

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:
ANDAREconsideration@fda.hhs.gov

