

# FDA's Office of the Ombudsman

Assisting in resolving disputes between companies or individuals and FDA offices.



**CONSULTATION  
DISPUTE RESOLUTION  
MEDIATION**

**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

## 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, tobacco) and office of regulatory affairs

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 from regulated industry regarding agency product center actions, or lack of action, and those issues that cut across center jurisdictions
- Disputes from regulated industry related to interactions with agency field offices, including inspection and compliance issues
- Concerns from small businesses, including those referred by the U.S. Small Business Administration
- Inquiries about the agency's handling of 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

The various methods used by the FDA Office of the Ombudsman for handling disputes 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:

- Certain appeals made under 21 CFR 10.75
- Complaints received under the Information Quality Act
- Certain administrative hearings that fall under 21 CFR Part 16

# CONTACT

## FDA OFFICE OF THE OMBUDSMAN

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## FDA PRODUCT CENTER OMBUDSMEN

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Devices  
Phone: (301) 796-0293  
E-mail: [cdrhombudsman@fda.hhs.gov](mailto:cdrhombudsman@fda.hhs.gov)

Biologics  
Phone: (240) 402-7912  
E-mail: [cberombudsman@fda.hhs.gov](mailto:cberombudsman@fda.hhs.gov)  
Office of Regulatory Affairs  
Phone: (844)-871-4536  
[oraombudsman@fda.hhs.gov](mailto:oraombudsman@fda.hhs.gov)

Tobacco  
Phone: (301) 796-3095  
E-mail: [ctpombudsman@fda.hhs.gov](mailto:ctpombudsman@fda.hhs.gov)

General FDA Information  
Phone Toll-Free: 888-INFO-FDA (888-463-6332)  
[www.fda.gov](http://www.fda.gov)

U.S. Department of Health and Human Services  
U.S. Food and Drug Administration  
FDA Office of the Ombudsman  
Office of Scientific Integrity  
Office of the Chief Scientist  
Office of the Commissioner