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