GDUFA II – IR and DR Letters

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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
- Multiple DRLs and IRs can be issued in one GDUFA cycle
- There are no longer ECDs

What is New/Changed in GDUFA II? Discipline Review Letters (DRLs)

- Issued at the "conclusion" of the discipline (i.e., labeling, bioequivalence, quality) review
- Communicates the preliminary thoughts on possible deficiencies found by the discipline
  - May or may not reflect input from supervisory levels
- 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
  - Multiple DRLs from a discipline may be possible

What is New/Changed in GDUFA II? Information Request (IR) Letters

- Used to request further information or clarification to allow completion of the discipline review
- May include a requested response date
- The first IR letter may be issued as early as shortly after the ANDA is “Received”

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 in that review cycle
- The goal is to improve review efficiency and reduce review cycles (get generics to market faster)

What Can Industry Do to Assist?

- Submit high quality submissions at the start
- Respond to the IR and DRL promptly
- Submit only requested information
- Learn from previous DRL and IR requests

Who is Responsible?

- **YOU!** Everyone plays a role
- 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

How Will it be Monitored?

- Internal dashboards will help project managers monitor the review process and issuance of IRs and DRLs

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- Draft Guidance for Industry - *Information Requests and Discipline Review Letters Under GDUFA*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

External Contact

- **General ANDA questions** – start with your OGD Regulatory Project Manager (RPM)
- **IR/DRL questions or delays in responding** – start with your discipline PM (RBPM for OPQ/quality)


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