

FDA OII OMBUDSMAN PROGRAM (OOP)

Erica M. Katherine, OII Ombudsman
FDA Office of Inspections and Investigations

AGENDA

- What is an Ombudsman?
- The FDA Ombudsmen Ecosystem
- The OII Ombudsman Program
- Common Questions and Information

What is an Ombudsman?

- A neutral, confidential, informal, and independent resource
- Guided by USOA (United States Ombudsman Association) standards
- ACUS (Administrative Conference of the U.S.)
- Voluntary and non-adversarial process

The FDA Ombudsmen Ecosystem

- **Center for Biologics Evaluation and Research** - Telephone: 301-837-7292 - E-mail: CBEROmbudsman@fda.hhs.gov
- **Center for Drug Evaluation and Research** - Telephone: 301-796-3436 - E-mail: CDEROmbudsman@fda.hhs.gov
- **Center for Devices and Radiological Health** - Telephone: 301-796-0293 - E-mail: CDRHombudsman@fda.hhs.gov
- **Center for Tobacco Products** - Telephone: 301-796-3095 - E-mail: CTPOmbudsman@fda.hhs.gov
- **Center for Veterinary Medicine** - E-mail: CVMOMBUDS@fda.hhs.gov
- **Office of Inspections and Investigations** - Telephone: (844) 871-4536 (toll-free) - E-mail: OIombudsman@fda.hhs.gov
- **FDA Office of the Commissioner** - Telephone: 301-796-8530 - E-mail: Ombuds@oc.fda.gov



About the OI Ombudsman Program

- Part of FDA's Office of Inspections and Investigations
- Resolves concerns informally—does not launch investigations
- Internal problem-solving when communication breaks down
- Supports transparency and effective engagement

The OII Ombudsman

- Offers an impartial perspective
- Identifying options and resources
- Internal problem-solving when communication breaks down
- Supports transparency and effective engagement

How We Help – In the Context of Inspections

- Confusion about procedures or communication delays
- Concerns about professionalism
- Questions about record requests or private information
- We don't change findings—but we ensure concerns are acknowledged and reviewed

Common Questions We Receive

- Q: Does the Ombudsman make the final regulatory decision?
 - A: No – the Ombudsman does not reverse or substitute for formal regulatory or enforcement actions.
- Q: Is the conversation confidential?
 - A: Yes – we offer confidentiality to the extent permitted by law and maintain neutrality.
- Q: When should I contact the Ombudsman?
 - A: You may contact us any time you have process, communication or coordination concern with OII. We're especially helpful before issues escalate.
- Q: Does the Ombudsman replace formal appeal or correction mechanisms?
 - A: No – we complement them by clarifying options and facilitating communication; formal appeals remain with regulatory channels.

Thank You

Erica M. Katherine

Toll-free 844-871-4536

www.fda.gov/Ollombudsman
OllOmbudsman@fda.hhs.gov

