG EVALUATION (HFV-100)

The Office Director is Dr. Claire M. Lathers. This Office is located at MPN II, 7500 Standish Place, Rockville, MD 20855. A contact phone number is: 301-827-1796.

This office is responsible for evaluating for animal safety and effectiveness new animal drugs in pharmaceutical dosage forms or feed delivered products. It evaluates the safety aspects of drug and food additive residues remaining in food produced for human consumption from animals given drugs or food additives. It also coordinates the development and implementation of regulations and policies pertaining to new drugs intended for animal use.

The five divisions in this office are:

1. Div. of Therapeutic Drugs for Non-Food Animals (HFV-110), Dr. Melanie R. Berson, DVM, Director
2. Div. of Biometrics & Production Drugs (HFV-120)
Woodrow M. Knight, Ph.D., Director
3. Div. of Therapeutic Drugs for Food Animals (HFV-130), Steven V. Vaughn, DVM, Director
4. Div. of Manufacturing Technologies (HFV-140)
William G. Marnane, Director
5. Div. of Human Food Safety (HFV-150)
Dr. Mark Robinson, Ph.D., Director

253 - OFFICE OF SURVEILLANCE AND COMPLIANCE (HFV-200)

The Acting Director for this office is Daniel G. McChesney, Ph.D. This office is located at MPN II. A contact phone number is 301-827-6644.

This office has the responsibility of maintaining the effectiveness of the animal drugs which have been approved and ensuring animals treated with drugs are safe for human consumption. It also maintains the safety and effectiveness of animal feeds, feed additives, veterinary medical devices, and other veterinary medical products.

The four divisions in this office are:

1. Division of Surveillance (HFV-210)
William C. Keller, DVM, Director
2. Division of Animal Feeds (HFV-220)
George Graber, Ph.D., Director
3. Division of Compliance (HFV-230)
Gloria Dunnavan, Director
4. Division of Epidemiology (HFV-250)
Charlotte Spires, Director

254 - OFFICE OF RESEARCH (HFV-500)

The Director is Norris E. Alderson, Ph.D. This office is located at MOD II, 8401 Muirkirk Road, Laurel, MD. A contact phone number is: 301-827-8010.

This office provides a focal point for all research activities in the Center. It serves as the liaison for intramural and extramural research. It evaluates and interprets results of scientific research, initiates and recommends action as appropriate to implement policy changes.

The three divisions in this office are:

1. Division of Residue Chemistry (HFV-510)
Michael H. Thomas, Director
2. Division of Animal Research (HFV-520)
Dr. David A. Frobish, Director
3. Division of Animal and Food Microbiology (HFV-530), Robert Walker, Ph.D., Director

SUBCHAPTER 260 - CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

260 - OFFICE OF THE CENTER DIRECTOR

The majority of CFSAN's offices moved to a new building in College Park, MD. This address is 5100 Paint Branch Parkway, College Park, MD 20740-3835. Agency and Center on-line directories have been updated.

The CFSAN director is Robert E. Brackett, Ph.D. The Center Director's Office consists of the Deputy Director, Janice F. Oliver; Director Food Safety Initiatives, **vacant**; Director Office of Regulations and Policy, L. Robert Lake; Director, Office of Constituent Operations, Catherine W. Carnevale, DVM; Director Office of Management Systems, Juanita Wills; and Director Office of Science, Robert L. Buchanan, Ph.D.

This Center develops FDA policy with respect to the safety, composition, quality (including nutrition), and labeling of foods, food additives, colors, and cosmetics.

CFSAN researches and develops standards on the safety and composition of foods, food additives, colors and cosmetics. CFSAN also conducts research to improve methodology and methods of detection of various contaminants for regulated products.

It develops and promulgates good manufacturing practice regulations (GMP's), model ordinances, compliance programs, reviews food and color additive applications and has other food related programs.

CFSAN has about 900 employees.

260.01 - Food Safety Staff (HFS-32) Vacant, Director

This office provides guidance, oversight, and coordination to a variety of substantive activities in response to the President's Food Safety Initiative mandates. Serves as liaison to appropriate Federal, State, local and foreign governments, industry, consumer groups, and academia with regard to the Food Safety Initiative activities.

260.02 - Office of Regulation and Policy (HFS-4), L. Robert Lake, Director

The Office of Regulations and Policy (ORP) coordinates the development and review of food regulations and policies and resolves food policy issues in collaboration with the Center Director and other members of the senior management team. ORP serves as the Center focal point and provides a centralized monitoring, coordinating, and advisory function for the Center on policies involving sensitive, controversial and complex food issues, including proposed regulations. ORP also advises Center officials on regulatory approaches and manages the planning of the Center's regulation development activities. There is one office staff, a Food Biotechnology Coordinator and one office under the Director of Regulation and Policy:

1. Regulations Coordination Staff
2. Food Biotechnology Coordinator

260.021 - Office of Constituent Operations The Office of Constituent Operations (OCO, HFS-550), Catherine W. Carnevale, V.M.D., Director

The Office of Constituent Operations (OCO) is responsible for managing and coordinating the Center's international activities, consumer outreach and education functions, day-to-day communication and outreach to the food and cosmetic industries, and coordinating the content of the CFSAN website.

OCO's international functions are managed by the OCO **Director's Office** and the **International Activities Staff**. The objectives of these activities are: (1) to provide a CFSAN interface with and support to the FDA Office of International Programs (OIP) in line with the OIP Action Plan on International Activities; (2) to provide programmat-

ic expertise and policy guidance to CFSAN Offices on Center and Agency regulatory decisions as they bear on, or are affected by, international considerations; and (3) to provide counsel and guidance to FDA staff and other U.S. government agencies to assure that CFSAN and FDA food and cosmetic regulatory activities and policies that are carried out under the Food, Drug and Cosmetic Act and other relevant statutes are also consistent with legally binding provisions of international trade agreements to which the United States is a party.

Consumer outreach is coordinated by the **Consumer Education Staff**. This staff maintains the CFSAN Outreach and Information Center (O&IC). The O&IC operates a 24-hour, multi-line telephone Food and Cosmetic Information Line where consumers can obtain up-to-date information on food and cosmetic safety and labeling issues. CES also handles the majority of FDA's consumer inquiries and correspondence about FDA-regulated foods and cosmetics.

OCO's **Industry Activities Staff** is a focal point for domestic and foreign food and cosmetic industries, principally production and distribution facilities, to obtain current information on FDA regulations, procedures and practices. This staff responds to day-to-day telephone, e-mail and letter inquiries to assist industry with understanding means of compliance with FDA regulations.

Finally, OCO, through the **Website Content Coordinator**, provides oversight and coordination of the content of CFSAN's internet website.

260.03 - Office of Management Systems (HFS-650), Juanita Wills, Director

Advise the Center Director on administrative policies and guidelines and scientific and technical information systems. Plans and directs all operations related to budget, financial, personnel management, training, employee development, etc. Provides guidance for Center ADP systems and their purchase.

The Office has the following:

Special Assistant: Michele Chatfield

Safety Management Staff: Director, Dorie Waddick

Division of Administrative Services: Director: Carolyn Redmond (Acting)

Division of Planning and Financial Resources Management: Director: Grover G. Heiman, III. The Division of Planning and Financial Resources Management has the following teams.

- Program Planning and Analysis Team
- Extramural and Operating Contracts Team
- Budget Execution Team

Division of Management Operations: Director: Denise K. Riley. The Division of Management Operations has the following teams

- Human Resources Development Team
- General Services Team
- Metro Lab and Offices Service Team

Division of Information Resources Management: Director: Charles Exley

The Division of Information Resources Management has the following:

Computer Systems Branch

- Personal Computer Management Team
- Database Applications Team
- Library Services Staff

Telecommunication and Scientific Computer Support Branch

- Data Communications and Network Team
- Intranet Services Team
- System Programming Team

**260.04 - Office of Science (HFS-6)
Robert L. Buchanan**

Advises Center Director and CFSAN management team on scientific issues related to food safety and applied nutrition. Provides coordination and review on matters related to cross-cutting scientific issues involving multiple offices or disciplines. Develops centerwide management systems for effective planning, use and mobilization of CFSAN scientific resources. Serves as focal point for activities related to scientific collaborations, particularly scientific consortia in which CFSAN is a member (i.e. National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, National Center for Natural Products Research.

