

# Where Do We Go From Here?

## How the Ombudsman Can Help

**FDA Small Business Regulatory Education for Industry (REdI)**

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# In your interactions with FDA, do you ever feel:

- Stuck
- Unheard
- Confused
- Misunderstood
- Not treated fairly

# Learning Objectives

- Describe the CDER Ombudsman's role
- Explain the ombuds standards of practice
- Identify situations when the ombudsman can help

# Navigating FDA



# Trouble Ahead? Dinged Up a Bit?



# What is an Ombudsman?

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Someone in any organization who receives complaints, informally looks into matters, mediates disputes, and in general attends to problems, while adhering to ombuds standards of practice

# Receive Concerns, Questions, Complaints

- Help think through options and advise; sounding board
- Exercise diplomacy and share varying perspectives
- Identify misunderstandings and efficiently resolve disputes
- Promote fairness, transparency, accountability, i.e. good government
- Report systemic issues; propose solutions



# Standards of Practice

# Core Standards

- Impartial
- Independent
- Confidential

# Standards – Common Characteristics

- Informal
- Commitment to fairness
- Credible process

# **When Can The Ombudsman Help?**

# What to Expect

- No formal submission needed
- If haven't used our services before, we'll review our process and role
- Gather regulatory history and dispute background
- Listen to your complaint and desired outcome
- Review options for path forward. You decide!

# I'm Stuck, What Are My Options?

- Do nothing, i.e. don't push back
- Try to work it out with the CDER review team
- OND Enhanced Communications Team
- Request CDER Ombudsman services for advice, informal discussion, facilitation
- Invoke a formal process (appeal, petition, legal)

# Why Use the Ombuds?

- Unique position
- Deep understanding of operations and how to navigate complex FDA
- Informal and efficient, saving resources
- Sounding board; opportunity to explore options
- Adept at interacting with FDA staff
- Improve communications and working relationships

# CDER Ombuds Will NOT

- Advocate for either party
- Violate standards of practice
- Violate trust
- Overturn a regulatory decision
- Engage in a matter that is in litigation



# Contact Us When Trouble is Brewing



# Not When It's Too Late



# Challenge Question #1

**The CDER Ombudsman will:**

- A. Advocate for your company
- B. Resolve misunderstandings/disagreements
- C. Overturn a wrong decision
- D. Violate ombuds standards of practice

## Challenge Question #2

Which is **NOT** a federal ombuds standard ?

- A. Confidentiality
- B. Impartiality
- C. Independence
- D. Approachability

# Summary

- Ombuds exist in the FDA
- We follow the federal ombuds standards of practice
- We can help you, or at least help you help yourself

# CDER Ombudsmen Contact

[www.fda.gov/CDEROmbudsman](http://www.fda.gov/CDEROmbudsman)

[CDEROmbudsman@fda.hhs.gov](mailto:CDEROmbudsman@fda.hhs.gov) (checked daily)

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# Questions



