Office of Inspections and Investigations

OMBUDSMAN PROGRAM

A confidential, neutral resource providing facilitated conflict resolution

ABOUT THE PROGRAM

THE OII OMBUDSMAN PROGRAM (OOP) was created to enhance the operations of FDA's Office of Inspections and Investigations (OII) by serving as a confidential resource to improve communication channels, facilitate the resolution of disputes, and foster positive relationships with internal and external stakeholders; including industry, government, and the public.

HOW DOES IT WORK?

The OOP operates in accordance with four Standards of Practice, which are widely accepted principles within the ombudsman community that enable the OOP to advocate for fair processes. A process is generally defined as a series of steps taken to achieve an outcome.

Examples of process issues handled by the OOP are (but is not limited to) concerns about review of imported products, facility inspections, and investigations.

CONFIDENTIALITY

The ombudsman does not share the identities of stakeholders, except where there is: imminent risk of serious harm to persons or property; allegations of fraud, waste, or abuse; specific permission given to waive confidentiality; or a requirement by law.

NEUTRALITY

The ombudsman maintains a neutral position and does not represent or act as an advocate for any person or entity in a dispute with OII. The ombudsman is an advocate for a fair process, considers the rights of all parties, and does not take sides.

INDEPENDENCE

To ensure independence and objectivity, the ombudsman does not report to any of OII's enforcement program offices.

INFORMALITY

The services offered by the OOP are voluntary and are not provided to initiate any formal proceedings against the OII or FDA. Contacting OOP is not a substitute for formal procedures. The ombudsman cannot compel action or compliance.

WHY SHOULD I CONTACT THE OMBUDSMAN?

The ombudsman can assist in informally resolving process issues by evaluating options and resources within OII and by facilitating discussions, offering an impartial perspective, ensuring confidentiality, providing referrals to specific contacts and recommendations.

WHEN SHOULD I CONTACT THE OMBUDSMAN?

Contact the ombudsman when you have not had success with existing OII processes to address your process concerns, or when you wish to keep your concerns confidential. You are welcome to contact the ombudsman at any time, but first try existing avenues of communication within OII.

HOW DOES THE OMBUDSMAN HELP?

The ombudsman analyzes and learns about all perspectives of an issue by:

Reviewing the applicable laws, regulations, policy, and data.

Talking with individuals and/or stakeholders involved.

Meeting with OII or other FDA officials.

Facilitating internal and external discussions.

The ombudsman can then make any applicable recommendation on how the stakeholder or OII can address the issue to provide fairness of the process in accordance with the public health mission.

THE OMBUDSMAN DOES NOT:

- Address matters in litigation
- Delay statutory, regulatory, or other OII deadlines
- Make decisions or legal determinations for the OII
- Serve as a formal office of legal notice for the OII
- Address internal human resources matters

FOR MORE INFORMATION:

www.fda.gov/OIIombudsman

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