

FDA ORGANIZATION

Leadership: [Margaret A. Hamburg, M.D.](#) Commissioner of Food and Drugs

FDA is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, products that give off radiation and for regulating tobacco. [FDA Basics](#)

FDA consists of six product centers, one research center, and two offices:

- Office of the Commissioner
- Office of Regulatory Affairs
- National Center for Toxicological Research (NCTR)
- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Veterinary Medicine (CVM)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Tobacco Products (CTP)

ORA

Leadership - [Dara A. Corrigan](#) Associate Commissioner for Regulatory Affairs (ACRA)

The Office of Regulatory Affairs is the lead office for all FDA Field activities as well as providing FDA leadership on imports, inspections, and enforcement policy. ORA supports the five FDA Product Centers by inspecting regulated products and companies, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States.

ORA employs nearly 4000 people. Over 85% of ORA employees work across the country in 5 Regions. Regions are made up of 20 district offices, 150 resident/border posts, and 13 laboratories.

NEW ENGLAND DISTRICT

Leadership: Mutahar Shamsi, District Director (DD)

Part of the Northeast Region (Gail Costello, Regional Food & Drug Director), the New England District Office is located in Stoneham, MA.

The District has resident/border posts located in Augusta, Calais, and Houlton, ME, in Concord, NH, in Highgate, VT, in Boston and Worcester, MA, in Hartford and Bridgeport, CT and in East Providence, RI. The majority of work in the District is in the Foods area (appx. 47%), followed Devices (appx. 34%). Drug work (drugs, biologics, vet.) makes up about 18% of our work.

The manuals, programs, policies and guides used by the District are all located in [Electronic Reading](#) room under ORA and Agency Manuals.

INVESTIGATIONS BRANCH

Leadership: Chris vanTwuyver, Director Investigations Branch (DIB)

The Investigations Branch is responsible for conducting inspections, investigations, sample collections, and review of import entries. Investigators conduct inspections in within the District and overseas as part of the Foreign Inspection Cadre. Some of the primary resources used by Investigators during inspections include:

- ⇒ Investigations Operation Manual (IOM)
- ⇒ Compliance Program Guidance Manual (CPGM)
- ⇒ Inspection Guides
- ⇒ Inspection Technical Guides

The IOM is the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors. It contains information on all primary activities including investigations, inspections, sampling, recalls, and federal and state cooperation. Chapter 5 specifically covers the policies and procedures for establishment inspections from preparation through write up of inspection reports.

Compliance Programs, found in the CPGM, provide guidance and instructions to FDA staff for obtaining information to help fulfill agency plans in program areas including biologics, bioresearch monitoring, devices, drugs, foods, cosmetics, and veterinary medicine. Compliance Programs include 6 sections, background, implementation, inspectional, analytical, regulatory/administrative strategy, and references, attachments, and contacts. Investigators use the inspectional section as a guide during their inspection.

COMPLIANCE BRANCH

Leadership: (VACANT), Director Compliance Branch

When inspection findings demonstrate that a firm is not operating in a state of control the Compliance Branch becomes involved to evaluate the need for advisory, administrative and/or judicial actions. If action is necessary to obtain compliance the Compliance Officer works with the appropriate product center (CDER, etc.), and the [Office of Chief Counsel](#) (within the Office of the Commissioner) to take the action(s). Some of the primary resources used by Compliance Officers when handling cases include:

- ⇒ Compliance Program Guidance Manual (CPGM)
- ⇒ Manual of Compliance Policy Guides (CPG)
- ⇒ Regulatory Procedures Manual (RPM)

The RPM provides information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. Regulatory matters covered include, but are not limited to, advisory actions such as warning letters and judicial actions such as seizure, injunction, and inspection warrants.

FOOD AND DRUG ADMINISTRATION [ENFORCEMENT POLICY](#) (07/15/10)

Commitment to our enforcement policy is consistent throughout the Agency. The July 15, 2010 the Enforcement Policy document is signed by the ACRA, each Center Director and [Ralph Tyler](#), Chief Counsel to the FDA. Key points of the document include, but are not limited to:

- ⇒ Enforcement is one of the Agency's highest priorities.
- ⇒ If a significant violation is identified, FDA will determine as quickly as possible what further agency action might be necessary.
- ⇒ FDA will use any and all available enforcement tools, as appropriate, based on the facts of the case and the nature and seriousness of the violation. After initiating an advisory, administrative or judicial action, FDA will follow-up promptly to assess whether the regulated entity has made required changes in its practices.
- ⇒ When FDA obtains information that an FDA-regulated product poses a significant risk to the public health, our first priority will be to determine whether the product should be removed from the marketplace and if so, to take swift action to ensure such removal and notification either by voluntary effort on the part of the responsible firm or, when voluntary action is not rapid or complete or the company is not responsive, through use of FDA's enforcement tools.

