

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)

