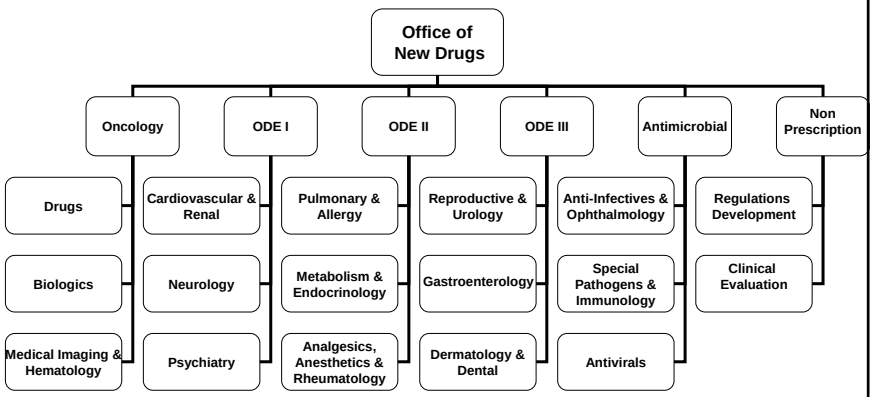
Overview of the Office of New Drugs (OND)

Kim Colangelo
Associate Director for Regulatory Affairs
Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

Topics for discussion

- Organizational structure
- The role of OND in the review process
- Interactions with regulated industry
- OND-led programs and initiatives

Organizational Structure



OND Scientific Review Staff

- Clinical (M.D.)
- Pharmacology/Toxicology (Ph.D)
- Regulatory Project Management (R.N., Pharm.D., B.S.)

Reviewers also specialize in:

- Chemistry (Ph.D.)
- Clinical Pharmacology (Ph.D., Pharm.D.)
- Statistics (Ph.D.)

The role of OND in the review process

- Provide advice and guidance to regulated industry during drug development
- Signatory authority for regulatory decisions related to new (i.e., not generic) drugs
  - Working in conjunction with the other offices within CDER
- Establish policy and procedures governing the above

Interactions with regulated industry

Why are interactions important?

Communication between

the Agency and industry

facilitates a common goal –

more efficient drug development.

Procedures for meetings

- Meetings can be requested by industry or by FDA
- Meeting requests from industry should be submitted in writing
- Relevant background in the written request
  - ***Guidance for Industry, Formal Meetings with Sponsors and Applicants for PDUFA Products***

Procedures for meetings (cont.)

- CDER will respond to a written meeting request within 14 days (granted/denied)
- Meeting Types:
  - Type A: stalled drug development program
  - Type B: “milestone meetings” (pre-IND, end of Phase 1, end of Phase 2/pre-Phase 3, pre-NDA/BLA)
  - Type C: all others

Procedures for meetings (cont.)

- Meetings are scheduled to be held within a set number of days from receipt of the meeting request based on meeting type
  - Type A: 30 days
  - Type B: 60 days
  - Type C: 75 days

Procedures for meetings (cont.)

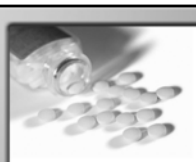
- Background packages are due 2 weeks prior to a Type A meeting, 4 weeks prior to Type B or C meetings
- Background package content needs to support intended objectives
- Internal CDER pre-meeting ideally 2-7 days prior to the meeting*

Procedures for meetings (cont.)

- Draft/preliminary responses to questions submitted in background package sent 24-48 hours before meeting*
- CDER will generate meeting minutes within 30 days of the meeting
  - CDER version is the official version: industry is advised to submit disagreements in writing
  - Minutes are not transcripts of the meeting but contain discussion summaries, decisions, and action items

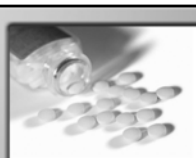
Other interactions

- Written advice, including special protocol assessments, during development
- Labeling, risk management, postmarketing study commitment discussions during application review
- Advisory Committee meetings
- Workshops and public dialogues on policy development (e.g., adaptive trial design)



OND-led programs and initiatives

- Guidance and Policy
- Pediatric and Maternal Health
- Pharmacology/Toxicology
- Regulatory Affairs
- Study Endpoints and Label Development



OND - Guidance and Policy

- Aid in the development and implementation of review policies and procedures within OND to ensure a clear, consistent, efficient, and standardized new drug review process (including development, review and clearance)
- Oversight of PDUFA-mandated activities
- Facilitation of OND-jurisdictional matters

OND – Pediatric and Maternal Health

- Implementation of pediatric and maternal health policy and procedures designed to promote the study of drug and biological products in the pediatric population and improve pregnancy and lactation-related information in product labeling
- Consultative services to OND, CDER and FDA

OND – Pharmacology/Toxicology

- Pharmacology and Toxicology reviewers evaluate nonclinical data to aid in:
  - Selecting safe starting and stopping doses for "first in man" clinical trials
  - Identifying potential toxicities that should be monitored in the clinic
  - Assessing toxicities that cannot be addressed in clinical trials such as potential for carcinogenicity, teratogenicity, mutagenicity and chronic toxicity

OND – Regulatory Affairs Team

- Provide regulatory and project management support to the Office of New Drugs, Immediate Office, and to lead various OND and Center-wide initiatives
  - Postmarketing Study Commitment Program
  - Formal Dispute Resolution
  - Biologics Expert Review Staff

OND – Study Endpoints and Label Development

- Oversees quality initiatives and provides expert consultative services in labeling development:
  - Physician's Labeling Rule
  - Structured Product Labeling
- …and study endpoints:
  - Patient reported outcomes

OND Quality Systems – Process Improvement

- Deliberative structure in place to identify, develop, implement and monitor process improvement initiatives
  - Change Coordination Group
  - Process Improvement Teams
- First challenge/accomplishment – move to White Oak and concurrent reorganization

Ongoing process improvement initiatives

- Meeting management
  - Processes implemented – guidance pending
- Postmarketing safety
  - Interactions with Office of Surveillance and Epidemiology
  - Identification of focal points within each division to coordinate activities
- NDA/BLA Review
  - Operationalize Good Review Management Practices and Principles (GRMP) Guidance

Ongoing process improvement initiatives (cont.)

- Administrative management
  - Including personnel issues
- Document Room Advisory Board
- Independent Contractors:
  - Postmarketing study commitment decision-making evaluation
  - Prospective first-cycle review process
  - Meeting minutes

Questions?

Thank you for your attention.