- ⇒ FDA will use risk informed approaches to compliance and enforcement activities focusing both Agency and industry attention on critical areas.
- ⇒ FDA will clearly communicate its enforcement strategy and priorities and implement them in a vigilant, strategic, swift and visible manner.
- ⇒ FDA will work with federal, state, and local public health protection and law enforcement on risk control and enforcement strategies.
- ⇒ FDA will work with its international regulatory and law enforcement counterparts on partnerships, information sharing, and risk control and enforcement strategies.
- ⇒ Businesses and persons who make FDA-regulated products have a legal and ethical duty to protect the health and safety of consumers by adopting and faithfully implementing rigorous quality management systems that ensure continuous compliance with the food and drug laws. Violations of FDA laws and regulations, whether intentional or unintentional, are unacceptable and may be addressed civilly and with criminal sanctions.

TRANSPARENCY INITIATIVE

In June 2009, Food and Drug Administration (FDA) Commissioner Dr. Margaret Hamburg launched FDA's Transparency Initiative and formed an internal task force to develop recommendations for making useful and understandable information about FDA activities and decision-making more readily available to the public, in a timely manner and in a user-friendly format.

- ⇒ Provide the public with basic information about FDA and how the Agency does its work.

The Agency launched a web-based resource called [FDA Basics](#).

- ⇒ Proactive disclosure of information the Agency has in its possession.

FDA has released a [Transparency Report](#) containing 21 draft proposals about expanding the disclosure of information by the agency while maintaining confidentiality for trade secrets and individually identifiable patient information.

- ⇒ Transparency to regulated industry

Work of the Transparency Task force included [meetings](#) with regulated industry to obtain input on ways FDA can increase transparency between FDA and regulated industry.

Stay informed - FDA has multiple forms of [interactive media](#): Email updates, podcasts, videos, news feeds, RSS feeds, Widgets, FDA on Facebook, Flickr, and Twitter.

[FDA TRACK](#)

FDA-TRACK is a new agency-wide program performance management system that monitors over 100 FDA program offices through key performance measures. Access to this information enables all interested external and internal visitors to view FDA's performance data at the program office level and gain a better understanding of the breadth of FDA's core responsibilities, as well as see progress on important projects and programs.

FDA-TRACK program areas include all 6 centers, ORA, NCTR, the Office of the Commissioner in addition to cross-agency programs for example Freedom of Information. Data available includes, but is not limited to, number of inspections per program area, number of inspections classified NAI, VAI, OAI, number of recalls, as well as status updates on key projects.

[FREEDOM OF INFORMATION ACT](#)

The Freedom of Information Act (FOIA) provides that any person has the right, enforceable in court, to obtain access to federal agency records, unless those records (or portions of the records) are protected from public disclosure by an exemption contained within the statute. There are various exemptions in certain areas, and it is these that mostly affect your operations in FDA. The regulations exempt certain information, such as personal privacy, deliberative process, open investigatory, as well as a company's trade secrets or confidential commercial information.

FDA personnel cannot release or divulge any information obtained during FDA investigative or inspectional operations, unless they are authorized to do so and the sharing (regardless of the manner) complies with FDA's information disclosure laws and procedures. This includes information contained in diaries and field notes, except for official issuance of forms or documents to addressees.

FAQ on FOIA:

- ⇒ Exemption from Public Disclosure: Trade Secrets and Confidential Commercial or Financial Information [45 CFR 5.65](#); [21 CFR 20.61](#)

Trade secrets are found in records containing secret, commercially valuable plans, formulas, processes, or devices used for making, preparing, compounding or processing trade commodities that are the end product of either innovation or substantial effort. Confidential commercial or financial information is found in records containing valuable, non-public data or information relating to businesses, commerce, trade, employment, profits, or finances (including personal finances).

- ⇒ FOIA request processing procedures are located in our [Staff Manual Guides](#)

- ⇒ The [Electronic Reading Room](#) contains frequently requested FDA documents such as Warning Letters, manuals and procedures and FDA records released in response to a FOI request that have become or are likely to become the subject of subsequent requests for substantially the same records. Tip: When searching for records such as Warning Letters or an FDA-483 look under the issuing office for example Warning Letters to drug companies may be under either CDER, CBER or ORA depending on the issuing office.

- ⇒ The agency policy on posting Warning Letter responses on the internet is found in Regulatory Procedures Manual Chapter 4, Section 4-1-8. Also, see [Federal Register Notice on Posting Warning Letter Responses, June 23, 2003](#).

FOLLOW UP RESOURCES

Contact the New England District if you are looking for information or have questions. Our main phone number is (781) 596-7700.

Q. Information sharing with foreign regulatory agencies?

A. [International MOU's](#) are posed in the Electronic Reading room. The Office of International Programs ([OIP](#)), located in the Office of the Commissioner, is the focal point for all international matters concerning the Agency.

Q. Is information on recalls is available?

A. Yes, some is available on the Agency website through Open Government: [FDA Data Sets](#). This is a gateway that provides access to data sets in a variety of formats. Data sets include recalls and fraudulent H1N1 products. Recall information is also posted on the main website under [Recalls & Safety Alerts](#).