

# Review Classification: General Considerations

Andrew Kim, PharmD

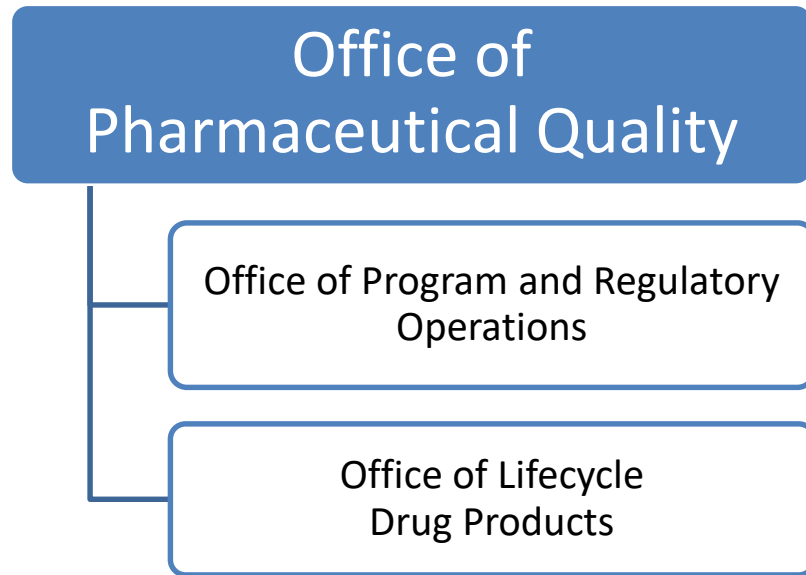
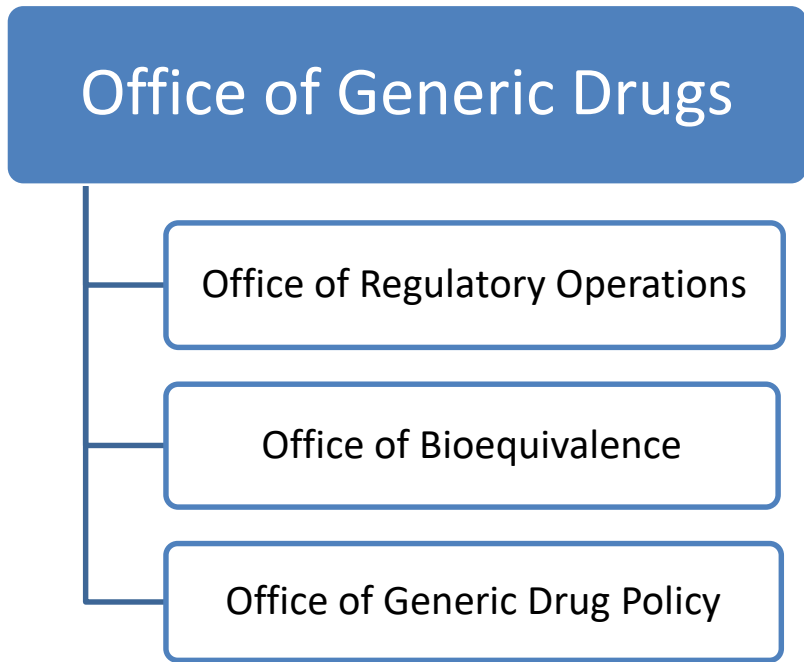
Supervisory Regulatory Project Manager

Division of Project Management, ORO, OGD

# Commitment Letter Language

- Section I – Submission Review Performance Goals
  - I.A. – Original ANDAs and ANDA Amendments
  - I.B. – PASs and PAS Amendments
- Section II – Original ANDA Review Program Enhancements
  - II. A. – ANDA Receipt
  - II. C. – Review Classification Changes During the Review Cycle

# Work Group Organization



# What is New/Changed?

- Prioritization MAPP 5240.3 Prioritization of the Review of Original ANDAs, Amendments, and Supplements (Prioritization MAPP)  
<https://www.fda.gov/downloads/AboutFDA/CentersOfices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf>
- Acknowledgment letters will state review classification

# What Does it Mean?

- New submission review goals
  - Priority ANDAs, PASs and their amendments
  - Pre-Submission Facility Correspondence

# What is the Impact?

- Opportunity to receive shorter goal dates
- Priority designation is submission-based, not application-based

# 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 Pharmaceutical Quality (OPQ)/Office of Program and Regulatory Operations (OPRO)**
  - Quality-only PAS and amendments

# 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)