Associate Senior Science Advisor: Patricia Hansen
Associate Senior Science Advisor for Research and Planning: V. Kelly Bunning

Advisory Committee Staff: Catherine DeRoever
Joint Institute for Food Safety and Applied Nutrition:
Arthur J. Miller, Ph.D.

Staff College: George J. Jackson, Ph.D.
National Center for Food Safety and Technology:
David Armstrong

Lead Scientist for Nutrition: Elizabeth Yetley
Lead Scientist for Epidemiology: Morris E. Potter, DVM

**261 - OFFICE OF THE DEPUTY DIRECTOR,
JANICE F. OLIVER**

This office advises and assists the Center Director and other key officials on Center programmatic matters. It provides direction, coordination and oversight for the programmatic activities of the center.

**261.01 - Associate Director of Operations,
Arnold P. Borsetti, Ph.D.**

Assists the Deputy Center Director in providing direction and oversight to CFSAN program functions.

261.02 - EEO Office, Joan J. Jappa, Ph.D.

This office plans, develops and implements the Center's Affirmative Action and Equal Employment Opportunity Programs.

**261.03 - Executive Operations Staff,
Catherine J. Bailey, Director**

This office provides correspondence control for the Center; processes Agency public correspondence referred to the Center Director; develops and operates tracking systems designed to provide early warning and to resolve delays in controlled correspondence. It provides direct support to the Center Director and to the Deputy Center Director including briefing materials, background information for meetings and preparation and coordination of speeches. The staff manages the Center's Freedom of Information Act activities, coordinating responses with other Center technical, regulatory and policy units as well as developing direct responses and performs special Center wide assignments involving complex problems and issues related to Center programs, strategies and activities.

**261.04 - Office of Cosmetics and Colors
(HFS-100), Linda Katz, Ph.D., Director**

Serves as focal point for actions involving colors and cosmetics including, but not limited to scientific studies, toxicological studies, microbiological studies, etc. It also serves as reviewer of cosmetic and color petitions, legal actions involving these products and develops regulations, compliance policy, position papers, regulatory guidelines and advisory opinions.

**261.05 - Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-800),
Christine J. Taylor, Ph.D., Director**

Has the primary responsibility for all matters pertaining to food labeling, food standards, dietary supplements and special nutritionals, including infant formula and medical foods. The office develops regulations, compliance policy, position papers, regulatory guidelines, and advisory opinions for matters within the scope of the responsibility of the Office and establishes labeling requirements appropriate for such foods, in coordination with other Center components. Reviews proposed regulatory actions for policy consideration, and provides technical evaluation and necessary scientific support. Develops appropriate methods for food and dietary supplement analyses and, in cooperation with the Field, maintains the Center's analytical capability for labeling compliance. Provides expert advice and assistance to the Center Director, other key officials, and the field on policy issues, field programs, and responses to petitions, initiatives, and related activities within the scope of the responsibility of the Office. The Office of Nutritional Products, Labeling and Dietary Supplements has four divisions which are:

- 1, Division of Compliance and Enforcement (HFS-810), John B. Foret
2. Division of Standards and Labeling Regulations (HFS-820), Felicia B. Satchell
3. Division of Nutrition Science and Policy (HFS-830), Lynn A. Larsen

4. Division of Research and Applied Technology (HFS-840), Jeanne I. Rader
5. Infant Formula and Medical Foods Staff (HFS-850), Dr. Charles Mize, Acting Director

261.06 - Office of Food Additive Safety (HFS-200), Alan M. Rulis, Ph.D., Director

Develops regulations, advisory opinions, guidelines, position papers, etc. related to safe uses of food additives, color additives, GRAS substances, prior sanctioned substances and bioengineered foods. Manages petition review process for food and color additives and notification processes for food contact substances, GRAS substances, and bioengineered foods. Reviews proposed regulatory actions.

261.07 - Office of Plant and Dairy Food and Beverages (HFS-300) Terry C. Troxell, Ph.D., Director

Develops regulations, compliance policy, position papers, regulatory guidelines, etc. on food production and packaging techniques including chemical and microbial issues of food safety. Assesses chemical and biological contaminants including pesticides and industrial chemicals in foods for safety. Reviews proposed regulatory actions.

261.08 - Office of Seafoods (HFS-400), Philip Spiller, Director

Develops regulations, compliance policy, regulatory guidelines, labeling requirements, etc. for seafood and related products. Manages voluntary and mandatory seafood safety programs and researches various seafood industries such as aquaculture, harvesting and processing. Administers the National Shellfish Sanitation Program. Reviews proposed regulatory actions.

The Office of Seafood has two Divisions which are:

1. Division of Programs and Enforcement Policy (HFS-415) - Mary I. Snyder, Director
2. Division of Applied Science and Technology (HFS-425) - George Hoskin, Director

261.09 - Office of Applied Research and Safety Assessment (HFS-025), Thomas A. Cebula, Director

The Office of Applied Research and Safety Assessment (OARSA) recommends, develops, coordinates and conducts research in the areas of molecular biology, microbiology (virulence assessment), toxicology and nutrition to help meet the research needs of the Center's Program Offices. The Office also coordinates development of long-term research planning, in responsible program areas, with other Center and Agency components, and serves as the Center's principal research liaison with other agency centers and organizations outside the Agency. Within the molecular biology and microbial areas, OARSA scientists provide materials and training in gene probe methodology

and conduct research on: the effects of microbes, their toxins and metabolic products using a variety of animal and in vitro models; identification of unknown microbial illness factors; and the mechanisms of gene activation. The toxicology divisions conduct research to determine the safety and health hazards of foods, nutritional supplements, food and color additives, chemical contaminants, cosmetic ingredients and natural toxicants, and the metabolites of these substances. The elucidation of toxicological effects is undertaken using a variety of short-term indicators, including tissue and cell culture methods, as well as through the conduct of standard regulatory toxicology studies.

261.10 - Office of Compliance (HFS-600), Joseph Baca, Director

Serves as CFSAN's liaison and focal point with the field. Serves as Center's lead office for all communications between ORA/ORO/Emergency Operations Center, HFC-160 and CFSAN relating to emergency response. Coordinates Center's program office activities with the Office of Regional Operations in development of field programs and evaluates field accomplishments by providing feedback to Center management. Manages and provides guidance to the various cooperative programs such as shellfish, milk safety, food service, interstate travel sanitation and HACCP.

This Office has the following three divisions:

1. Division of Enforcement (HFS-605)
Judith Gushee, Director
2. Division of Field Programs (HFS-615)
Leslie Bluhm, Director
3. Division of Cooperative Programs (HFS-625)
Faye Feldstein, Acting Director

261.11 - Office of Scientific Analysis and Support (HFS-700) Kenneth J. Falci, Ph.D., Director

Provides scientific analysis and support to all CFSAN offices in carrying out their mission. This includes developing economic impact analyses for food and cosmetic regulations, conducting consumer attitude and behavior studies related to diet and disease, biotechnology, food labeling and claims, and infant feeding and food safety practices. Provides epidemiological reviews for microorganism risk assessment, acute health hazard evaluations, and estimates the burden of foodborne illness. Supports CFSAN research through assistance with experimental design, mathematical input and statistical analysis of experimental data. Conducts post-market surveillance and assesses adverse reactions to food products. Develops compliance and survey sampling plans. Assists international organizations such as the AOAC International and CODEX in the development of policy and criteria for review of analytical methods performance and in developing sampling plans to ensure fair and valid procedures are used when food is being tested for compliance with commodity standards. Provides pathology support to the in-house experimental studies for animal necropsies and processing and evalua-

tion of animal tissues, in evaluating pathology data and reviewing microslides provides to the Agency as part of industry submissions, and in assisting other FDA Centers with pathology issues when requested. Provides analytical support. Additionally, the Office contributes to the activities of the Health Hazard Evaluation Board, the Institutional Animal Care and Use Committee (IACUC), and Cancer Assessment and Quantitative Risk Assessment Committees.

