Mid-Review Cycle Meetings for Complex Products

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Commitment Letter Language

• Section [III. F. 2. a.]: As set forth in guidance issued pursuant to Section III(A)(1), the Project Manager and other appropriate members of the FDA review team will call the applicant to provide the applicant with an update on the status of the review of their application. An agenda will be sent to the applicant prior to the mid-review-cycle meeting. The Project Manager will coordinate the specific date and time of the telephone call with the applicant. (emphasis added)
What is New?

GDUFA II Establishes a Pre-ANDA Program for Complex Generic Drug Products

- Applicants granted a Product Development Meeting OR a Pre-submission Meeting have the option of a Mid-Review Cycle Meeting (MRCM) in the form of a 30-minute teleconference

Goals:

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<th>Clarify regulatory expectations in early development</th>
<th>Assist applicants with developing more complete submissions</th>
<th>More efficient/effective review process</th>
<th>Reduce # of cycles</th>
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What Does it Mean?

- FDA Schedules Telephone Conference
- FDA Asks Questions
- Applicants
- FDA Sends Agenda
- FDA Provides Review Status
What is the Impact?

- More complete ANDA submissions
- More efficient/effective review process
- Reduced Number of cycles
- Decreased time from ANDA acceptance to approval
Who is Responsible?

- Applicant
- Regulatory Project Managers (RPMs)
- Review Teams
- Regulatory Business Process Managers (RBPMs)
- Discipline Project Managers (DPMs)
What Will They Do?

- Schedule MRCM Meetings
- Send meeting notifications
- Reserve phone lines
- Draft & distribute meeting minutes
- Facilitate meetings
- Draft & send agenda
What Will They Do?

- **Notify disciplines of pre-meetings and MRCMs**
- **Attend internal pre-meetings**
- **Coordinate reviewer input**
- **Attend MRCMs**
- **Assist with meeting minute endorsement**
What Will They Do?

- Attend internal pre-meeting
- Provide comments & edits to MRCM minutes
- Provide applicable agenda items
- Lead applicable scientific discussion
- Attend MRCM
What Can Industry Do to Assist?

- Review agenda items
- Prepare responses
- Attend meetings
- Discuss responses
- Follow agenda

Applicant
Summary

Goals of the Mid-Review Cycle Meeting

What this Means to Industry & FDA

Overall Impact

FDA Responsibilities

How Industry Can Assist
For questions, please contact the Regulatory Project Manager assigned to the respective ANDA