GDUFA II Performance Goals

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What is New/Changed?

- GDUFA II removes tier classification of amendments
- Standard or Priority Designations
- All ANDAs will have a GDUFA II Goal date (Bridging section of GDUFA II Commitment Letter)
- 90 Percent metric applies to all ANDA originals, amendments, and prior approval supplements (PAS)

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?

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

Responsibilities and Roles

- Applicant submits ANDAs, Amendments and Supplements and all 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 Managers for: PASs

How Will Success be Measured?

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

What Can Industry Do to Assist?

- Applicants can ensure 356h is accurate and all portions have been completed
- Ensure submissions contain necessary verification statements (e.g., 21 CFR 314.96(d) and PFC)
- Clearly identify purpose, if relevant request for priority review, and any changes to their submissions on the cover letter

Resources

- GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter)
- Draft Guidance for Industry *ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA*
- Prioritization of the Review of Original ANDAs, Amendments, and Supplements (MAPP 5240.3)

External 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


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