

Post-Complete Response Letter Meeting Request

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- 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





- 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