This office has the following divisions:

1. Division of Mathematics - Foster D. McClure, Director
Petition Review and Experimental Design Team
Biometrics and Risk Assessment Team
2. Division of General Scientific Support - Prem N. Dua, DVM, Ph.D., Director
3. Division of Market Studies - Richard A. Williams, Jr., Ph.D., Director
4. CFSAN Adverse Events Reporting (CAERS) Staff
The Division of Market Studies has the following Teams:
 - A. Economics Team
 - B. Consumer Studies Team
 - C. Epidemiology Team

SUBCHAPTER 270 - OFFICE OF REGULATORY AFFAIRS

270 - ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS (HFC-1)

The Associate Commissioner for Regulatory Affairs (ACRA) is John M. Taylor, III and the Deputy Associate Commissioner for Regulatory Affairs is John Marzilli. The Assistant Commissioner for Regulatory Affairs is Steven Nidelman.

ORA is under the leadership of an Associate Commissioner known as the ACRA. This office is responsible for the activities and operations of the field headquarters staff and the field staff of FDA. The Regional Food and Drug Directors (RFDD's) report to this office.

This office advises and assists the Commissioner and other key officials on regulations and compliance oriented matters which have an impact on policy development and execution and long-range program goals.

As of August 2003, there were about 626 employees in ORA headquarters and about 3508 additional employees in the ORA field organization. For ORA contact information, see the ORA Field Contacts Directory at the end of this chapter.

Immediate office of ORA:

- Special Assistant to ACRA - Alyson Saben
- Special Assistant for Import Policy - Vacant
- Regulatory Counsels - Carolyn Becker and Ann Kirchner
- Performance Results Staff Coordinator - Marie Urban
- Equal Employment Opportunity Staff - Mary Davis
- Senior Advisor for Clinical Science - Lori Love

271 - ORA HEADQUARTERS ORGANIZATION

ORA consists of four individual offices which operate independently of each other. However, their functions are related and they support each other. A description of the function of each office is outlined below.

271.01 - Office of Resource Management (ORM) (HFC-10), Vacant, Director

ORM is basically responsible for the planning, management, and evaluation of the operations of the field offices. It is also responsible for the computer systems which handle the information generated by the field offices.

The Division of Management Operations in ORM controls the budget for the field's day to day operations. ORM allocates funds as determined by actual needs of the field and headquarters units.

The training of personnel stationed in the field is also coordinated by The Division of Human Resource Development in ORM coordinates training of field personnel. The Deputy Director of ORM is James M. Strachan.

ORM has the following divisions:

1. Division of Management Operations (HFC-20)
Director - Richard Garwood; Deputy Director - Vacant
 1. Management Operations & Analysis Group
Director - Vacant
 2. Financial & Program Analysis Group,
Lee Swerock, Director
 3. Facilities Management Group,
Randy Higgins, Director
2. Office of Information Technology (HFC-30)
Mark Gregory, Director
Donald Chi, Associate Director
 1. Paul Banas, Director, Infrastructure
Management and Operations Branch
 2. Carole Stone, Director, Infrastructure
Applications Branch
 3. Marvin Bell, Director, Enterprise Systems
Branch
 4. Laurie Hager, Director, Customer Support
Branch
 5. David Graves, ORA IT Enterprise Architect
3. Division of Planning, Evaluation and
Management (HFC-40), Susan C. Baer, Director
Vacant, Deputy Director
 1. Program Planning & Workforce Mgmt.
Branch, Michael W. Roosevelt, Director
 2. Program Evaluation Branch
John A. Lechus, Director
4. Division of Human Resource Development
(HFC-60), Gary German, Director
Leona O'Reilly, Deputy Director
5. Division of Personnel Operations
Vacant, Director
6. Commissioned Corps Liaison, Virginia Mahady

Also included within ORM is the FDA History Office (HFC-24): John Swann, Suzanne White Junod, Ronald Ottes, and Robert Tucker.

271.02 - Office of Regional Operations (ORO) (HFC-100) Deborah D. Ralston, Director

The Director of ORO is currently Deborah D. Ralston. The Deputy Director is Steven Solomon, Ph.D. Special Assistant to the Director is Kara Lynch.

ORO coordinates and manages all Agency field operations and the Team Biologics Core Team on behalf of the ACRA; 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.

It evaluates the overall management and capabilities of the Agency's field organization; initiates action to improve the management of field activities. Coordinates nationwide health fraud activities between the field, states, and Headquarters organizations. Coordinates field public affairs and information programs; distributes timely information to the field; coordinates activities with Agency counterpart organizations. Serves as the Agency focal point in developing and maintaining international regulatory policy and activities to assure the safety, efficacy, and wholesomeness of regulated imported products. Coordinates Agency procedures with Headquarters and field offices and is the primary contact with the U.S. Customs Service and others among those offices. Develops and/or recommends to the ACRA policy, program, and plans for applied research relating to Agency enforcement problems; coordinates such research efforts with appropriate agency components. Directs and coordinates the Agency's emergency preparedness and civil defense programs. Provides other Agency components with laboratory support in highly specialized areas.

ORO has the following components:

1. Emergency Operations Center (HFC-160)

Ellen Morrison, Director

Conception Cruz, Deputy Director

The Emergency Operations Center, was recently reorganized into the new Office of Crisis Management under the Office of the Commissioner. Future IOM updates will reflect this change. It coordinates and provides facts regarding epidemiological investigations and other potential imminent dangers to public health on a 24-hour, seven-day-a-week basis to Headquarters, regional and district staff.

The Division Director and Deputy Director may be reached at (301) 827-5653, the 24 hour emergency line (301)443-1240 or on their direct lines (301) 827-5660 (Ellen Morrison) and (301)827-5655 (Dep. Director).

Personnel assigned to the Emergency Operations Center:

Pete Cook	Emergency Coordinator	(301) 827-5630
Lara Davidson	Bioterrorism Coordinator	(301) 827-2170
Mark I. Fow, Ph.D.	Emergency Coordinator	(301) 827-5650
Sandra Hanson	Emergency Coordinator	(301) 827-5642
Vacant	Epidemiologist	(301) 827-2180
Israel Santiago	National Consumer Complaint and Emergency Operations Coordinator	(301) 827-5670

2. Division of Field Investigations (HFC-130)

Michael C. Rogers, Director (301) 827-5653

DFI provides coordination, direction, assistance, and management for the field's domestic and foreign investigative activities. It serves as the Agency focal point for Headquarters/field relationships on investigational and inspection problems, and programs and operations.

It develops and reviews investigative and inspectional procedures, training programs, and prepares and issues investigative and inspectional guidance manuals. The division provides the field investigative and engineering technical assistance and guidance for foreign inspections.

DFI has two branches: Domestic Operations Branch and International Operations Branch. The Division's deputy director manages ORA's National Experts.

Patricia Alcock Lefler is the Deputy Director. She can be reached at (301) 827-5653.

Gerald Miller is the Director of the Domestic Operations Branch. He can be reached at (301) 827-5653.

Rebecca Ramos Hackett is the Manager of the International Operations Branch. She may be reached at (301) 827-5653.

