FDA Labeling Review Process

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Agenda

- Pre-submission
- Receipt to mid-cycle
- Mid-cycle to final action
- Challenges and recommendations

Focus on the **process**

Labeling *content and format* will not be addressed

Types of labeling reviews

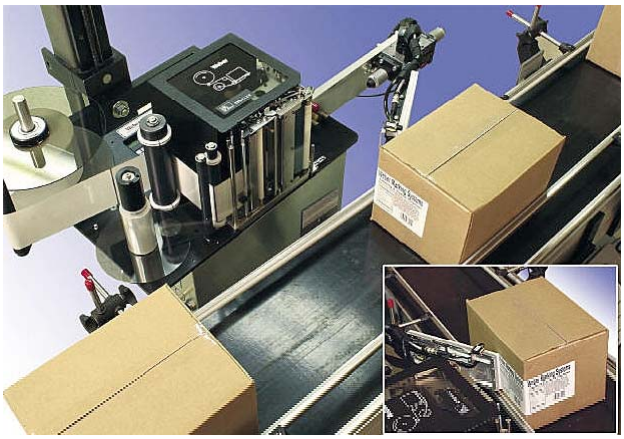
- **Prescribing information**
- **Labeling for patients**
- **Packaging**
- Proprietary name*

* Beyond the scope of this presentation

Rules of the game

- Team effort
- Many players
- Numerous steps
- Timelines

Not as simple as it appears…



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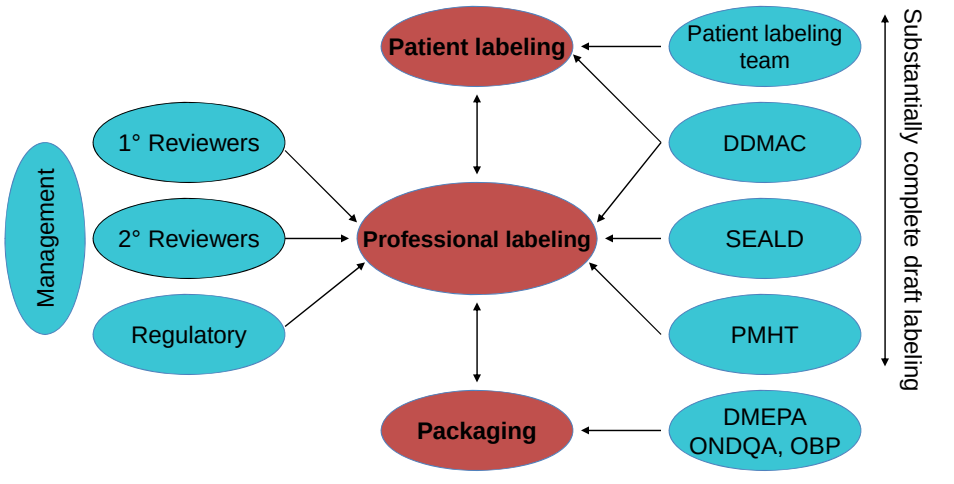
Players in CDER



Regulatory = Regulatory Project Management Staff

DDMAC – Division of Drug Marketing Advertising and Communication
SEALD – Study Endpoints and Labeling Development
PMHT – Pediatric and Maternal Health Team
DMEPA – Division of Medication Errors and Prevention Analysis
ONDQA – Office New Drug Quality Assessment
OBP – Office of Biotechnology Products

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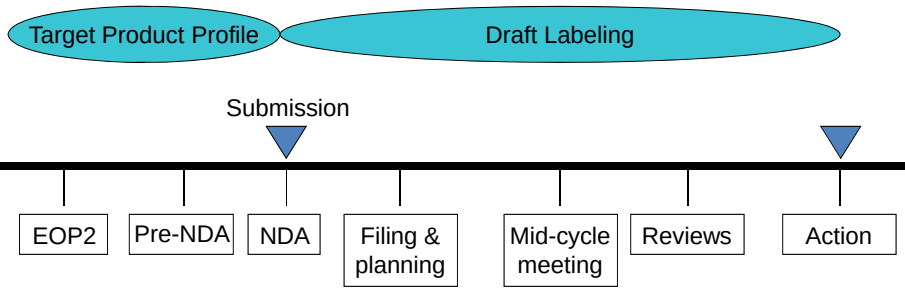
Sequence of events



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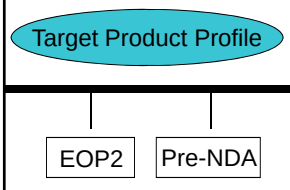
Pre-submission recommendations

- Consider available resources
  - Discuss the target product profile (TPP)
  - Regulations and guidance
  - Benchmark against approved labeling



