OFFICE OF THE CENTER DIRECTOR

Role and Procedures of the CDER Ombudsman

CONTENTS

PURPOSE

- This MAPP describes the role and functions of the Ombudsman in the Center for Drug Evaluation and Research (CDER) and outlines the policies and procedures for bringing matters to the CDER Ombudsman.

BACKGROUND

- The first use of ombudsmen in CDER came with the rewrite of the investigational new drug (IND) and new drug application (NDA) regulations in 1985. Regulations covering dispute resolution for both INDs and NDAs provide that administrative or procedural issues that cannot be resolved by the applicant and the reviewing division may be brought to an ombudsman for resolution. An ombudsman's role is to receive complaints, to investigate them, and to facilitate a timely and equitable resolution. In 1985, the Center designated an ombudsman for the new drug review area and another for generic drugs. Both, however, were managers in the respective offices, and neither received many complaints.

- In 1990, the FDA created the position of Chief Mediator and Ombudsman, reporting to the Commissioner. This office includes staff who handle not only complaints but also jurisdictional issues between the Centers. In 1991, regulations were issued for requesting a determination of which Center has primary jurisdiction over a

product (21 CFR part 3). In that same year, agreements between the Centers dealing with drugs, biologics, and devices were signed and published.

- In 1995, a new position was created for a CDER Ombudsman, reporting directly to the Center Director. The role of the CDER Ombudsman is described in this MAPP and in the Ombudsman's page on the CDER web site. The Center's ombudsman receives complaints directly from regulated industry, health associations, the public, and CDER staff, and coordinates activities with the FDA Chief Mediator and Ombudsman's office. To facilitate consistency with the Commissioner's Office, the CDER Ombudsman also makes recommendations to the FDA Ombudsman and consults with the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research on intercenter jurisdiction issues.

REFERENCES

- 21 CFR part 3, Product Jurisdiction
- 21 CFR 312.48, Dispute Resolution (INDs)
- 21 CFR 314.103, Dispute Resolution (NDAs)
- The Ombudsman Association: Code of Ethics, Standards of Practice (www.igc.org/toa)
- Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (October 31, 1991)
- Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research (October 31, 1991)
- CDER Ombudsman web site [www.fda.gov/cder/ombud.htm]
  FDA Ombudsman web site [www.fda.gov/oc/ombudsman/homepage.htm]
- FDA guidance for industry on *Formal Dispute Resolution: Appeals Above the Division Level* (February 2000)

DEFINITIONS

Bargaining unit: Any CDER unit represented by the National Treasury Employees Union (NTEU)

Conciliation: A mechanism for resolving disputes through an intermediary, not usually involving confrontation

Mediation: A process by which parties agree to facilitation by a neutral person or persons to discuss and resolve a dispute

Union: NTEU, the labor union representing CDER employees

POLICY

- The CDER Ombudsman solicits and receives complaints, questions, and suggestions from any source affected by CDER actions, processes, decisions, requirements imposed, or advice given by any CDER staff or manager, subject to limitations in this MAPP. The Ombudsman also receives complaints from CDER staff relating to problems with external or internal interactions, policies, and procedures.

- The CDER Ombudsman is an independent, neutral advocate for fair process and a confidential source of advice on CDER policies, processes, and procedures. The CDER Ombudsman reports directly to the Center Director, but does not represent management, employees, or complainants. However, the CDER Ombudsman may become an advocate for change where the process demonstrates a need for it.

- At the request of one or more involved parties, the CDER Ombudsman will investigate alleged problems and use appropriate means (e.g., investigation, mediation, conciliation, negotiation) to resolve issues and disputes that arise between external constituents and CDER staff or among CDER staff.

- The CDER Ombudsman does not make or alter Center decisions. Such decisions should be sought through CDER's appeals and formal dispute resolution processes. The Ombudsman may, however, guide appellants through these processes and participate in CDER meetings with appellants at their request.

- The CDER Ombudsman may investigate observed problems on his or her own initiative,

inform CDER management, and advocate a solution.

