

60-Day NF Qualifying (A)NADA Labeling SUPPLEMENTs (QLS)

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What are Labeling Supplements?

- Labeling Supplements not Requiring Prior Approval (“Changes Being Effected” or CBE Labeling Supplements):
 - NL subclass code
 - 21 CFR 514.8 (c)(3)
 - 60-day review time
- Prior Approval (PA) Labeling Supplements:
 - NF subclass code
 - 21 CFR 514.8(c)(2)
 - 180-day review time
- Both types of labeling supplements are non-fee paying

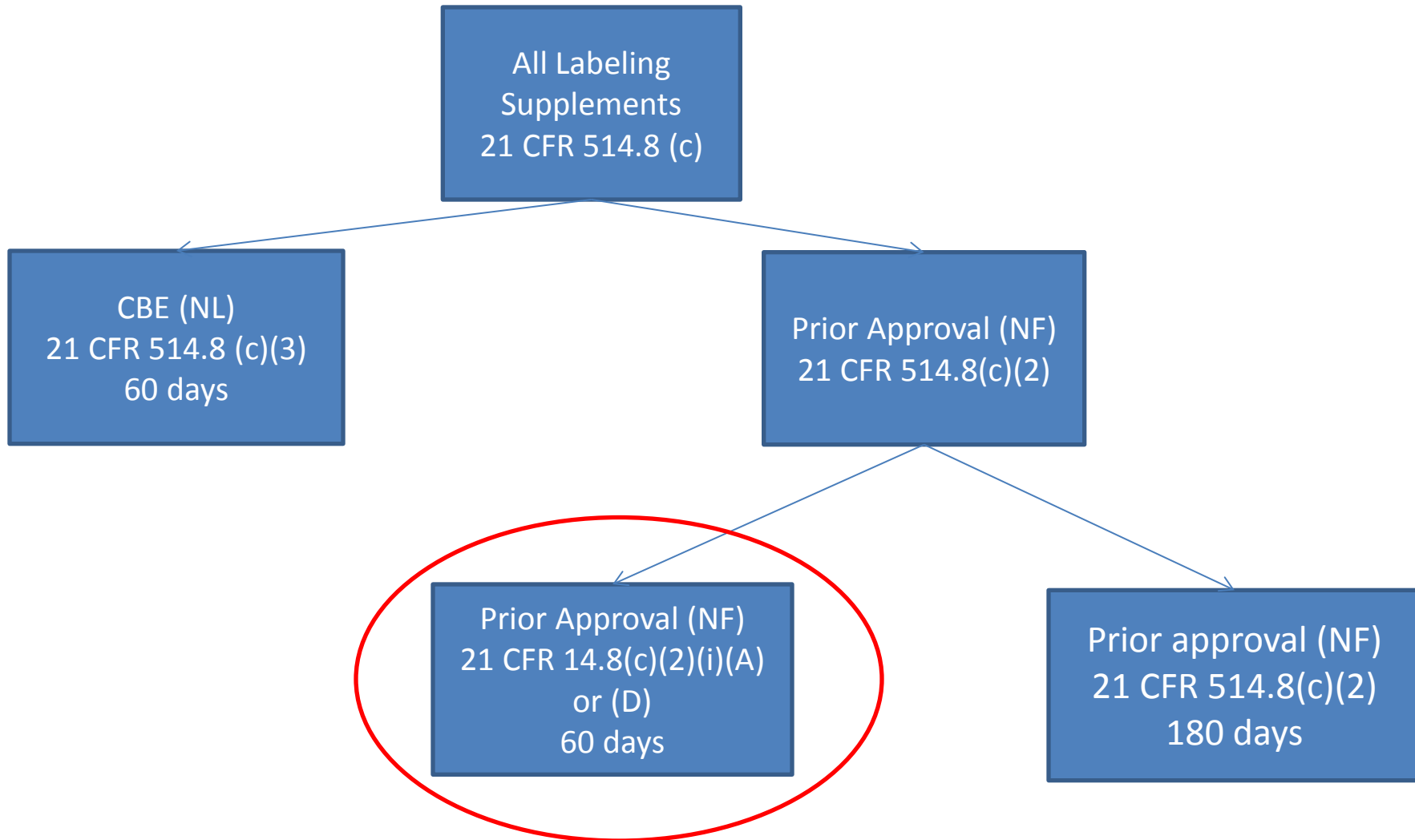
What are 60-Day NF Labeling Supplements?

