FDA Labeling Review Process

Dan Brum
FDA, CDER, Office of New Drugs, Division of Cardiovascular and Renal Products
Commander, U.S. Public Health Service
Commissioned Corps

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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...

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
Pre-submission recommendations

- Consider available resources
  - Discuss the target product profile (TPP)
  - Regulations and guidance
  - Benchmark against approved labeling
Receipt to mid-cycle recommendations

- Conduct early labeling review
- Plan for review of labeling

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

* 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
Labeling discussions

Target Product Profile → Draft Labeling

1) PLR review
2) labeling plan

Decision

SCPI

EOP2 Pre-NDA NDA Filing & planning Mid-cycle meeting Reviews Action

Draft labeling to sponsor

PLR – Physicians Labeling Rule
Decision – Shall revise labeling / shall NOT revise labeling
SCPI – Substantially Complete Prescribing Information

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
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

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...

And more like this...
Resources

- Desk reference guide

- Requirements for Prescribing Information

Contact information

Dan Brum, PharmD, MBA, RAC
Commander, US Public Health Service
Food and Drug Administration
White Oak 22, Room 4160
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
office (301)796-0578
dan.brum@fda.hhs.gov