- The CDER Ombudsman will keep contacts strictly confidential and will not disclose (or be required to disclose) any information provided in confidence, subject to the exceptions below. Information obtained through inquiries or investigations within CDER, however, is not presumed to be confidential. If a CDER staff member believes he or she needs confidentiality in responding to an Ombudsman inquiry, the Ombudsman will discuss the appropriateness of such confidentiality with the individual.

- Ombudsman confidentiality may be breached only (1) to address an imminent risk of serious harm or (2) to discuss allegations of wrongdoing by CDER employees or by the regulated industry with CDER's Associate Director for Policy. Such discussions are for the purpose of possible referral to the FDA Office of Internal Affairs (OIA) or Office of Criminal Investigations (OCI). Nothing in this MAPP is intended to limit the ability of any CDER employee to report allegations directly to OIA or OCI in accordance with 21 CFR 19.21.

- The CDER Ombudsman will operate in conformance with the Code of Ethics and Standards of Practice set by The Ombudsman Association.

- The CDER Ombudsman will honor bargaining agreements between management and the union representing CDER employees. The CDER Ombudsman will inform complainants who are in the bargaining unit of their rights to union processes and refer them to appropriate union officers. At the request of the union and complainant, the Ombudsman may work with the union to effectively resolve disputes or issues involving members of the bargaining unit.

- The CDER Ombudsman has no authority to compel testimony or evidence, or to decide disputes or impose solutions. Further, the CDER Ombudsman does not address issues such as ongoing litigation, formal regulatory action, or cases filed in alternative appeal systems, such as EEO, formal grievance procedures, or union actions. The Ombudsman generally does not address issues arising from actions that have not been endorsed at the division level or above. Complainants in these cases are advised to communicate further with division staff before bringing an issue to the Ombudsman.

- Complaints about final CDER actions or decisions made by the Center Director should be appealed to the Commissioner through the Office of the FDA Ombudsman, not the CDER Ombudsman.

- Complaints about conduct, action, or inaction by the CDER Ombudsman should be

discussed with the Center Director after attempts to resolve the issues with the Ombudsman have been unsuccessful.

RESPONSIBILITIES AND PROCEDURES

- **The CDER Ombudsman will:**

  Conduct inquiries in an impartial manner, free from initial bias and conflicts of interest.

  Respond directly to or ensure that all inquiries, complaints, and referrals are answered in a timely manner.

  Determine that all complaints are ripe for investigation, referring complainants, when appropriate, for further discussions with CDER staff.

  Exercise discretion in acting or declining to act on a complaint or question.

  At the request of any party to a dispute, use mediation or negotiation to seek an equitable solution.

  Solicit internal and external input on CDER's policies, procedures, and communications.

  Foster good communication between CDER staff and interested parties.

  Consult with the CDER Associate Director for Policy concerning allegations of wrongdoing by CDER staff or by a regulated entity and refer them to OIA or OCI, as appropriate.

  Within ethical limits imposed by pledges of confidentiality, advise the Center Director or other appropriate CDER managers on current issues and problems and suggest solutions when appropriate.

  Periodically report on observed trends in CDER problems and issues, generally through informal discussions with CDER managers and by publishing aggregate data (e.g., numbers and categories of complaints) annually.

  Work closely with the FDA Ombudsman's office and communicate and coordinate activities with other Federal ombudsmen to ensure consistency among various offices, enabling common issues to be addressed effectively.

Serve as CDER's expert in matters relating to intercenter jurisdiction and respond to all Requests for Designation from the FDA Ombudsman's office or to other requests for jurisdictional consults in a timely manner.

- **CDER staff and management will:**

  Cooperate fully with the CDER Ombudsman in investigations and related activities and make no attempt to hinder or unduly influence an investigation, withhold information from the Ombudsman, or undermine the Ombudsman's effectiveness or confidentiality agreements.

  Refer appropriate issues and potential disputes to the CDER Ombudsman as soon as they are recognized.

- **The CDER Associate Director for Policy will:**

  Evaluate any complaints referred by the CDER Ombudsman that allege illegal activities by CDER employees or regulated entities and ensure they are referred to FDA's OIA or OCI, as appropriate.

EFFECTIVE DATE

This MAPP is effective upon date of publication.