Draft Guidance for Industry: Information Requests and Discipline Review Letters Under GDUFA

Overview of Presentation

- Background
- Discipline Review Letter (DRL)
- Information Request (IR)
- IR/DRL Timing
- IR/DRL Responses
- Key Takeaways
- Resources

Background

- The Generic Drug User Fee Amendments of 2017 (GDUFA II) was signed into law on August 18, 2017 in order to facilitate timely access to high quality, affordable generic medicines.
- As part of GDUFA II, FDA agreed to two program enhancements centered on improving communications during a review-cycle:
  - Discipline Review Letters; and
  - Information Requests.
- The recently published draft guidance entitled *Information Requests and Discipline Review Letters Under GDUFA,* explains how the Agency intends to deploy these two program enhancements during the review of an original abbreviated new drug application (ANDA).

Discipline Review Letter (DRL)

GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2018-2022

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VIII. DEFINITIONS

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K. Discipline review letter (DRL) – means a letter used to convey preliminary thoughts on possible deficiencies found by a discipline reviewer and/or review team for its portion of the pending application at the conclusion of the discipline review.

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- Generally, a DRL will be issued from each discipline as it finishes its initial review of its portion of a received ANDA.
- It will not represent a complete review of the entire submission and does not necessarily reflect input from all supervisory levels.
- It allows applicants to know, as soon as possible, early thoughts on possible deficiencies within specific sections of an application.

Information Request (IR)

GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2018-2022

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VIII. DEFINITIONS

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O. Information Request (IR) – means a letter that is sent to an applicant during a review to request further information or clarification that is needed or would be helpful to allow completion of the discipline review.

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- A DRL is intended to convey early thoughts on possible deficiencies found during a discipline review whereas an IR will request further information or clarification that is needed or would be helpful to proceed with the discipline review.
- As with DRLs, an IR will not represent a complete review of the entire submission and will not necessarily reflect input from all supervisory levels.

IR/DRL Timing

GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2018-2022

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II. ORIGINAL ANDA REVIEW PROGRAM ENHANCEMENTS

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B. **ANDA Review Transparency and Communications Enhancements**

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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.

2. Following the IR and/or DRL at about the mid-point of the review, IRs and/or DRLs will, as appropriate, continue from each review discipline on a rolling basis.

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5. FDA will continue to issue IRs and/or DRLs late in the review cycle, until it is no longer feasible, within the current review cycle, for applicant to develop and FDA to review a complete response to the IR and/or DRL.

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- Generally, no later than about the mid-point of the GDUFA goal date:
  - Discipline reviews will be complete; and
  - IRs and/or DRLs will have been issued.
- While DRLs may only be issued after the completion of a discipline review, IRs may be issued at any time.

IR/DRL Responses

GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2018-2022

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II. ORIGINAL ANDA REVIEW PROGRAM ENHANCEMENTS

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B. **ANDA Review Transparency and Communications Enhancements**

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3. Neither IRs nor DRLs stop the review clock or add to a GDUFA goal.
4. If an applicant is unable to completely respond within the time frame requested by FDA, including any extensions that may be granted by FDA, then FDA will generally issue a CRL.

- DRLs and IRs may contain a requested response date; an applicant may request a short extension if they are unable to respond by a requested response date.
- Responses to an IR or a DRL generally will not affect the review clock.
- FDA will strive to review a response during the review cycle in which it is received if such review can be completed during such review cycle.

Key Takeaways

- **Anticipated Impact of IRs and DRLs:**
  - Improve FDA's predictability and transparency
  - Promote the efficiency and effectiveness of FDA's review process
  - Minimize the number of review cycles necessary for approval
  - Increase FDA's overall rate of approval, and facilitate greater access to generic drug products
- **How Industry Can Help:**
  - Submit high quality ANDAs from the start
  - Respond to the IR and DRL promptly
  - Submit only requested information
  - Learn from previous DRL and IRs

Resources

- GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter)
- Draft Guidance for Industry on Information Requests and Discipline Review Letters Under GDUFA
- CDER MAPP on Issuance of Information Requests and/or Discipline Review Letters for Abbreviated New Drug Applications


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