CDER Office of Compliance Drug Shortage Overview

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OBJECTIVES

- Discuss CDER Office of Compliance's Mission, Organizational Structure, and Role.
- Define CDER's Multidisciplinary Drug Shortage Mitigation Process.
- Describe Interagency Coordination Efforts between Office of Compliance and the Drug Shortage Staff.
- Provide Key Recommendations.

Who We Are

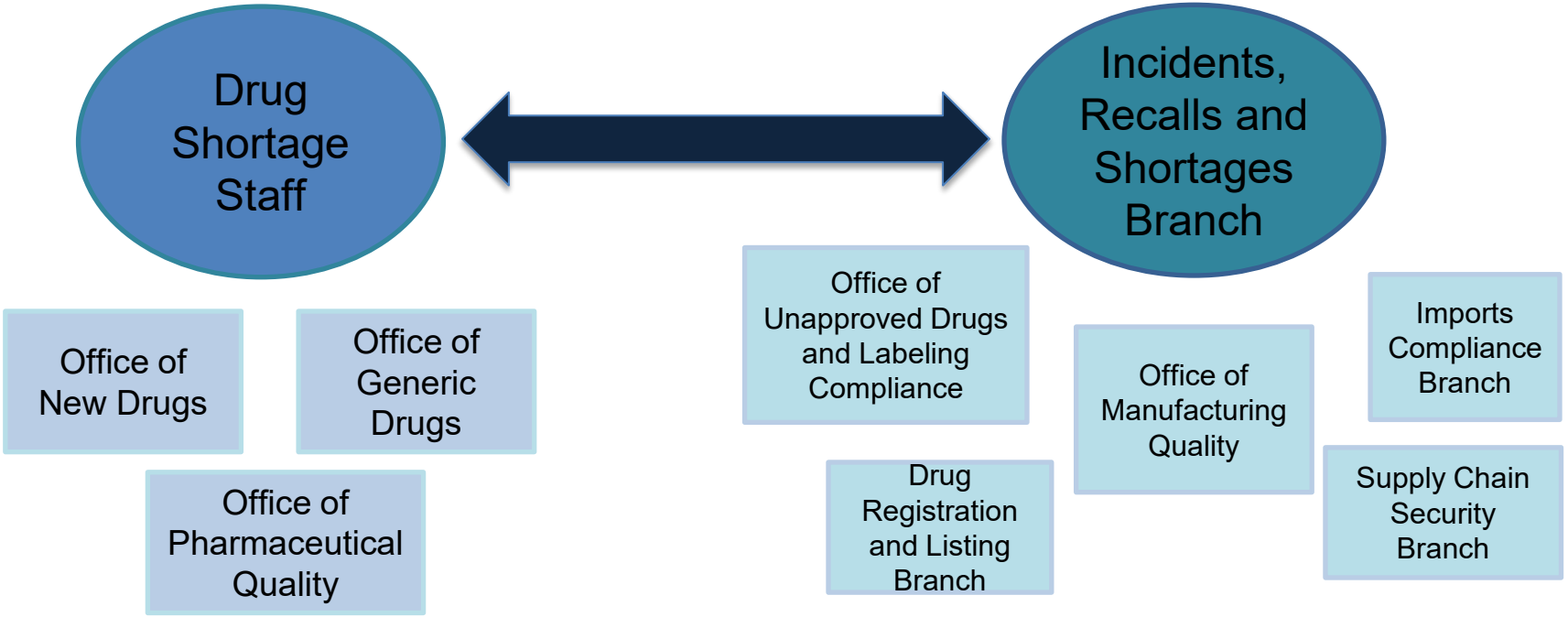
CDER Office of Compliance Mission:

To shield the public from poor quality, unsafe, and ineffective drugs through proactive compliance strategies and risk-based enforcement actions.

Incidents, Recalls, and Shortages Branch Role:

Evaluation and classification of drug recalls; FDA's point of contact for and support to the Drug Shortage Staff by coordinating all CDER Office of Compliance program actions for management of a drug shortage.

Drug Shortage Mitigation: A Multidisciplinary Approach



Drug Shortage Mitigation

- Incoming shortage proposals from Industry:
  Incidents, Recalls and Shortages Branch (IRSB) consolidates CDER Office of Compliance (OC) recommendations and provides OC's position to a firm's shortage proposal to the Drug Shortage Staff (DSS).

