Requests for Reconsideration at the Division Level Under GDUFA

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What is New/Changed?

• Goal dates for formal dispute resolution above the division level

• Request for Reconsideration process formalized
  – Goal dates for reclassification of a major amendment or standard review status
What is the Impact?

• Goal Dates
  – Predictability
  – Tracking
• Formalized Process for Requests for Reconsideration
• Guidance
  – Details and Recommendations
  – Goals
  – FDA’s Roles/Responsibilities
Roles and Responsibilities

• Industry
• Project Manager
• Original Signatory Authority
• Associate Director of Operations
How Will it be Evaluated?

• Request for Reconsideration
  – Accepted vs. Not Accepted
  – Goal Dates vs. no Goal Date

• Goal Dates
  – 90% metric for requests to reclassify a major amendment or standard review status
  – Enhanced tracking
What Can Industry Do to Assist?

• Follow content and format outlined in guidance
• Submit within seven calendar days
• Send courtesy copies
Resources

• Guidance for Industry, *Formal Dispute Resolution: Appeals Above the Division Level*

• Guidance for Industry, *Requests for Reconsideration at the Division Level Under GDUFA*

• GDUFA II Commitment Letter
External Contact

• Associate Director of Operations:
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