- ADUFA III Goal (implemented October 1, 2014)
 - Review and act on 90 percent of qualifying labeling supplements as described in 21 CFR 514.8(c)(2)(i)(A) and (D) within 60 days after the submission date. The Agency will review and act on 90 percent of non-qualifying labeling supplements within 180 days after the submission date.

What are NOT 60-Day NF Labeling Supplements?

- The 60-day NF process does not apply to **MOST** Generics
 - The 60-day NF process applies **ONLY** to ANADAs that have an approved B1 supplement (B1 Generic designation) and does not apply to non-fee supplemental applications submitted to an approved ANADA.
- The 60-day NF process does not apply to CBE (NL) Labeling supplements
 - **No change** to current process
 - NL supplements currently have a 60 day review time

LABELING SUPPLEMENTS



Requirements for 60-Day Review

- Must be submitted using eSubmitter
- The sponsor must provide a complete list of labeling changes and certify that no other changes have been made
- CVM must be able to determine upon initial review that the changes will not decrease the safety of drug use

eSUBMITTER TEMPLATE UPDATES

- Qualifying Labeling Supplement (60-day NF)
Template question

Screen: 1.0 General Information

Non-Fee Supplement

Are you submitting a labeling supplement that qualifies for a 60 day review (21 21CFR514.8 (c)(2)(i) (A) or (D))?

Yes
 No

Provide a summary of the labeling changes.

Please certify that there are no additional changes to the labeling except those changes that are specifically described in the summary of labeling changes above.

Examples of changes That May qualify for 60-Day review*

- Changes or deletions to existing text or addition of new text, which can be adequately verified, validated, and evaluated within the 60-day timeframe, and do not require review of safety or effectiveness information
- Change in existing graphics or addition of new graphics
- Change in trade dress not otherwise covered under 21 CFR 514.8(c)(3)(i) and (ii)
- Change in proprietary name
- Addition of new presentation that is similar to the approved labeling (e.g., a single dose carton)
- Minor changes to feeding and mixing directions that can be adequately evaluated in 60 days

*These are general examples- specific cases may or may not qualify.

EXAMPLES OF CHANGES THAT MAY NOT QUALIFY FOR 60-DAY REVIEW*

- Labeling appears to include significant changes, including the addition or deletion of sections, major changes to the text or font size
- Labeling includes Type A medicated article labeling with extensive changes to the mixing directions
- Labeling change is to a Type A Medicated Article label and it impacts Type B/C blue bird labels that are not included in the submission or have not been previously reviewed by CVM
- Submission of promotional or advertising information. Exceptions may include promotional statements or rebate coupons.

*These are general examples- specific cases may or may not qualify.

PROCESS

- Standing CVM Triage Group (consisting of members from ONADE and OSC) will confirm that a proposed 60-day NF submission qualifies as a 60-day NF QLS
- If changes do not qualify the submission as a 60-day NF QLS, it will be converted to a 180-day prior approval (NF) labeling supplement and the sponsor will be issued a letter informing them that the supplement has been converted to a 180-day NF labeling supplement

QUESTIONS?

- Refer to the CVM Policy and Procedures Manual 1243.6040 for ONADE's internal procedures

CENTER FOR VETERINARY MEDICINE
ADMINISTRATIVE PROCEDURES MANUAL

1243.6040

OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

Review of (A)NADA 60-day NF Qualifying Labeling Supplements

- <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/UCM416781.pdf>
- Ask the Team Leader of the target animal division that would receive the submission