CDER Ombudsman's Operating Principles

Confidentiality

If requested, the Ombudsman will hold all information confidential unless imminent risk of serious harm is evident or if allegations of criminal activity are made.

Neutrality & Impartiality

The Ombudsman strives to be objective, free from bias, and to treat all parties fairly without favor or prejudice.

Informality

The Ombudsman informally receives and listens to complaints, provides advice and feedback, and informally investigates complaints. The Ombudsman does not make binding decisions or mandate change. Use of the Ombudsman's Office is purely voluntary.

The Ombudsman will NOT:

- Overturn a decision/action, as the Ombudsman is not a deciding official
- Force anyone to overturn or modify a decision/action
- Take the position of advocate
- Work on a dispute while the case is pending in a formal appeals process or in litigation
- Violate the Ombudsman's operating principles

Contact the CDER Ombudsman

Office of the Ombudsman
Center for Drug Evaluation and Research
Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993

Phone: 301-796-3436

e-mail: CDERombudsman@fda.hhs.gov or Virginia.Behr@fda.hhs.gov

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm

Relation to the FDA Office of the Ombudsman

The role of the CDER Ombudsman (Center level) is similar to the FDA Ombudsman (Agency level) and both offices follow the same operating principles. However, utilizing the CDER Ombudsman provides a way for anyone with a complaint or dispute involving CDER entities or programs to work through their problem at a level closer to the source.

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

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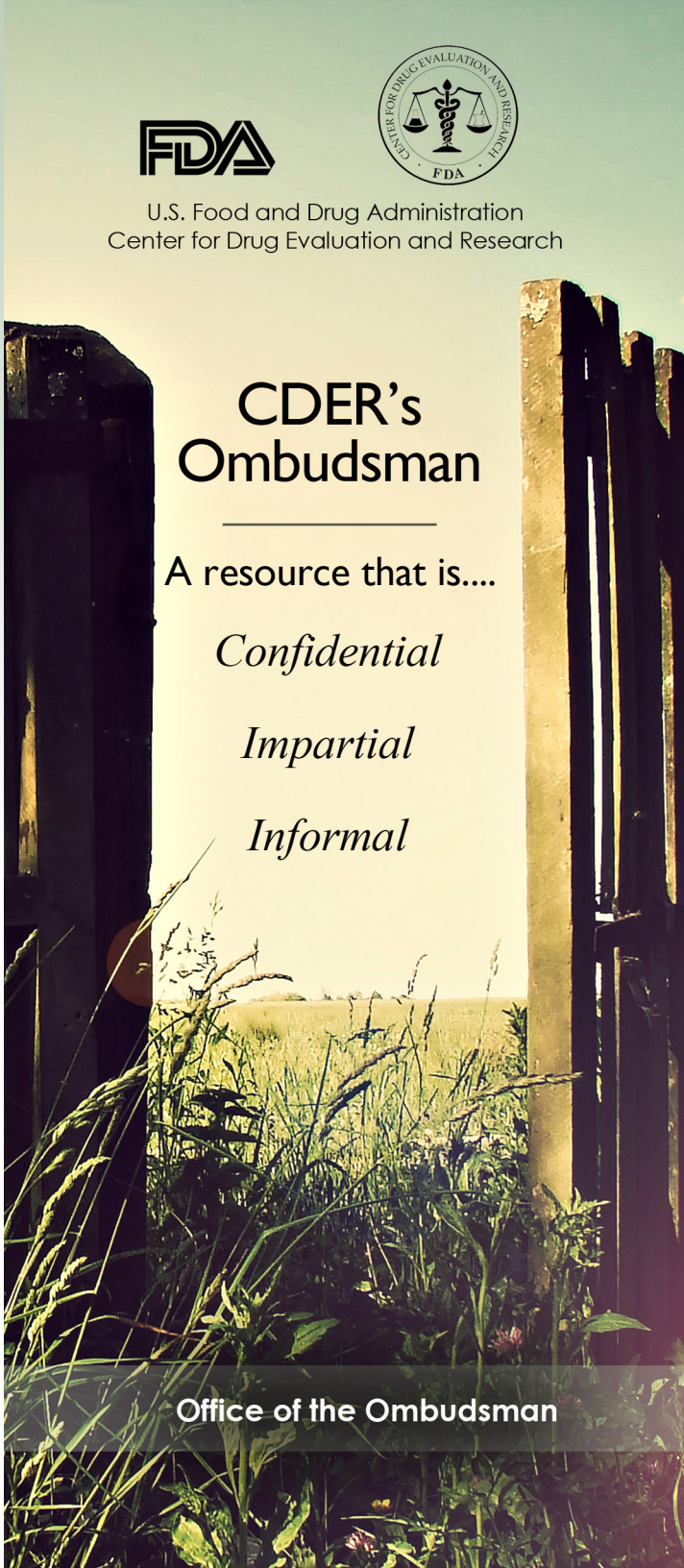

U.S. Food and Drug Administration
Center for Drug Evaluation and Research

CDER's Ombudsman

A resource that is....

Confidential

Impartial

Informal

Office of the Ombudsman

What is an Ombudsman?

An ombudsman is a high-level person in an organization who receives and investigates complaints, and facilitates resolution of problems in an informal, unbiased manner.

What Does CDER's Ombudsman Do?

The Ombudsman receives questions and investigates complaints from CDER-regulated industry, law firms, health care providers, and consumers, and informally resolves disputes between those entities and CDER. The disputes or questions can be of a regulatory, scientific, or administrative nature. The Ombudsman serves as a one-stop-shop for quick and informal advice or referrals, whatever the question or problem might be. Also, the Ombudsman receives feedback about CDER's programs and overall performance, advises management about program issues, and can assist with resolution of scientific differences of opinion among CDER staff.

Mission

To quickly and impartially investigate complaints and resolve disputes between CDER and CDER-regulated industry, health care providers, and consumers by offering an informal, confidential, and neutral environment.

Dispute Resolution

Anyone having interactions with CDER should find our staff professional and helpful and our decisions based on sound science and policy. Given that expectation, there will still be instances when an individual or company disagrees with a decision or action or feels that they have been treated unfairly. There are several paths available for seeking resolution of a dispute. The Ombudsman will review those options with you and offer practical advice. Options might include several different dispute resolution possibilities, including asking the Ombudsman to informally investigate and facilitate resolution of the problem in a timely and equitable manner. Ultimately, a formal appeal may be the best approach and you can discuss this option with the Ombudsman.

What Should I Do Before Contacting the CDER Ombudsman?

If you are experiencing problems with a matter involving one of CDER's Divisions or Offices, please first discuss it with your point of contact (usually the project manager) and/or the director of that Division/Office. If you are not satisfied with the outcome of that discussion, you may then take the matter to the CDER Ombudsman to discuss your options. Although some might think of contacting the Ombudsman as a last resort, the earlier you contact the Ombudsman, the more options may be available for addressing your problem, particularly if there are statutory, regulatory, or administrative time constraints.

What happens when I contact the Ombudsman?

The Ombudsman will listen to your complaint, ask questions (including your desired outcome), and review your options for achieving resolution. Every effort is made to respond to all complaints in a timely and effective manner. Upon request, communication with the Ombudsman will be considered confidential.

Vision

To improve CDER's operations and enhance transparency by providing efficient resolution of disputes and by fostering communication with stakeholders.