- Outgoing shortage evaluations from Office of Compliance to Drug Shortage Staff:
  IRSB communicates CDER OC considerations to DSS prior to issuance of a Warning Letter or taking any enforcement action.

- Proactive Recall notifications to the Drug Shortage Staff

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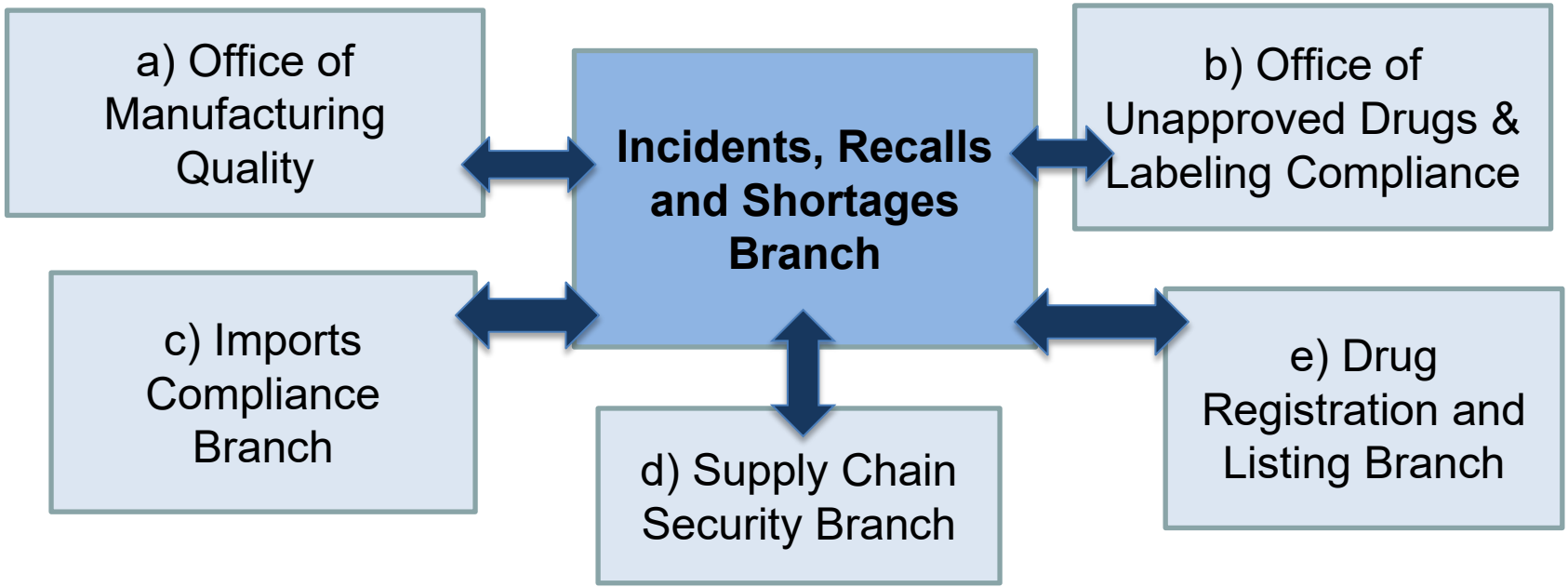

Key Recommendations

	**Promote Voluntary Compliance** *Adhere to the Food, Drug, and Cosmetics Act*
	**Ensure Adequate Investigation** *Thoroughly analyze root cause of shortage*
	**Provide a Realistic Timeline** *Outline a timeline for investigating product defects and scheduling restarts after shutdowns*
	**Anticipate Potential Issues and Maintain Frequent Communication** *Identify risks that could lead to shortages early* *Ensure up-to-date knowledge of CMO processes and facilities*

Key Recommendations

	**Consult with FDA Field Offices** *Reach out for guidance on potential recalls*
	**Build Robust Inventories** *Prior to major manufacturing changes (e.g., facility upgrades or ownership transfers)*
	**Provide Short-Long-Term Proposals** *Address potential shortage issues in notifications to the FDA*
	**Engage in Dialogue with FDA** *Collaborate on long-term solutions and remediation efforts*


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