Labeling Finalization: Recommendations for Final Check of Prescribing Information Format and Appearance

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Disclaimer

• The views expressed in this presentation are those of the speaker, and do not necessarily represent an official FDA position.

• The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates.
Learning Objectives

• Understand labeling quality and important format/appearance issues that can arise

  – Learn to identify and correct the 5 common format¹ issues in the Prescribing Information

1. This presentation will not focus on content issues

www.fda.gov
Importance of Quality

VS

www.fda.gov
CDER Cares About Quality Too!

- Prescription Drug Labeling is CDER’s primary tool for communicating drug information
- CDER has developed an internal process to identify and correct Prescribing Information format/appearance issues
  - Labeling review specialists
  - Multiple types of internal labeling training
  - Collaborative review of the Prescribing Information
  - Access to various labeling format/appearances resources (e.g. Selected Requirements of Prescribing Information)

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CDER Looks for Every Opportunity to Increase Format Quality

- Pre-Submission
- Submission
- End of Cycle
- Post-Approval
Post Approval Labeling Quality Review Is Key

• Quality is based on labeling regulations and guidances, scientific content, and format/appearance

• We evaluate overall labeling format/appearance quality routinely
  – Publicly available approved labeling (Drugs@FDA)
  – Reviewed approximately 1400 PLR labeling in the past year

1. Last approved labeling for all CDER regulated NDA and BLA products with PLR labeling. CBER products are not included on Drugs@FDA. Did not include ANDA products
Labeling Format/Appearance Analysis Summary of All Approved PLR Labeling

• Of the 1400 PLR labeling the majority do not have format/appearance issues

• Of the labeling that do contain significant format/appearance issues; a noticeable trend arose. These 5 issues will be the focus of my presentation today
  – Significant format/appearance issues are confusing and distract from information in the Prescribing Information
Suboptimal Labeling

- May decrease confidence in quality of all FDA-approved labeling.
- May distract from required and recommended information in labeling.
- May diverge from regulatory requirements and guidance recommendations.
Challenge Question: Can You Find the 5 Major Format Issues in the Following Labeling?
1. Annotations
2. Line Numbers
3. Number of Columns
3. Number of Columns

• Should be in **two column format** *

* 21 CFR 201.57(d)(8) and guidance for industry: Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements (February 2013)
3. Number of Columns

Table of Contents

• Should be in two column format

Table of Contents

• Should be in two column format*

* Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements (February 2013)
3. Number of Columns

- Highlights
  - Should be in **two** column format

- Table of Contents
  - Should be in **two** column format

- Full Prescribing Information
  - Consider putting into **one** column format
4. Correct Dates
4. Correct Dates

Never updated

Conflicting
5. Appropriate Page Numbering

This is not page 3, it is page 1.
5. Appropriate Page Numbering

First page of the Medication Guide is incorrectly identified as page 38
5. Appropriate Page Numbering

For example, a labeling document with attachments is 40 pages long (30, 5, and 5 pages for PI, MG, and IFU, respectively). Ensure that:

- PI is numbered Pages 1 to 30
- MG is numbered Pages 1 to 5
- IFU is numbered Pages 1 to 5

PI = Prescribing Information, MG = Medication Guide, IFU = Instructions for Use
# Updated Optimal Labeling

## Dosage Forms and Strengths

<table>
<thead>
<tr>
<th>Dosage form(s)</th>
<th>strength(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>(5)</td>
</tr>
</tbody>
</table>

## Containcations

- Test (4)
- Test (5)

## Warnings and Precautions

- Test (5)
- Test (5)

## Adverse Reactions

Most common adverse reactions (incidence > 5%) are listed (5).

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

## Drug Interactions

- Test (7)
- Test (7)

## Use in Specific Populations

- Test (8)
- Test (8)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling (1) and Medication Guides.
Resources for Format and Appearance of the Prescribing Information

FDA’s Prescription Drug Labeling Resources website provides format resources for the development of Prescribing Information:

https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources

- Selected Requirements of Prescribing Information (SRPI) – A 41-item, drop-down checklist of important format elements of the PI based on regulations (21 CFR 201.56 and 201.57) and guidances.

- Sample PLR Template.
Summary

• Lets collaborate together, so we can maintain quality labeling and identify and correct any format issues
  – We are working hard to improve format and appearance issues within CDER.
  – Perform a quality check of labeling prior to approval that includes the following items:
    • Annotations, Line Numbers, Correct Number of Columns, Correct Dates, Appropriate Page Numbering
Thanks!