The following personnel within the Domestic Operations Branch are available to help you in various program related activities and may be reached at DFI's main number (301) 827-5653 or at the number below:

Charles Ahn	Computers/Computer Utilization, Human Drugs	(301) 827-5637
James Dunnie	Human Drugs, Veterinary Drugs	(301) 827-5652
Alan Gion	Medical Devices	(301) 827-5649
Norman Fogg	Foods	(301) 827-5645
Gail Katz	Biologics	(301) 827-3357
Ruark Lanham	Foods	(301) 827-6691
Barbara Marcelletti	Foods, Seafood HACCP	(301) 827-5635
Diann Shaffer	Bioresearch Monitoring	(301) 827-1124
Christine Twohy	Biologics, Microbiology	(301) 827-5662
Valerie Wright	Medical Devices	(301) 827-5646

Personnel responsible for foreign inspections and trip planning in the International Operations Branch:

Linda Adams	Tech. Asst. Int'l Inspections	(301) 827-5648
Thanh Andrews	Devices Int'l Inspections	(301) 827-2975
Doreen Chin	Quee Tech Asst. Int'l Inspections	(301) 827-5632
Pattie Everett	Tech Asst. Int'l Inspections	(301) 827-5629
Cherae Frazier	Tech Asst. Int'l Inspections	(301) 827-5628
Atilla Kadar	BIMO Int'l Inspections	(301) 827-5647
vacant	Drug Int'l Inspections	(301) 827-2975
Irma Rivera	Tech Asst. Intl. Inspections	(301) 827-5665
Janet Rowe	Tech. Asst. Int'l Inspections	(301) 827-5633
Patricia Simmons	Tech. Asst. Int'l Inspections	(301) 827-5668
vacant	Drug Int'l Inspections	(301) 827-5653
Joyce Watson	Biologics Int'l Inspections	(301) 827-5636

The National Experts assigned to DFI are:

Thomas Arista	DAL-DO Biotechnology NE	(214) 655-5308
Mary T. Carden	NYK/BUF Biologics NE	(716) 551-4461
Karen A. Coleman	ATL-DO Devices NE	(404) 347-3218
Robert Coleman	ATL-DO Drugs/Bimo NE	(404) 347-3218
Debra Devlieger	SEA-DO Food/LACF NE	(206) 553-7001
Charles M. Edwards	PHI-DO Drugs/Bimo NE	(215) 597-0983
Mike Ellison	BLT-DO Food/LACF NE	(410) 749-0540
Brian Hendrickson	DET-DO Food/LACF NE	(317) 226-6500x12
Joan Loreng	PHI-DO Biologics NE	(215) 362-0740
Rebecca Rodriguez	SJN-DO Drug NE	(787) 474-9556
Robert D. Tollefsen	SEA-DO Computer NE	(425) 486-8788
David B. Wieneke	MIN-DO Food, Aseptic Processing, Dairy NE	(612)334-4100
Monica J. Wilkins	DAL-DO Devices NE	(214) 253-5200
Norman Wong	SEA-DO Devices NE	(206) 483-4935

3. Division of Field Science (DFS) HFC-140

Michael Olson, Director
 Thomas Savage, Deputy Director
 (301) 827-1232

DFS provides a focal point for all aspects of ORA Field Laboratories and serves as the Headquarters' scientific and technical staff. It manages FDA's overall field scientific resources to assure their coordinated, efficient, and effective use; provides coordination between field and center scientific programs, and develops and manages the Science Advisor Program and Department of Defense Shelflife Extension Program.

DFS manages field research programs and the applicability of new, complex, scientific instruments for field analyses and provides scientific and analytical expertise related to laboratory automation, analysis, process control and acquisition of automated data laboratory instruments. DFS manages the scientific aspects of the FACTS. The Division participates in the determination of long and short-range field scientific facility needs and in the formulation, delivery, and evaluation of training and career development plans for field scientists. Program contacts in DFS are:

- a. Carl Sciacchitano, Research Planning & Coordination Team Leader (301) 827-7606
- b. Larry D'Hoostelaere, CBER/CDRH programs contact
- c. Marsha Hayden, CFSAN programs contact
- d. Elise Murphy, CDER programs contact
- e. George Salem, CVM programs contact

4. Division of Federal-State Relations (DFSR)

HFC-150 - Richard Barnes, Director
 (301)443-3360
 Paul Raynes, Deputy Director

DFSR is the ORA headquarters focal point for interactions with the regional specialists located in every region, that comprise the Federal-State Cooperative Programs (SCP). The SCP are composed of three separate food safety programs, the Interstate Milk Shippers Program, the National Shellfish Sanitation Program and the Retail Food Protection Program. The authority for these programs is provided in the Public Health Service Act (42 USC 243).

FDA has signed Memoranda of Understanding (MOU's) with the Interstate Milk Shippers Conference and the Interstate Shellfish Sanitation Conference. These MOU's spell out FDA and state responsibilities that must be met to insure the uninterrupted shipment of these commodities between states. FDA has also signed an MOU with the Conference of Food Protection that will guide future federal-state cooperation in this program. See IOM Chapter 3 for an explanation of all MOU's.

Funding and position allocation for the Cooperative Programs is through the Center for Food Safety and Applied Nutrition (CFSAN) which makes allocations to ORA for the programs.

Regional Specialists are the first point of contact for the states for answers and explanations on any technical issues that arise. Several Cooperative Program Specialists are located in each Region and are available to answer questions and offer assistance and expertise when investigations involve these products.

- RETAIL FOOD PROTECTION PROGRAM (Retail Food Safety Program)

The primary objective of the Retail Food Safety Program is to prevent foodborne illness at the retail level of the food industry by directing activities toward promotion of effective state and regulatory programs. Regional Food Specialists (RFS) are responsible for state program evaluations, standardization of state officials, training and technical assistance to state programs. Interstate Travel Sanitation Program (ITP) Specialists, located in the Districts, receive training and standardization from the RFS. Regional Food Specialists may be asked for technical assistance on a variety of food safety and public health topics.

- INTERSTATE MILK SHIPPERS PROGRAM (Milk Safety Program)

The objectives of the Milk Safety Program activities are to provide assistance to the states in the prevention of foodborne and communicable diseases and in the adoption, implementation and enforcement of the uniform technical guidelines, administrative procedures and regulatory standards provided in the Pasteurized Milk Ordinance (PMO) and related documents. Regional Milk Specialists (RMS) provide technical assistance and training, conduct check-ratings (audits) and standardize state officials. The RMS's also evaluate state programs to measure state program effectiveness, provide advice on the program's strengths and weaknesses and make recommendations for improvements.

- NATIONAL SHELLFISH SANITATION PROGRAM (Shellfish Safety Program)

The objective of the Shellfish Safety Program is to prevent food-borne illness from the consumption of raw Molluscan shellfish, primarily oysters, clams and mussels. Food borne illnesses from these organisms include a variety of hazardous materials such as heavy metals, biological toxins, and pathogens. FDA provides oversight to 29 states and four foreign countries that are members in the National Shellfish Sanitation Program (NSSP). The NSSP provides for a system of controls, which follow the shellfish from their growing area through harvest, distribution and wholesale sale. FDA Regional Shellfish Specialists (RSS) evaluate state and foreign programs, and provide training and technical assistance regarding the current practice in shellfish control and related topics of environmental science and shellfish processing.

5. Division of Import Operations Policy (DIOP) HFC-170

Director Carl Nielsen
 Deputy Director, Joseph L. McCallion

This division provides direction, assistance, management and oversight of field import operations. Serves as Agency focal point for contact with U.S. Customs and other Federal Agencies regarding import activities. Develops and reviews agency import policies, procedures, programs, etc. and is responsible for issuing import informational directives (Import Alerts, Bulletins, etc.) and RPM, Chapter 9. DIOP is responsible for the maintenance of the Operational

and Administrative System for Import Support (OASIS), including the coordination with program Centers to establish automated screening criteria.

Contact points within DIOP are:

- a. Systems Branch (HFC-171)
Vacant, Director
- b. Operations and Policy Staff (HFC-172)
Rotational Coordinator
- c. Customs Liaison (HFC-170)
Vacant

271.03 - Office of Enforcement (OE) - HFC-200 David K. Elder, Director

The Director of OE is David K. Elder and the Director of Compliance is Carl E. Draper.

OE advises and assists the ACRA and other key officials on regulations and compliance policy matters which impact on policy development, implementation and long range goals. OE also coordinates, interprets, and evaluates the FDA's overall compliance efforts and, as necessary, establishes compliance policy and recommends policy to the ACRA.

