

# How to Engage with the OII OMBUDSMAN

FDA

## WHO

Any individual, company, organization, or entity with concerns or questions related to OII regulatory activities or processes—including inspections, investigations, imports, and emergency response—may contact the OII Ombudsman for assistance.

## WHAT

The OII Ombudsman Program serves as a neutral, confidential, and informal resource to address concerns, facilitate open communication, and offer guidance on dispute resolution options.

## WHERE

The OII Ombudsman operates independently within OII and can be reached by phone or email. Meetings can be scheduled upon request.

## WHEN

At any stage of a regulatory process where you feel stuck or have not been able to obtain a response for information.

## WHY

The OII Ombudsman Program helps clarify regulatory expectations, prevent unnecessary escalations, and facilitate fair and transparent communication between stakeholders and OII.

## HOW

Engaging with the OII Ombudsman is voluntary and confidential. No formal documentation is required, but inquirers should be prepared to discuss concerns in detail.

# HOW TO REACH THE OII OMBUDSMAN PROGRAM

The OII Ombudsman Program is here to help at any stage before, during, or after an inspection. Common reasons to reach out include seeking clarification on a regulatory notification, if communication challenges arise, prior to considering a formal appeal, or if you are unsure of who to contact to discuss an OII process issue.

To get in touch with the OII Ombudsman Program, please contact us through the following options:

## EMAIL

[OIIombudsman@fda.hhs.gov](mailto:OIIombudsman@fda.hhs.gov)

This is the best way to start a conversation and request a meeting.

## PHONE

1 (844) 871-4536

Call and leave a private message; only the OII Ombudsman has access to this line.

## MEETING REQUEST

Virtual and in-person meetings can be scheduled based on location, resources, and the availability of the OII Ombudsman.

## WEBSITE

For more information, visit [www.fda.gov/OIIombudsman](http://www.fda.gov/OIIombudsman)