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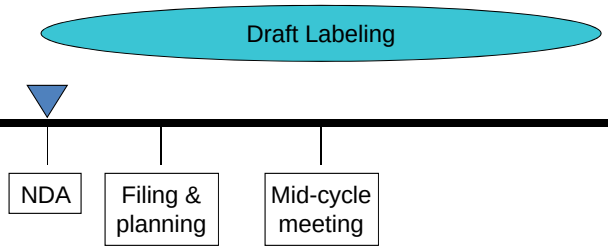
Receipt to mid-cycle recommendations

- Conduct early labeling review
- Plan for review of labeling



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Strong start & early review

- Sponsors should submit labeling that meets the regulatory requirements and follows relevant guidance
- FDA review of labeling starts at the time of submission and continues throughout the review process

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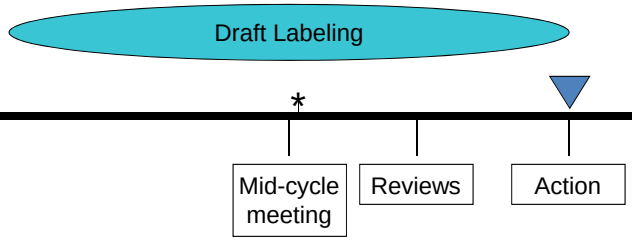
Mid-cycle to action recommendations

- Discuss plans for labeling at mid-cycle*
- Clarify responsibilities and due dates



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***** Brief labeling planning meeting within 1 week after mid-cycle *if needed*

Address challenges

Issue: Labeling often *reviewed* and finalized *very* close to the time of approval

- Potential reasons for untimeliness
  - Reluctance for reviewers to edit labeling *prior* to completing their reviews
  - Challenge for reviewers to edit labeling if *against* approval

Solution: discuss labeling review plans & set goal dates

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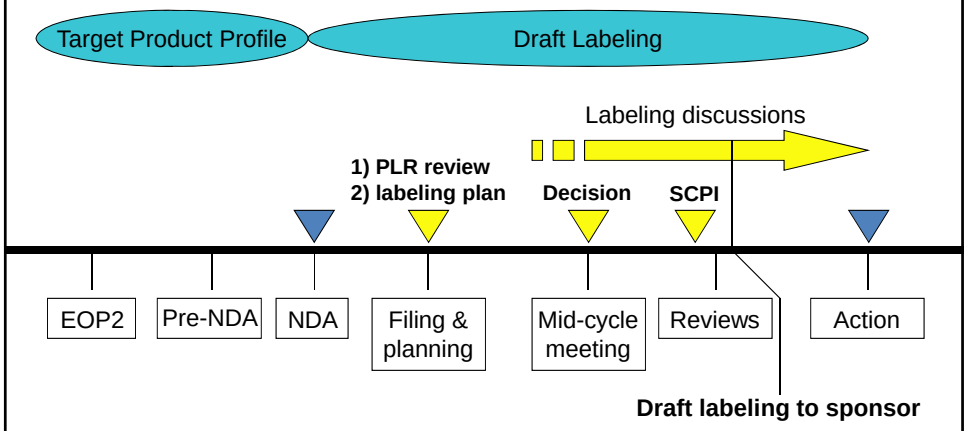
Labeling discussions



PLR – Physicians Labeling Rule

Decision – Shall revise labeling / shall NOT revise labeling

SCPI – Substantially Complete Prescribing Information

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FDA team labeling meetings

- Invite key players and a decision maker
  - Smaller discipline specific meetings if needed
- Prepare thoroughly in advance (or cancel)
- Focus on major issues and controversies
  - Send out agenda prior to meeting

Some challenges

1. Reviewer(s) argue against approval, but management plans to approve
2. Significant issues will be discussed at an upcoming Advisory Committee Meeting; meeting occurs late in the review cycle
3. Individuals providing various recommendations, some of which conflict

Possible solutions (1)

1. Reviewer(s) argue against approval, but management plans to approve

Recommendations

- Finalize the plan for labeling by mid-cycle
- Reviewers should document their views
- Let the data do the talking

Possible solutions (2)

2. Significant issues will be discussed at an upcoming Advisory Committee Meeting

Recommendations

- Labeling reviews should proceed
- Sections may need to be revisited based on AC Meeting discussion

Possible solutions (3)

3. Many individuals offering different viewpoints

Recommendations

- Have meetings to discuss and debate
- A decision maker should be there
- Consider seeking “outside” expertise

In conclusion,
the labeling review process
should look and feel *less* like this…

Resources

- Desk reference guide
  http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM218757.pdf
- Requirements for Prescribing Information
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm

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