OE also acts as liaison with other federal agencies on compliance matters, evaluates proposed legal actions, coordinates actions with the Office of Regional Operations (ORO) and the Office of Chief Counsel (OCC) and handles appeals of proposed compliance actions which are disapproved by the centers or OCC.

This office coordinates agency bioresearch monitoring activities and serves as Agency focal point for the Federal Medical Products Quality Assurance Program (GWQAP).

OE consists of the following elements:

1. Division of Compliance Management and Operations & Recall Staff (HFC-210)
Sandra Whetstone, Director
2. Division of Compliance Policy (HFC-230)
Lana Ogram, Director
3. Division of Compliance Information & Quality Assurance Staff (HFC-240)
Scott MacIntire, Director

271.04 - Office of Criminal Investigations (OCI) (HFC-300) Terrell L. Vermillion, Director

This office advises and assists the ACRA and other key officials on regulations and criminal violations involving regulated activities and products.

OCI directs and conducts criminal investigative activities in coordination with FDA headquarters units and with other Federal, state and local law enforcement agencies. OCI is instrumental in implementing FDA criminal investigation policy, training, and coordination. OCI interfaces directly with Federal and local prosecutorial offices and participates in grand jury proceedings and judicial actions as required.

OCI has 170 employees in headquarters and the field.

272 - ORA FIELD ORGANIZATION

The ORA field organization is divided into regional offices. The Regional Offices are under the control of Regional Food and Drug Directors (RFDD's) who report to the ACRA. There are currently five regional offices which are located as follows:

- Northeast New York, NY
- Central Philadelphia, PA
- Southeast Atlanta, GA
- Southwest Dallas, TX
- Pacific San Francisco, CA

Each regional office controls 2 to 7 district offices.

There are currently 20 district offices located in major cities around the country. IOM Appendix G shows the location of these district offices. The regional affiliation of these offices is also indicated in the Appendix.

Each district office (DO) is usually comprised of four branches or units as follows:

1. Administrative Branch
2. Compliance Branch
3. Investigations Branch - some DO's may have 2 investigations sections, one for domestic products and one for imported products.
4. Laboratory Branch - not all DO's have laboratories

Some districts have combined branches and some have gone to team based structures which are different from the traditional branch structure.

ORA HEADQUARTERS DIRECTORY

Associate Commissioner for Regulatory Affairs, (ACRA), 5600 Fishers Lane, Rockville, MD 20857

Emergency (after hours) Answering Service - Office of Crisis Management (301) 443-1240

John M. Taylor III, Associate Commissioner for Regulatory Affairs, Rm. 14-90, HFC-1 (301) 827-3101 FAX (301) 443-6591

(Carolyn Becker and Ann Kirchner), Regulatory Counsels to ACRA, HFC-1, (301) 827-2806 FAX (301) 827-0963

John Marzilli, Deputy Associate Commissioner, Rm. 14-90, HFC-2, (301) 827-3101 FAX 301-443-6591

Steven M. Niedelman, Assistant Commissioner for Regulatory Affairs, HFC-1, (301) 827-3101 FAX (301) 443-6591

Alyson L. Saben, Special Assistant to the ACRA, Rm. 14-90, HFC-1, (301) 827-3101 FAX (301) 443-6591

Amy R. Folden, Executive Assistant, Rm. 14-90, HFC-1, (301) 827-3101 FAX (301) 443-6591

(vacant) Senior Advisor for Regulatory Policy, Rm. 14-90, HFC-2, (301) 827-2682

Lori Love, Senior Advisor for Clinical Science, Rm. 12-A46 HFC-2, (301) 827-3684 FAX (301) 443-6591

Marie Urban, Director, Performance Results Staff, Rm. 13-93, HFC-2, (301) 827-0947 FAX (301) 827-0963

Mary Davis, Equal Opportunity Staff, Rm. 12A-05, HFC-15, (301) 827-2883 FAX (301) 480-7803

Office of Resource Management, (ORM), 5600 Fishers Lane, Rockville, MD 20857

(vacant), Director ORM, Rm. 13-45, HFC-10, (301) 443-2175 FAX (301) 443-7270

James M. Strachan, Deputy Director ORM, Rm. 13-45, HFC-10, (301) 443-2175

CAPT Virginia Mahady, Commissioned Corps Liaison, HFC-10, HFC-10, Rm. 163, 109 Holton St., Winchester, MA 01890, (781) 729-5700 Ext. 702

(vacant), Labor Management Relations Specialist, Rm. 13-45, HFC-10, (301) 827-1643

Richard Garwood, Dir. Div. of Management Operations, Rm. 5A-55, HFC-20, (301) 443-5821

Lee Swerock, Dir., Financial Program & Analysis Group, Rm. 5A-55, HFC-21, (301) 827-1206

Randy Higgins, Dir., Facilities Mgmt. Group, Rm. 5A-55, HFC-21, (301) 827-1202

Karen Flanigan, Safety Management Officer, Rm. 5A-55, HFC-21, (301) 827-1212

Ron Ottes, FDA History Office, Rm. 12-69, HFC-24, (301) 827-3758

John Swann, FDA History Office, Rm. 12-69, HFC-24, (301) 827-3756 FAX (301) 443-7270

Suzanne White Junod, FDA History Office, Rm. 12-69, HFC-24, (301) 827-3759 FAX (301) 443-7270

Mark Gregory, Director, Office of Information Technology, Rm. 5A-05, HFC-30, (301) 827-4090 FAX (301) 443-7270

Donald Chi, Associate Director, Office of Information Technology, Rm. 5A-05, HFC-30, (301) 827-1562 FAX (301) 443-0868

Carol Stone, Director, Infrastructure Applications Branch, Rm. 12-77, HFC-33, (301) 827-1561

Marvin Bell, Dir. Enterprise Systems Br., Rm. 5A-08, HFC-4, (301) 827-5504

Laurie Hager, Dir. Customer Support Branch, Rm 5A-05, HFC-31 (301) 827-2683

David Graves, ORA IT Enterprise Architect, Twinbrook 5, HFC-30 (301) 827-2887

Susan C. Baer, Dir. Planning, Evaluation & Management Div., Rm. 12-38, HFC-40, (301) 827-1626 FAX (301) 443-7212

(vacant), Deputy Dir. Planning, Evaluation and Management Br., Rm. 12-38, HFC-41, (301) 827-1629

Michael Roosevelt, Dir. Prog. Planning & Workforce Management Br., Rm. 12-38 HFC-41, (301) 827-1638

John A. Lechus, Dir. Program Evaluation Br., Rm. 12-38, HFC-42, (301) 827-1637

Gary German, Dir. Div. of Human Resource Development, HFC-60, (301) 594-1710 FAX (301) 594-1966

Leona O'Reilly, Dep. Dir. Div. of Human Resource Development, HFC-60, (301) 594-2174 FAX (301) 594-1966

(vacant), Dir., Div. Of Personnel Operations, HFC-50, Rm. 7B-24, (301) 827-4074

Office of Regional Operations, (ORO), 5600 Fishers Lane, Rockville, MD 20857

Emergency (after hours) Answering Service (301) 443-1240

Deborah D. Ralston, Dir. ORO, Rm. 13-61, HFC-100, (301) 443-6230 FAX (301) 443-1778

Steven M. Solomon, DVM, Dep. Dir. ORO, Rm. 13-61, HFC-101, (301) 443-6230

Kara Lynch, Special Assistant to the Dir., Rm. 13-61, HFC-102, (301) 443-6230

Michael C. Rogers, Dir. Div. of Field Investigations, Rm. 13-64, HFC-130, (301) 827-5653 FAX (301) 443-3757

Patricia Alcock Lefler, Dep. Dir. Div. of Field Investigations, Rm. 13-64, HFC-130, (301) 827- 5653 FAX (301) 443-3757

Gerald W. Miller, Dir., Domestic Operations Branch, Rm. 13-64, HFC-130, (301) 827-5653 FAX (301) 443-3757

