U.S. FOOD & DRUG ADMINISTRATION

GDUFA II Goals

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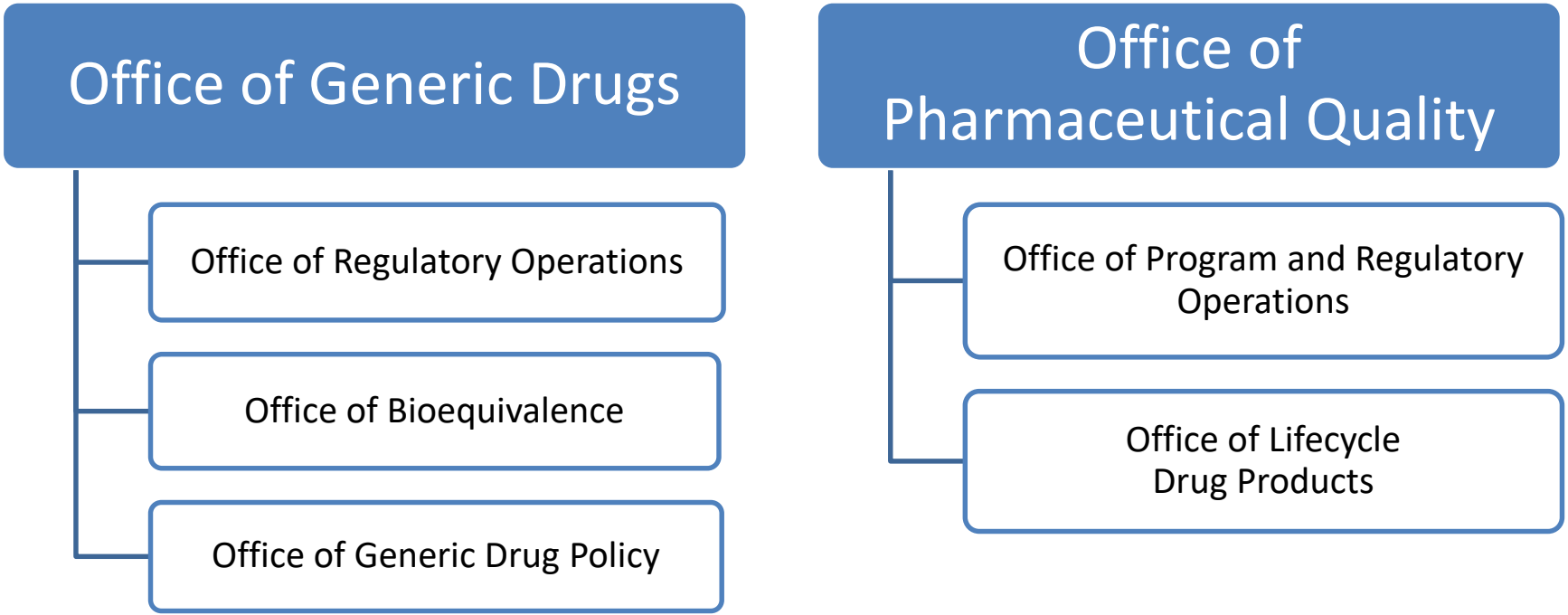
Commitment Letter Language

- Section
  - [I.] Submission Review Performance Goals
    - [A.] Original ANDAs and ANDA Amendments
  - [I.] Submission Review Performance Goals
    - [B.] PASs and PAS Amendments

https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf

Work Group Organization



What is New/Changed?

- All ANDAs will have a GDUFA II Goal date
  - Pre-GDUFA II applications received a goal date through the bridging process
- GDUFA II removes tier classification of amendments
- 90 Percent metric applies to all ANDA originals, original amendments, prior approval supplements (PAS) and PAS Amendments
- Standard or Priority designations

What is New/Changed?

	Submission Type	Goal
Originals	Standard	90% within 10 months of submission date
	Priority	90% within 8 months (w/ PFC unchanged) or 10 months (w/o PFC or changed) of submission date
Amendments	Standard Major	90% within 8 months (no inspection) or 10 months (w/ inspection) of submission date
	Priority Major	90% within 6 months (no inspection), 8 months (w/ inspection & PFC unchanged), and 10 months (w/insp. & no PFC or changed) of submission date
	Standard/Priority Minor	90% within 3 months of submission date

What is New/Changed?

	Submission Type	Goal
PASs	Standard	90% within 6 months (no inspection) or 10 months (w/inspection) of submission date
	Priority	90% within 4 months (no inspection), 8 months (w/ inspection & PFC unchanged), or 10 months (w/inspection & no PFC or changed) of submission date
PASs Amendments	Standard Major	90% within 6 months (no inspection) or 10 months (w/ inspection) of submission date
	Priority Major	90% within 4 months (no inspection), 8 months (w/ inspection & PFC unchanged), and 10 months (w/inspection & no PFC or changed) of submission date
	Standard/Priority Minor	90% within 3 months of submission date

What is the Impact for Applicants?

- Opportunity for applicants to receive shorter goal dates
- More predictable timelines for ANDA actions and communications during the review cycle

Responsibilities and Roles

- **Applicants** submit ANDAs, Amendments and Supplements with required information such as the 356h form
- **FDA** determines Goal Date and Priority Designation
  - Division of Filing Review (DFR): original ANDA
  - Regulatory Project Manager (RPM): Amendments
  - RPM / Regulatory Business Process Manager (RBPM) / Labeling Project Manger: PASs

Industry Expectation of Success

- Goal date success will be measured against the 90 percent metric required by the commitment letter for:
  - ANDA originals
  - ANDA amendments
  - PAS
  - PAS amendments

How Can Applicants Assist?

- Ensure 356h is accurate and all portions are completed
- Ensure submissions contain necessary verification statements (e.g., 21 CFR 314.96(d) and PFC)
- Clearly identify purpose and changes to their submissions on the cover letter

External Points of Contact

- ANDA questions
  - Start with your Regulatory Project Manager (RPM)
- PAS questions – discipline dependent
  - Labeling PASs will be the Labeling PM
  - Quality PASs will be the RBPM
  - PASs with two or more disciplines will be the RPM

Resources

- GDUFA II Commitment letter
  https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf
- Amendments Guidance:
  https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm578371.pdf
- MaPP 5240.3: Prioritization of the Review of Original ANDAs, Amendments, and Supplements
  https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf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