U.S. FOOD & DRUG ADMINISTRATION

GDUFA II – IR and DR Letters

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2017 AAM Fall Technical Conference

November 06, 2017

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

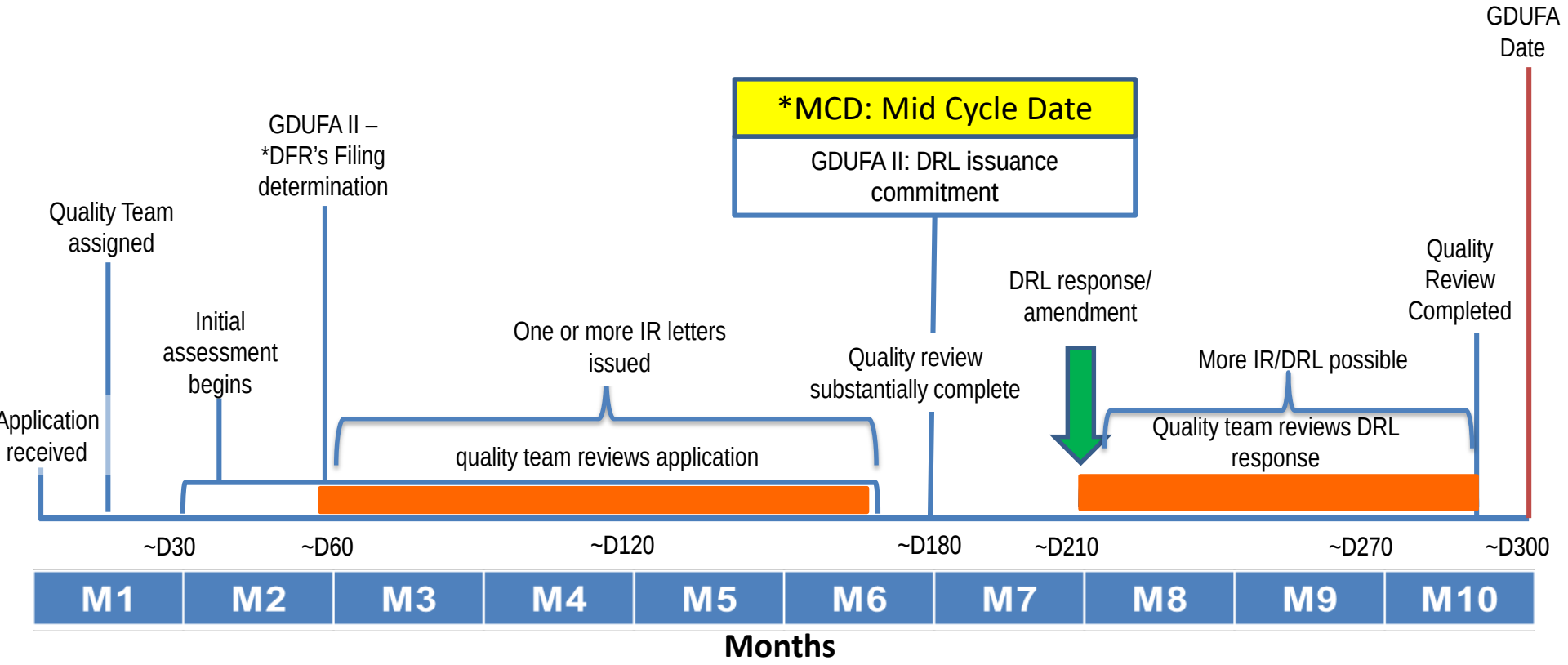
Discipline Review Letters (DRLs)

- 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



*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 through out 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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