Rebecca Ramos Hackett, Manager, Internat'l Oper. Br., Rm. 13-71, HFC-130, (301) 827-3777 FAX (301) 827-6685

Michael Olson, Dir. Div. of Field Science, Rm. 12-41, HFC-140, (301) 827-1232 FAX (301) 827-4575

Thomas Savage, Dep. Dir. Field Science, Rm. 12-41, HFC-140, (301) 443-3320

Richard H. Barnes, Div. of Fed-State Rel, Rm. 12-07, HFC-150, (301) 827-2905 FAX (301) 443-2143

Paul Raynes, Dep. Dir. Div. of Fed-State Rel., Rm. 12-07 HFC-150, (301) 827-2910

Cynthia Leggett, Pub Affairs & Health Fraud, Rm. 12-17, HFC-110, (301) 827-2914 FAX (301) 443-2143

Carl R. Nielsen, Dir. Div. of Import Oper & Policy, HFC-170, (301) 443-6553 FAX (301) 594-0413

(Overnight/Express Mail to: 5600 Fishers Lane, Room 12-38, Rockville, MD 20857)

Joseph L. McCallion, Deputy Dir. Div. of Import Operations and Policy, HFC-170, (301) 594-1218 FAX (301) 594-3787

(vacant), Dir., Systems Branch, HFC-171, (301) 443-6553

Office of Enforcement, (OE), 1350 Piccard Dr., 4th Floor, Rockville, Md. 20850

(Regular Mail to: 5600 Fishers Lane, Rockville, MD 20857)

David Elder, Director OE, HFC-200, (301) 827-0421 FAX (301) 827-1222

Carl Draper, Director of Compliance, HFC-201, (301) 827-0421 FAX (301) 827-1222

Donald Vasbinder, Special Assistant OE, HFC-201, (301) 827-0414 FAX (301) 827-1222

Sandra Whetstone, Dir. Div. of Compl Mgmt & Oper, HFC-210, (301) 827-0391 FAX (301) 827-0342

Lana Ogram, Dir. Div. of Compl Policy, HFC-230, (301) 827-0393 FAX (301) 827-0482

Scott MacIntire, Dir. Div. Comp Info & QA, HFC-240, (301) 827-0386 FAX (301) 827-0482

Office of Criminal Investigations, (OCI), HFC-300, 7500 Standish Place Suite 250 N., Rockville, MD 20855

Terrell L. Vermillion, Director, HFC-300, (301) 294-4030 FAX (301) 594-1971

Horace Coleman, Deputy Director, HFC-300, (301) 294-4030 FAX (301) 594-1971

James Dahl, Assistant Director (Special Programs), HFC-300, (301) 294-4030 FAX (301) 594-1971

Rodney V. Turner, Special Agent in Charge (SAIC), Investigative Operations Division, HFC-300, (301) 294-4030, FAX (301) 594-1971

Kathleen Martin-Weis, SAIC, Administrative Operations Division, HFC-300, (301) 294-4030 FAX (301) 827-1234

OCI, Chicago Field Office, HFH-530, 901 Warrenville Road, Suite 360, Lisle, IL 60532

Michael Cleary, SAIC, HFH-530 (630) 769-5520 FAX (630) 769-5550 (Covers IL, IN, MI, MN, ND, SD, WI)

OCI, Minneapolis Domicile, 21985 Keather Avenue North, Forest Lake, MN 55025

Kenneth Kulick, Special Agent (SA), (651) 433-5404 FAX (651) 433-4110

OCI, Kansas City Field Office, HFH-510, 5799 Broadmoor Street, Suite 600, Mission, KS 66202

Larry Sperl, SAIC, HFH-510 (913) 384-7400 FAX (913) 384-7421 Covers AR, CO, IA, KS, MO, NE, NM, UT, WY)

OCI, Austin Resident Office, HFH-511, 9430 Research Blvd., Bldg 2, Ste 250, Echelon II, Austin, TX 78759

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DAL-DO:	Lynnette Riggio	(214) 253-5260
DEN-DO:	Michael J. Quinn	(303) 236-3058
DET-DO:	Eric E. Joneson	(313) 393-8157
FLA-DO:	Ronald T. Weber	(407) 475-4724
KAN-DO:	Robert Wilson	(913) 752-2426
LOS-DO:	Vickie Anderson	(949) 798-7760
MIN-DO:	Rhonda Mecl	(612) 758-7198
NOL-DO:	Michael R. Duran, NSV-BR	(615) 781-5375 x116
NWE-DO:	William Boivin	(781) 596-7783
NWJ-DO:	Toniette Williams	(973) 526-6018
NYK-DO:	Upstate: Ray Kent	(716) 551-4461 x3126
	Downstate: Otto Vitillo	(516) 921-2869
PHI-DO:	Daniel R. Tammariello	(412) 644-3394 x16
SAN-DO:	vacant	(408) 291-4360 x25
SEA-DO:	David Pettenski	(425) 483-4911
SJN-DO:	Gilbert Andino	(787) 474-9502

DEVICE REGISTRATION MONITORS:

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BLT-DO:	Lori Lawless	(410) 779-5442
CHI-DO:	Linda E. Whitehead	(312) 596-4246

CIN-DO:	Laureen M. Geniusz	(330) 273-1038
DAL-DO:	Warren L. Landry	(214) 253-5230
DEN-DO:	Nicholas R. Nance	(303) 236-3052
DET-DO:	Eric E. Joneson	(313) 393-8157
FLA-DO:	Ronald T. Weber	(407) 475-4724
KAN-DO:	Robert Wilson	(913) 752-2426
LOS-DO:	Kirsten Tharp	(949) 798-7720
MIN-DO:	Rhonda Mecl	(612) 758-7198
NOL-DO:	Marion J. Ferrante	(504) 253-4523
NWE-DO:	William Boivin	(781) 596-7783
NWJ-DO:	Rosa Brown	(973) 526-6007
NYK-DO:	Upstate: Ann Okon	(716) 551-4461 x3120
NYK-DO:	Downstate: Elizabeth Jacobson	(914) 682-6166 x27
PHI-DO:	Steven L. Carter	(215) 597-4390 x4520
SAN-DO:	vacant	(408) 291-4350 x25
SEA-DO:	David A. Pettenski	(425) 483-4911
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DRUG MONITORS:

ATL-DO:	Leah Andrews	(404) 253-1285
BLT-DO:	Matthew Henciak	(410) 779-5438
CHI-DO:	Nick Lyons	(312) 596-4247
CIN-DO:	Steven P. Eastham	(513) 679-2700 x123
DAL-DO:	Jose Martinez	(210) 308-4528 x18
DEN-DO:	Elvin R. Smith	(303) 236-3087
DET-DO:	Patsy Domingo	(313) 393-8145
FLA-DO:	Keith S. Ehrlich	(561) 338-7631 x11
KAN-DO:	David Glasgow	(314) 645-1167 x116
LOS-DO:	Virgilio Pacio	(858) 550-3850 x116
MIN-DO:	Charles R. Cote	(608) 264-5322
NOL-DO:	M. Anthony Abel I, NSV-BR	(615) 781-5374 x111
NWE-DO:	Steven Souza	(203) 240-4289
NWJ-DO:	Meyer Slobotsky	(732) 940-8946 x12
NYK-DO:	Ray Kent	(716) 551-4461 x3126
PHI-DO:	Susan Laska	(215) 362-0740 x21
SAN-DO:	Darlene Almogela	(510) 337-6769
SEA-DO:	Carol A. Gripp	(425) 483-4905
SJN-DO:	Rebecca Rodriguez	(787) 474-9556

DRUG DEFECT REPORTING MONITORS:

