

# Best Practices for Generic Drug Labeling

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# Learning Objectives

- Discuss best practices to update abbreviated new drug application (ANDA) labeling following revisions to the approved labeling of a reference listed drug (RLD).
- Review best practices for addressing patents and exclusivities as it relates to generic drug labeling.
- Provide updates on the current best practices on distributing electronic labeling.

# Updating ANDA Labeling Following Revision of the RLD Labeling

# Background

- Generic drugs are required to have the same labeling as the RLD, except for differences allowed under Section 505(j)(2)(A)(v) of the Act and 21 CFR 314.94(a)(8).
- Applicant expected to update labeling *at the earliest time possible* after FDA has approved labeling for the corresponding RLD.

# Labeling Updates for Non-Marketed ANDAs



- Labeling for non-marketed ANDAs that are not withdrawn must also be the same as the most recently approved RLD label.
- If the RLD is withdrawn, refer to the draft guidance titled [“Updating ANDA Labeling after the Marketing Application for the Reference Listed Drug has been Withdrawn”](#).

# Physician Labeling Rule (PLR)



- Generic drugs must update their labeling to be in PLR format when the RLD labeling is approved with PLR format.
- PLR format labeling:
  - Communicates accurate and up-to-date information on the safe and effective use of drugs,
  - Reduces the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information, and
  - Makes the PI more accessible for use with electronic prescribing tools and other electronic information resources.

# Where to Find Information on Changes to RLD Labeling



- [Drugs@FDA](#) lists recently approved RLD labeling
- Subscribe to *CDER Drug Safety Labeling Changes* and *CDER New* email updates
  - <https://www.fda.gov/about-fda/contact-fda/get-email-updates>

# How to Submit Updated ANDA Labeling



- Unapproved ANDAs: submit an amendment
  - [ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA](#)
- Tentatively approved ANDAs: submit an amendment
  - [ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs](#)
- Approved ANDAs: submit a changes being effected (CBE) supplement
  - [Changes to an Approved NDA or ANDA](#)



# Challenge Question #1

Which resource should be used to find the last approved labeling for the RLD?

- A. DailyMed
- B. Orange Book
- C. Drugs@FDA
- D. USP-NF

# Addressing Patents & Exclusivities

Disclaimer: the following section reviews best practices for addressing patents and exclusivities as it relates to generic drug labeling.

# Patent Certifications

- If there are no patents listed in the Orange Book, or if the patents have expired, the applicant must submit one of the following:
  - Paragraph I certification, paragraph II certification, or a statement that there are no relevant patents
- For each *unexpired* patent listed in the Orange Book, the applicant must provide the patent number and submit one of the following:
  - Paragraph III certification, paragraph IV certification, or a section viii statement

# New Patent Use Codes

- Need to address any new, timely filed patent use code(s) when added to an existing patent
  - **New** PIII or PIV certification,
  - or **new** section viii statement
- Reference to a previously submitted certification is **not** sufficient

# Exclusivities

For approved ANDAs:

- New labeling carve-outs due to exclusivities should be submitted as a prior approval supplement (PAS).
- Labeling carve-outs to align with an Agency-issued BPCA template should be submitted as a CBE.
- Submission should include a statement addressing the new exclusivity(ies) to clearly state intent.

# Patent Certifications and Exclusivities



- Include a screenshot of the Orange Book listing patents and exclusivities for the RLD.
- Submit a patent and exclusivity table under module 1.3.5 listing how each patent and exclusivity is addressed.
- Certifications or statements should include references to patent use codes, if applicable.
- Ensure all patent certifications and exclusivity statements are congruent among themselves and with the proposed labeling.

# Challenge Question #2



## Is the following patent certification acceptable?

[Firm] previously submitted a Paragraph IV Certification pursuant to 21 CFR 314.94(a)(12)(i)(A)(4) with respect to patent 1234567. [Firm] hereby states that we intend to extend its Paragraph IV certification to the newly listed patent use code, U-1234.

A. Yes

B. No

# Electronic Labeling



# Electronic Medication Guides



- Medication Guides may be distributed to authorized dispensers through a website.
  - Website must be non-promotional
  - Website should display a PDF of the Medication Guide
  - Applicants remain responsible for fulfilling its obligations under 21 CFR 208.24(b)(2) to produce Medication Guides in sufficient numbers
- May be submitted as a CBE supplement, if this is the only change to the labeling components.

# Electronic Medication Guides



- Add a statement to the immediate container label and carton identifying the website for the electronic Medication Guide, such as:
  - “Dispense with Medication Guide available at: [www.companyname/medguide/drugname.com](http://www.companyname/medguide/drugname.com).”
  - “Dispense the Medication Guide provided separately to each patient.” on the principal display panel (PDP) and the URL on the side panel.
- Ensure that the link(s) and/or QR codes are correctly listed and operational.
- Do not add a Medication Guide dispensing statement to the Prescribing Information or to the Medication Guide.

# Electronic Prescribing Information



- **Acceptable** to provide the Prescribing Information in an electronic format in addition to providing it in a printed copy in accordance with FDA's regulations.
- Proposing to discontinue printing the Prescribing Information and substitute a website URL in its place is **not acceptable**.
  - Under 21 CFR 201.100(d), prescription drug labeling must contain the prescribing information required, and in the format specified, by 21 CFR 201.56, 201.57, and 201.80.

# Other Electronic Patient Labeling



- **Acceptable** to put a URL or QR code to distribute electronic labeling on the container and carton labeling in addition to providing a physical copy of labeling.
- Proposing to discontinue printing the patient labeling, such as the Patient Information Leaflet, and substitute a website URL in its place is **not acceptable**.
  - Under 21 CFR 201.57(c)(18), patient labeling must be printed immediately following the Prescribing Information or otherwise accompany the drug product.

# Challenge Question #3

The proposal to distribute an electronic Medication Guide via the addition of a URL to the container and carton labeling with no other changes may be submitted as a/n:

A. Annual report

B. Changes being effected supplement

C. Prior approval supplement

# Resources



- [Drugs@FDA](#)
- [Revising ANDA Labeling Following Revision of the RLD Labeling](#)
- [Updating ANDA Labeling after the Marketing Application for the Reference Listed Drug has been Withdrawn](#)
- [ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA](#)
- [ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs](#)
- [Changes to an Approved NDA or ANDA](#)
- [Orange Book](#)
- [Medication Guides — Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies \(REMS\)](#)

# Summary



- Update generic drug labeling at the earliest time possible after FDA has approved labeling for the corresponding RLD.
- All newly listed, timely filed patent use codes must be addressed when added to an existing patent.
- It is acceptable to distribute electronic Medication Guides to a dispenser via a URL or QR code in lieu of printing physical copies.

# Closing Thought

Adherence to ANDA labeling best practices facilitates the labeling review process and enables the fulfillment of GDUFA III labeling commitments – resulting in the approval of safe and effective generic drugs for the American public.



# Thank you!

Division of Labeling Review (DLR),  
Office of Regulatory Operations (ORO), Office of Generic Drugs (OGD)  
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