GDUFA II – IR and DR Letters

Michael Folkendt, M.S.
Associate Director for Regulatory Affairs
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality, CDER, FDA
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The Commitment Letter Language

Section II.B.

ANDA Review Transparency and Communications Enhancements

1. FDA will issue the appropriate IR(s) and/or DRL(s) from each review discipline as soon as the discipline has completed its review, with the first IR(s) and/or DRL(s) at about the mid-point of the review.
What is New/Changed in GDUFA II?

• Two program enhancements centered on improving communications during a review-cycle:
  - Discipline Review Letters (DRLs)
  - Information Request (IR) Letters
• There are no longer ECDs
• Multiple DRLs and IRs can be issued in one GDUFA cycle
Discipline Review Letters (DRLs)

- Defined in the commitment letter (sec. VII.K.)
- Communicates the preliminary thoughts on possible deficiencies found by the discipline
  - May or may not reflect input from supervisory levels
- Issued at the “conclusion” of the discipline review
  - Discipline: labeling, bioequivalence, and quality
- DRLs are expected to be issued at about the mid-point of the review cycle
  - “About the mid-point” means the midpoint of the GDUFA goal date plus 1 month (mid-cycle date or MCD)
  - Multiple DRLs from a discipline may be possible
Information Request (IR) Letters

• Defined in the commitment letter (sec. VII.O.)
• Used to request further information or clarification to allow completion of the discipline review
• Likely include a requested response date
• The first IR letter may be issued as early as shortly after the ANDA is “Received”
OPQ GDUFA II snapshot of OPQ process
Quality Review timeline – 10 month example for Original ANDAS

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*DFR = OGD’s Division of Filing Review; MCD = Mid Cycle Date
What is the Impact?

• Reviews of ANDAs will begin earlier in the review cycle
• Applicants will receive *preliminary* thoughts on their application at about the mid-point of the review period
• Applicants may have an opportunity to resolve issues during the review cycle
• The goal is to improve review efficiency and reduce review cycles (get generics to market faster)
What Should Industry Expect?

• The reviewers will be evaluating the application earlier in the review cycle.
• Applicants may receive one or more IR letters throughout the review cycle.
  – Can be soon after notice that the ANDA is received.
• Applicants will receive at least one DRL for each discipline around the midpoint of the review cycle.
• Unresolved IR or DRL items may appear in a subsequent CR letter.
What Can Industry Do to Assist?

• Submit high quality submissions at the start
• Respond to the IR and DRL promptly
  – IR/DRL likely to include requested response dates
  – If an extension is needed, request it within 7 days of the IR letter
• Submit only requested information
• Learn from previous DRL and IR requests
Remember

• Everyone plays a role in realizing the benefits of the GDUFA II IR and DRLs

• DRL is a GDUFA commitment
  – FDA will strive to issue DRLs from each of the 3 disciplines by about the mid-point of the review cycle

• A prompt complete response to IR/DRLs will facilitate the review of the application
Resources

• GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter)

• Draft Guidance for Industry - Information Requests and Discipline Review Letters Under GDUFA

• CDER MAPP - Issuance of Information Requests and/or Discipline Review Letters for Abbreviated New Drug Applications under the Reauthorization of the Generic Drug User Fee Act
Who do I call if I have questions?

- **General ANDA questions** – Start with your OGD Regulatory Project Manager (RPM)
- **IR/DRL questions or delays in responding** – start with your discipline PM (e.g., RBPM for OPQ/quality)
  - The contact name should be included in the letter