ATL-DO:	Tracy L. Ball	(704) 344-6116
BLT-DO:	Melissa Garcia	(410) 779-5461
CHI-DO:	Kathy Haas	(312) 596-4250
CIN-DO:	David C. Radle	(513) 679-2700 x124
DAL-DO:	Jose Martinez	(210) 308-4528 x18
DEN-DO:	Michael J. Kuchta	(303) 236-3059
DET-DO:	Anthony C. Taube	(313) 393-8176
FLA-DO:	Susan M. Corrales	(561) 338-7631 x19
KAN-DO:	Gwyn Dickinson	(913) 752-2446
LOS-DO:	Binh Nguyen	(949) 798-7665
MIN-DO:	Kristine Zuroski	(612) 758-7169
NOL-DO:	M. Anthony Abel I, NSV-BR	(615) 781-5374 x111
NWE-DO:	Ellen Madigan	(781) 596-7753
NWJ-DO:	Mimi Roa Remache (973) 526-6019
NYK-DO:	Upstate: John A. Podsadowski	(716) 551-4461 x3155
NYK-DO:	Downstate: Larry Farina	(516) 921-1601
PHI-DO:	Sharon Gordon	(215) 597- 9064
SAN-DO:	Darlene R. Almogela	(510) 337-6769
SEA-DO:	Carol A. Gripp	(425) 483-4905
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DRUG EFFICACY STUDY IMPLEMENTATION (DESI) MONITORS:

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DAL-DO:	Jose Martinez	(210) 308-4528 x18
DEN-DO:	Michael J. Kuchta	(303) 236-3059
DET-DO:	George Domingo	(313) 393-8142
FLA-DO:	Susan M. Corrales	(561) 338-7631 x19
KAN-DO:	Gwyn Dickinson	(913) 752-2446
LOS-DO:	Virgilio Pacio	(858) 550-3850 x116
MIN-DO:	Sharon Thoma	(612) 758-7159
NOL-DO:	M. Anthony Abel I, NSV-BR	(615) 781-5374 x111
NWE-DO:	Stephen Souza	(860) 240-4289
NWJ-DO:	Meyer Slobotsky	(732) 940-8946 x12
NYK-DO:	Ray Kent	(716) 551-4461 x3126
PHI-DO:	Steven Carter	(215) 597-4390 x4520
SAN-DO:	Rochelle Young	(510) 337-6804
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DAL-DO:	Jose Martinez	(210) 308-4528 x18
DEN-DO:	Donald L. Bean	(303) 236-3044
DET-DO:	Anthony C. Taube	(313) 393-8176
FLA-DO:	Paul L. Figarole	(813) 228-2671 x15
KAN-DO:	Gwyn Dickinson	(913) 752-2446
LOS-DO:	Caryn McNab	(949) 798-7722
MIN-DO:	Sharon Thoma	(612) 758-7159
NOL-DO:	M. Anthony Abel I, NSV-BR	(615) 781-5374 x111
NWE-DO:	Ellen Madigan	(781) 596-7753
NWJ-DO:	Ray Abrahams	(973) 526-6002
NYK-DO:	Upstate: John Podsadowski	(718) 551-4461 x3155
NYK-DO:	Downstate: Larry Farina	(516) 921-1601
PHI-DO:	Megan M. Lauff	(215) 597-4390 x4502
SAN-DO:	Darlene Almogela	(510) 337-6769
SEA-DO:	Carol A. Gripp	(425) 483-4905
SJN-DO:	Ivonne Ayala	(787) 474-9505

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CHI-DO:	Linda E. Whitehead	(312) 596-4246
CIN-DO:	Steven P. Eastham	(513) 679-2700 x123
DAL-DO:	Jose Martinez	(210) 308-4528 x18
DEN-DO:	Patricia A. Cortez	(303) 236-3086
DET-DO:	George A. Domingo	(313) 393-8142
FLA-DO:	Angela J. Davis	(561) 338-7631 x10
KAN-DO:	Gwyn Dickinson	(913) 752-2446
LOS-DO:	Kirsten Tharp	(949) 798-7720
MIN-DO:	Rhonda Mecl	(612) 758-7198
NOL-DO:	M. Anthony Abel I, NSV-BR	(615) 781-5374 x111
NWE-DO:	Ellen Madigan	(781) 596-7753
NWJ-DO:	Rosa Brown	(973) 526-6007
NYK-DO:	Upstate: Ann Okon	(716) 551-4461 x3120
	Downstate: Valerie Grecek	(781) 340-7000 x5572

PHI-DO: Susan Laska (215) 362-0740 x21
 SAN-DO: Darlene Almogela (510) 337-6769
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 DET-DO: George A. Domingo (313) 393-8142
 FLA-DO: Angela J. Davis (561) 338-7631 x10
 KAN-DO: Linda Kuchenthal (913) 752-2436
 LOS-DO: Kirsten Tharp (949) 798-7720
 MIN-DO: Rhonda Mecl (612) 758-7198
 NOL-DO: Marion J. Ferrante (504) 253-4523
 NWE-DO: Ellen Madigan (781) 596-7753
 NWJ-DO: Rosa Brown (973) 526-6007
 NYK-DO: Upstate: Ann Okon (716) 551-4461 x3120
 Downstate: Valerie Grecek (718) 340-7000 x5572
 PHI-DO: Steven L. Carter (215) 597-4390 x4520
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DRUG SAMPLING PROGRAM MONITORS:

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 DEN-DO: Elvin R. Smith (303) 236-3087
 DET-DO: George A. Domingo (313) 393-8142
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 MIN-DO: Marie Fadden (612) 758-7172
 NOL-DO: M. Anthony Abel I, NSV-BR (615) 781-5374 x111
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 NYK-DO: Upstate: John A. Podsadowski (716) 551-4461 x3155
 Downstate: Larry Farina (516) 921-1601
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FACTS PROFILE MONITORS (formerly Compliance Status Information System (COMSTAT):

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 CHI-DO: Linda Whitehead (312) 596-4246
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 DAL-DO: Pauline Logan (214) 253-5232
 DEN-DO: Elvin R. Smith (303) 236-3087
 DET-DO: George Domingo (313) 393-8142
 FLA-DO: Philip DeLisle (407) 475-4717
 KAN-DO: Robert Wilson (913) 752-2426
 LOS-DO: Kirsten Tharp (949) 798-7720

MIN-DO:	Rhonda Mecl	(612) 758-7198
NOL-DO:	M. Anthony Abel I, NSV-BR	(615) 781-5374 x111
NWE-DO:	Ellen Madigan	(781) 596-7753
NWJ-DO:	Shirley Isbill	(732) 940-8946 x13
NYK-DO:	Downstate: Jim Liubicich	(718) 662-5575
NYK-DO:	Upstate: Ray Kent	(716) 551-4461 x3126
PHI-DO:	Steven Carter	(215) 597-4390 x4520
SAN-DO:	Darlene Almogela (Drugs)	(510) 337-6769
	vacant (Medical Devices)	(408) 291-4350 x25
SEA-DO:	David A. Pettenski	(425) 483-4911
SJN-DO:	Ivonne Ayala	(787) 729-6728

FACTS TRAINING CADRE:

ARL:	Rick Crouch	(870) 543-4068
ARL:	Ralph Furth	(870) 543-4056
ARL:	William Parsons	(870) 543-4082
ATL-DO:	Sheryl Cruse	(404) 253-1278
BLT-DO:	vacant	(804) 379-1627 x13
CHI-DO:	vacant	(312) 596-4245
CIN-DO:	Mike Parmon	(513) 679-2700 x136
DAL-DO:	Sandy Ziegler	(214) 253-5237
DEN-DO:	Paul Teitell	(303) 236-3057
DET-DO:	George Domingo	(313) 393-8142
FLA-DO:	Virginia Jackson	(305) 526-2800 x931
FLA-DO:	Justin Price	(407) 475-4710
FLA-DO:	Shari H. Shambaugh	(407) 475-4730
KAN-DO:	Joyce Linhart (Lenexa)	(913) 752-2471
KAN-DO:	David Glasgow (St. Louis)	(314) 645-1167 x116
LOS-DO:	Lloyd Lehrer	(949) 608-4444
MIN-DO:	Anthony Duran	(612) 758-7174
NERL:	Phyllis Wilson	(718) 340-7000 x5378
NOL-DO:	Allen Carman, NOL	(504) 253-4512
NOL-DO:	Marie Clendening, NSV-BR	(615) 781-5372 x129
NWE-DO:	Maureen Donahue	(781) 596-7721
NWJ-DO:	Kimberly Bailey	(973) 526-6023
NYK-DO:	Ray Kent	(716) 551-4461 x3126
PHI-DO:	Kenneth Gordon	(215) 597-4390 x4611
SAN-DO:	Randy Plunkett	(510) 337-6858
	Kris Foster	(510) 337-6798
	Warren Savary	(510) 337-6821
	Kevin foley	(510) 337-6816
SEA-DO:	Dennis Kawabata	(425) 483-4904
SJN-DO:	Miguel Hernandez	(787) 474-9519
SERL:	Jackie Welch	(404) 253-1200 x5468
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FOOD PROGRAM MONITORS:

