

Clinical Research Dictionary & Introduction to the FDA Drug Approval Process

- **Clinical Research Dictionary**
- **Drug Development, Approval & Promotion**

New Drug Development Process
IND Review Process
NDA Review Process
Generic Drug Review Process
OTC Drug Review Process
Prescription Drug Advertising and Labeling

- **Post Drug Approval Activities**

Post-Marketing Surveillance
Medication Errors
Drug Shortages
Therapeutic Inequivalence Reporting
Patient Labeling and Risk Communication

- **Communicating with CDER
Other Drug Initiatives**

Orphan Drugs
Drug Registration & Listing System
Women's Health Issues
Pregnancy "Category C" Labeling
Pediatric Initiatives