FDA's Office of the Ombudsman is the agency's focal point for addressing complaints and assisting in resolving disputes between companies or individuals and FDA offices.

U.S. Department of Health and Human Services
U.S. Food and Drug Administration
www.fda.gov

# FDA's Office of the Ombudsman

Dispute Resolution and Problem Solving

*www.fda.gov/oc/ombudsman/homepage.htm*

U.S. Department of Health and Human Services
U.S. Food and Drug Administration

**Consultation**
**Dispute Resolution**
**Mediation**

## Who We Are, What We Do

An ombudsman is someone who looks into and addresses complaints and disputes involving an organization. But the role of the ombudsman here at the Food and Drug Administration (FDA) involves much more.

FDA's ombudsman function is handled at two levels:
- a separate office within the Office of the Commissioner (FDA Office of the Ombudsman)
- designated ombudsmen within specific product centers (drugs, devices, biologics, and veterinary medicine)

Companies can turn to the FDA Office of the Ombudsman for:
- dispute resolution
- mediation
- breaking up "log jams" with the agency
- guidance and assistance in solving problems with the agency or with FDA-regulated products
- general regulatory questions or concerns

## Cases We Handle

The following types of cases are routinely handled by the FDA Office of the Ombudsman:
- Disputes/complaints from regulated industry regarding agency product center actions, or lack of action, and those issues that cut across center jurisdictions
- Disputes/complaints from regulated industry related to interactions with agency field offices, including inspection and compliance issues
- Disputes/complaints about import detentions of agency-regulated products
- Complaints from small businesses, including those referred by the U.S. Small Business Administration
- Inquiries about the agency's handling of both consumer complaints and Freedom of Information Act (FOIA) requests
- Requests for information and assistance from regulated industry regarding agency policy and regulations, and on how to work with the agency

## How We Handle Disputes and Complaints

The various methods used by the FDA Office of the Ombudsman for handling disputes and complaints include consultation, dispute resolution, and mediation.

Typical actions include:
- Determining relevant issues and obtaining complete and accurate information about a case
- Reviewing and acting on cases in a timely manner
- Initiating meetings with affected parties
- Recommending more transparent reasons for agency action/decision, when warranted
- Recommending alternative courses of action

Confidentiality:
- May be requested with regard to identity and nature of complaints
- Will be honored, but may restrict complaint/dispute resolution actions

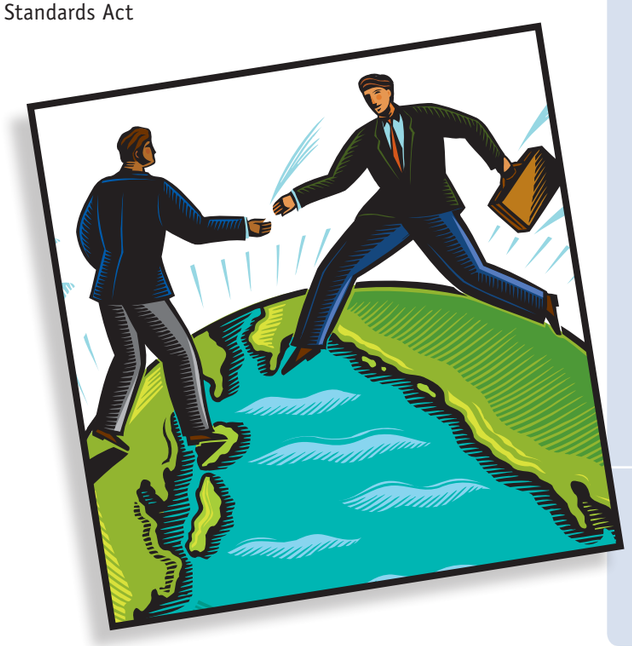
FDA has a strict non-retaliation policy that protects anyone who files a complaint against the agency.

## Other Functions

The FDA Office of the Ombudsman has responsibility for the following additional functions:

Liaison to the Small Business Administration
- Serves as FDA liaison to the National Ombudsman's Office at the Small Business Administration (SBA)
- Handles issues that fall under the Small Business Regulatory Enforcement Fairness Act (SBREFA)
- Responds to all complaints referred to FDA under SBREFA, involving any agency regulatory area

Coordination of:
- Complaints received under the Information Quality Act
- Appeals to the Office of the Commissioner after a final center level decision has been made (21 CFR 10.75)
- Certain administrative hearings that fall under 21 CFR Part 16
- Requests for reinstatement by disqualified clinical investigators
- Disputes arising under the Mammography Quality Standards Act



# CONTACT INFORMATION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