Review Classification

Andrew Kim, Supervisory Project Manager
Division of Project Management, ORO, OGD
What is New/Changed?

• Prioritization MAPP 5240.3
• Acknowledgment letters will grant/deny priority review requests
What is the Impact?

• Opportunity to receive shorter goal dates
• More transparency in priority designation
• Opportunity for reconsideration
Who is Responsible?

• Office of Generic Drugs (OGD)/Office of Regulatory Operations (ORO)
  – Division of Filing Review (DFR): Original ANDAs
  – Division of Project Management (DPM): ANDA amendments, multidiscipline Prior Approval Supplements (PAS) and amendments, bioequivalence only PAS
  – Division of Labeling Review (DLR): Labeling only PAS and amendments

• Office of Product Quality (OPQ)/Office of Program and Regulatory Operations (OPRO)
  – Quality only PAS
What Can Industry Do to Assist?

• Clearly identify priority classification request in cover letter

• Provide rationale and cite specific criteria per MAPP 5240.3
Resources

• GDUFA II Commitment Letter
• Prioritization of the Review of Original ANDAs, Amendments, and Supplements (MAPP 5240.3)
External Contact

• ANDA questions: Regulatory Project Manager (RPM)
• PAS questions:
  - Multidiscipline PAS and bioequivalence only PAS: RPM
  - Labeling only PAS: Labeling Project Manager (LPM)
  - Quality only PAS: OPQ Regulatory Business Project Manager (RBPM)