Post-Complete Response Letter Meeting Request

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What is New/Changed?

- Goal dates
  - Scheduled date for 90 percent of post-CRL meetings within 10 calendar days of receipt
  - Conduct 90 percent of post-CRL meetings within 30 calendar days of receipt
- Calendar days instead of business days
- Granting teleconference when requested
- Incomplete meeting packages may be denied and late submitted meeting requests that are otherwise complete may be granted with no goal dates

Complete Post-CRL Meeting Package

- List of proposed questions grouped by discipline
- Requested format
  - Teleconference or written response
- If teleconference:
  - Proposed agenda for 30-minute meeting
  - List of specific review disciplines to participate
  - List of all individuals who will attend teleconference from applicant's organization and consultants

What is the Impact?

- Goal dates
  - Provide predictability
  - Allows Agency to track
- Business days to Calendar days
  - Consistency with other goals
  - Consistency operationalizing goals
- Granting teleconference when requested
  - Provides opportunity for discussions
  - Reduces/eliminates follow-up meeting requests
  - Allows for earlier resubmissions

Roles and Responsibilities

- Industry
  - Submitting complete and timely meeting request packages
  - Clarifying questions only

- Regulatory Project Manager (RPM)
  (Project Managers for Quality or Labeling-only supplements)
  - Identify/triage/assign
  - Collaborate with the review team to provide grant/deny decision
  - Issue correspondence letters
  - Schedule/facilitate meetings
  - Take meeting minutes
  - Tracking goal dates

- Review team (Discipline Project Managers, Reviewers, Team Leaders)
  - Determine grant/deny decision
  - Provide responses to questions by agreed upon date
  - Attend meeting

How Will it be Evaluated?

- Evaluate contents of package
  - Verify requested information is included
- May grant meeting if:
  - Request has not already been submitted
  - Seeks clarification on deficiencies in complete response letter
  - Complete meeting package submitted
- May deny meeting if:
  - Questions are not clarifying, are outside scope, or require Agency review
  - Request is not submitted after issuance of a complete response letter
  - Meeting package is not complete

What Can Industry Do to Assist?

- Submit a complete meeting request package consistent with the guidance
- Agenda outlining how 30-minute timeframe
- Ensure questions are clarifying in nature and related to a specific deficiency in the complete response letter
- Do not submit questions outside of scope of post-CRL meeting requests
- Send a courtesy copy of the meeting package to the RPM when submitting the meeting request

Resources

- GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter)
- Draft Guidance for Industry *Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA*

Contacts

- Original ANDAs
  - OGD Regulatory Project Manager (RPM)

- Prior Approval Supplements (discipline dependent)
  - Labeling PAS: OGD Labeling Project Manager
  - Quality PAS: OPQ Regulatory Business Process Manager
  - PAS with two or more disciplines: OGD RPM


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