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CHI-DO:	Bradley Maunder	(312) 596-4244
CIN-DO:	Susan C. Morgan	(330) 273-1038 x233
DAL-DO:	Angela Moak	(214) 253-5258
DEN-DO:	Mario Seminara	(303) 236-3026
DET-DO:	Michael V. Owens	(313) 393-8167
FLA-DO:	Michelle S. Dunaway	(786) 437-4828 x4832
KAN-DO:	Eric Nielsen	(913) 752-2409
LOS-DO:	Carol Sanchez	(858) 550-3850 x103
MIN-DO:	Carrie Hoffman	(612) 758-7200
NOL-DO:	James W. Blakely, JKS-RP	(601) 965-4581
NWE-DO:	Willis I. Cobb	(207) 622-8268

NWJ-DO: Robert McCullough (856) 757-5389 x11
 NYK-DO: Upstate: Ray Kent (716) 551-4461 x3126
 NYK-DO: Downstate: Rick Ferfaglia (718) 340-7000 x5587
 PHI-DO: Al Puglia (215) 597-4390 x4540
 SAN-DO: Davina Watson (510) 337-6896
 SEA-DO: Christopher E. Rezendes (206) 553-7001 x21
 SJN-DO: Jaime Pares (410) 474-9548

FOOD REGISTRATION MONITORS:

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 CIN-DO: Marianne Allen (513) 679-2700 x145
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 DEN-DO: Mary Frances Bodick (303) 236-3088
 DET-DO: Anthony C. Taube (313) 393-8176
 FLA-DO: Michelle S. Dunaway (786) 437-4828 x4832
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 LOS-DO: Carol Sanchez (858) 550-3850 x103
 MIN-DO: Judy Heisick (612) 758-7118
 NOL-DO: Marion J. Ferrante (504) 253-4523
 NWE-DO: Willis I. Cobb (207) 622-8268
 NWJ-DO: Rosa Brown (973) 526-6007
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 NYK-DO: Downstate: Richard Ferfaglia (718) 340-7000 x5587
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 SAN-DO: Lorna Jones (510) 337-6818
 SEA-DO: Christopher E. Rezendes (206) 553-7001 x21
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GOVT. VEHICLE MONITORS:

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 CHI-DO: Lillian M. Starr (312) 596-4183
 CIN-DO: Patricia A. Cochran (513) 679-2700 x129
 DAL-DO: Stacie McAllister (214) 253-5259
 DEN-DO: Wendy Hettinger (303) 236-3041
 DET-DO: Melanie S. Bourcier (313) 393-8126
 FLA-DO: Stanley Ross (407) 475-4735
 KAN-DO: Mary Stroman (913) 752-2424
 KAN-DO: STL:David Glasgow (314) 645-1167 x116
 LOS-DO: Edward Whitford (949) 608-4405
 MIN-DO: Diane Amos (612) 758-7142
 NOL-DO: Ella Sue O'Regan (504) 253-4544
 NSV-BR: Betty Storey (615) 781-5380 x123
 NWE-DO: Alfred N. Levitt (781) 596-7747
 NWJ-DO: Steve Krause (973) 526-6022
 NYK-DO: Upstate: Ray Kent (716) 551-4461 x3126
 NYK-DO: Downstate: Richard Ferfaglia (718) 340-7000 x5587
 PHI-DO: Maryann Yates (215) 597-4390
 SAN-DO: William F. Hutson (510) 337-6812
 SEA-DO: Donald Martinson (425) 483-4943
 SJN-DO: Mario Guzman (787) 474-9516

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 CIN-DO: Susan C. Morgan (330) 273-1038 x233
 DAL-DO: Dallas Gilbreath (214) 253-5231

DEN-DO:	Mary Francis Bodick	(303) 236-3088
DET-DO:	Michael V. Owens	(313) 393-8167
FLA-DO:	Kathleen M. Sinninger	(305) 526-2800 x964
KAN-DO:	Peter E. Gruman	(913) 752-2771
LOS-DO:	Carol Sanchez	(858) 550-3850 x103
MIN-DO:	Frank Sedzielarz	(612) 758-7153
NOL-DO:	Carolyn W. White	(504) 253-4545
NWE-DO:	Willis I. Cobb	(207) 622-8268
NWJ-DO:	Robert McCullough	(856) 757-5389 x11
NYK-DO:	Upstate: Ray Kent	(716) 551-4461 x3126
NYK-DO:	Downstate: Elizabeth Jacobson	(914) 682-6166 x27
PHI-DO:	Alfred Puglia	(215) 597-4390 x4540
SAN-DO:	Lorna Jones	(510) 337-6818
SEA-DO:	Seafood: Christopher Rezendes	(206) 553-7001 x21
SEA-DO:	Juice: Janelle K. Martin	(425) 483-4928
SJN-DO:	Jaime Pares	(787) 474-9548

HEALTH FRAUD MONITORS:

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CHI-DO:	Kathy Haas	(312) 596-4250
CIN-DO:	David Radle	(513) 679-2700 x124
DAL-DO:	Reynaldo (Ricky) R. Rodriguez, Jr.	(214) 253-5215
DEN-DO:	Shelly Maifarth	(303) 236-3046
DET-DO:	Evelyn DeNike	(313) 393-8109
FLA-DO:	Martin Katz	(407) 475-4729
KAN-DO:	Marion Wimberly	(913) 752-2786
LOS-DO:	Diane Van Leeuwen	(949) 798-7707
MIN-DO:	M. Edith Snyder	(612) 334-4100 x165
NOL-DO:	Stacy M. Below	(504) 253-4506
NWE-DO:	Vacant	
NWJ-DO:	Mercedes Mota	(973) 526-6009
NYK-DO:	Upstate: Joan Trankle	(716) 551-4461 x3171
NYK-DO:	Downstate: Marlene Doherty	(718) 340-7000 x5588
PHI-DO:	Anitra Brown-Reed	(215) 597-4390 x4202
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HUMAN TISSUE REGISTRATION MONITORS:

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CHI-DO:	Linda Whitehead	(312) 596-4246
CIN-DO:	Marianne Allen	(513) 679-2700 x145
DAL-DO:	Warren Landry	(214) 253-5230 x518
DEN-DO:	Deborah Hammond	(303) 236-3082
DET-DO:	Catherine V. Quinlan	(313) 393-8153
FLA-DO:	Ronnie Jackson	(407) 475-4725
KAN-DO:	Gregory Dixon	(913) 752-2427
LOS-DO:	Kirsten Tharp	(949) 798-7720
MIN-DO:	Karen LaBounty	(612) 758-7154
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NYK-DO:	Downstate - Evelyn Taha	(718) 340-7000 x5574
PHI-DO:	Kim Crayton-Lee	(215) 597-4390 x4539
SAN-DO:	Deborah Kleinfeld	(510) 337-6825
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DET-DO:	Douglas L. Park	(616) 233-9311
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KAN-DO:	Robert Wilson	(913) 752-2426
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KAN-DO:	Joseph Kramer	(913) 752-2719
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KAN-DO:	Gerald Bromley	(913) 752-2403
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