

GDUFA II Review Timelines

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AGENDA/OVERVIEW

- GDUFA II Original Goal Calculation
- Review Timeline without PFC
- Review Timeline with PFC
- Review Timeline with Pre-ANDA Program
- GDUFA II Supplement Goal Calculation
- What these Timelines Mean/Impact for Applicants
- Points of Contact
- Useful Resources

Original Submission Goal Date Calculation



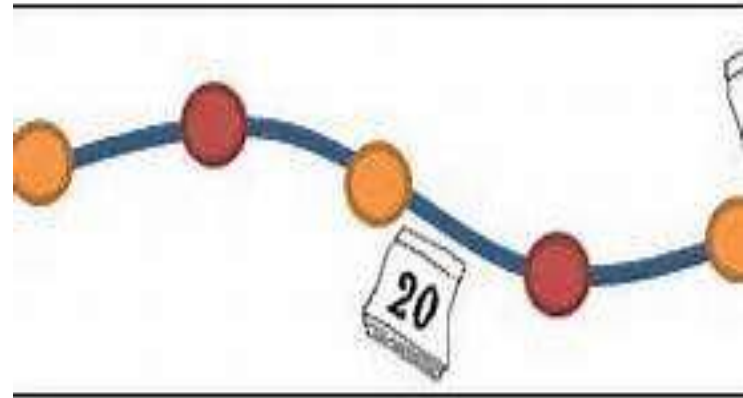
Direct from the GDUFA II Commitment Letter Originals



	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

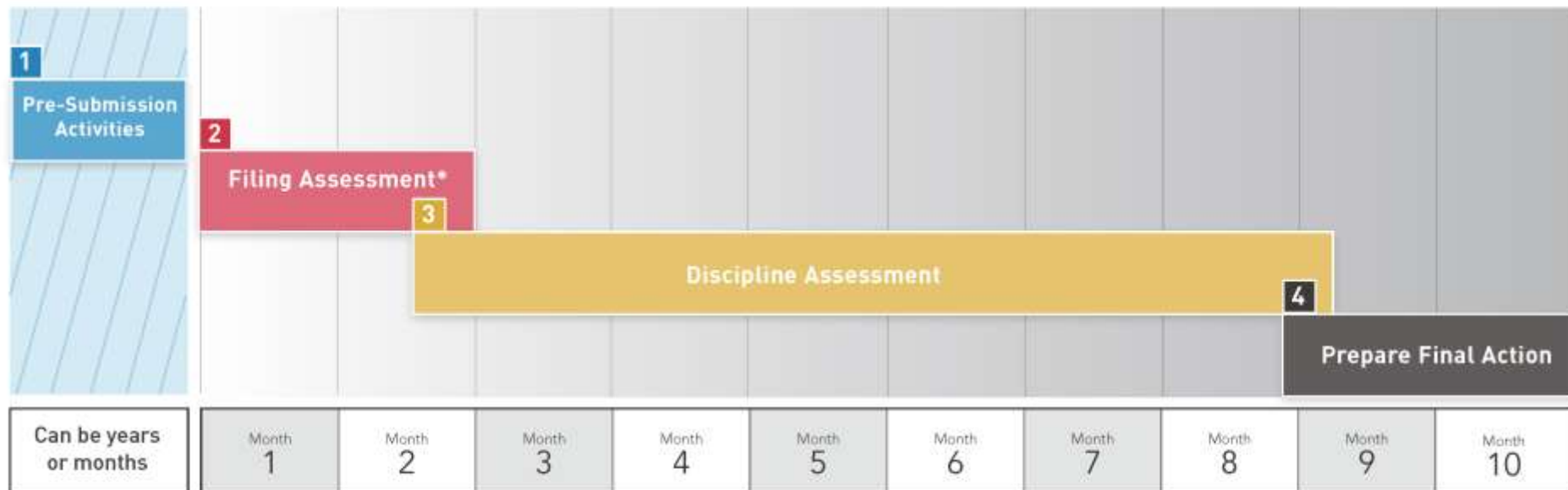
Review Timelines

- Original submission without PFC
- Original submission with PFC
- Original Submission with Pre-ANDA program



Abbreviated New Drug Application (ANDA) Review Timeline⁺

Standard Review 10-Month Goal

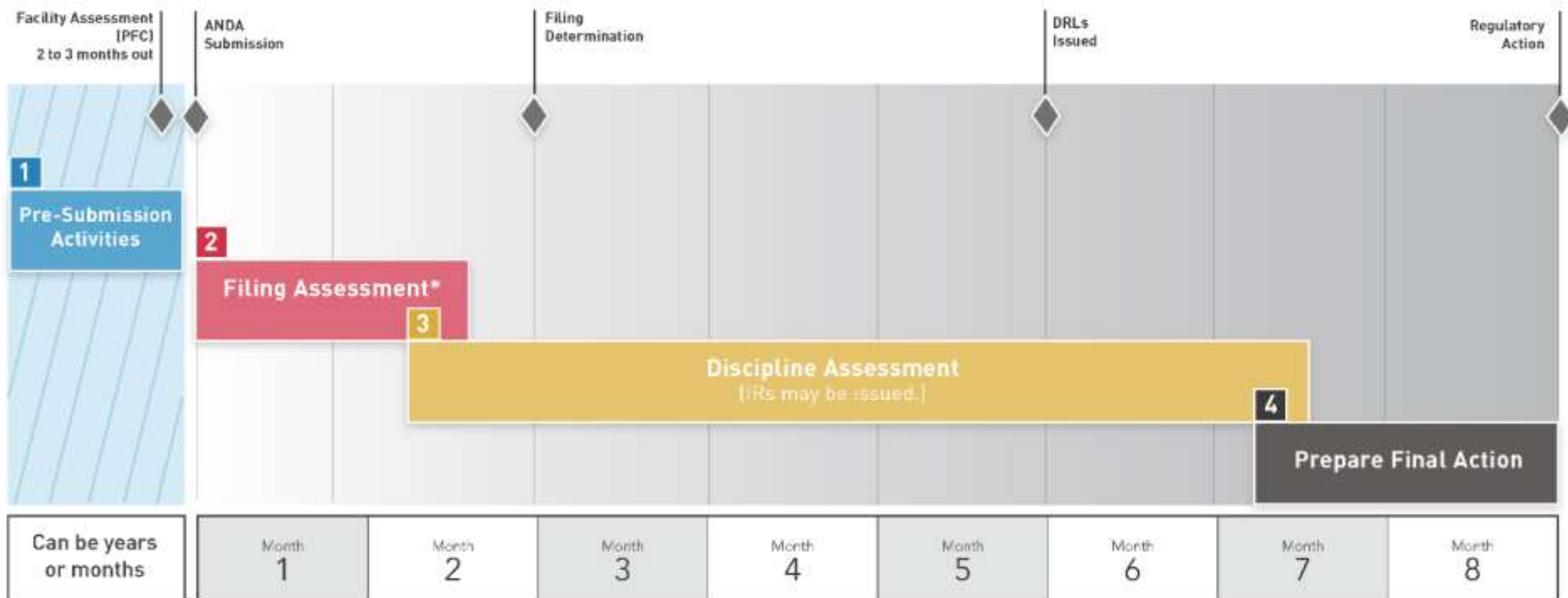


⁺ Each ANDA assessment progresses in a unique and iterative way. This is one example and is not reflective of every ANDA assessment.

* [Good ANDA Assessment MAPP](#)

Abbreviated New Drug Application (ANDA) Review Timeline⁺

Priority Review 8-Month Goal^{**}



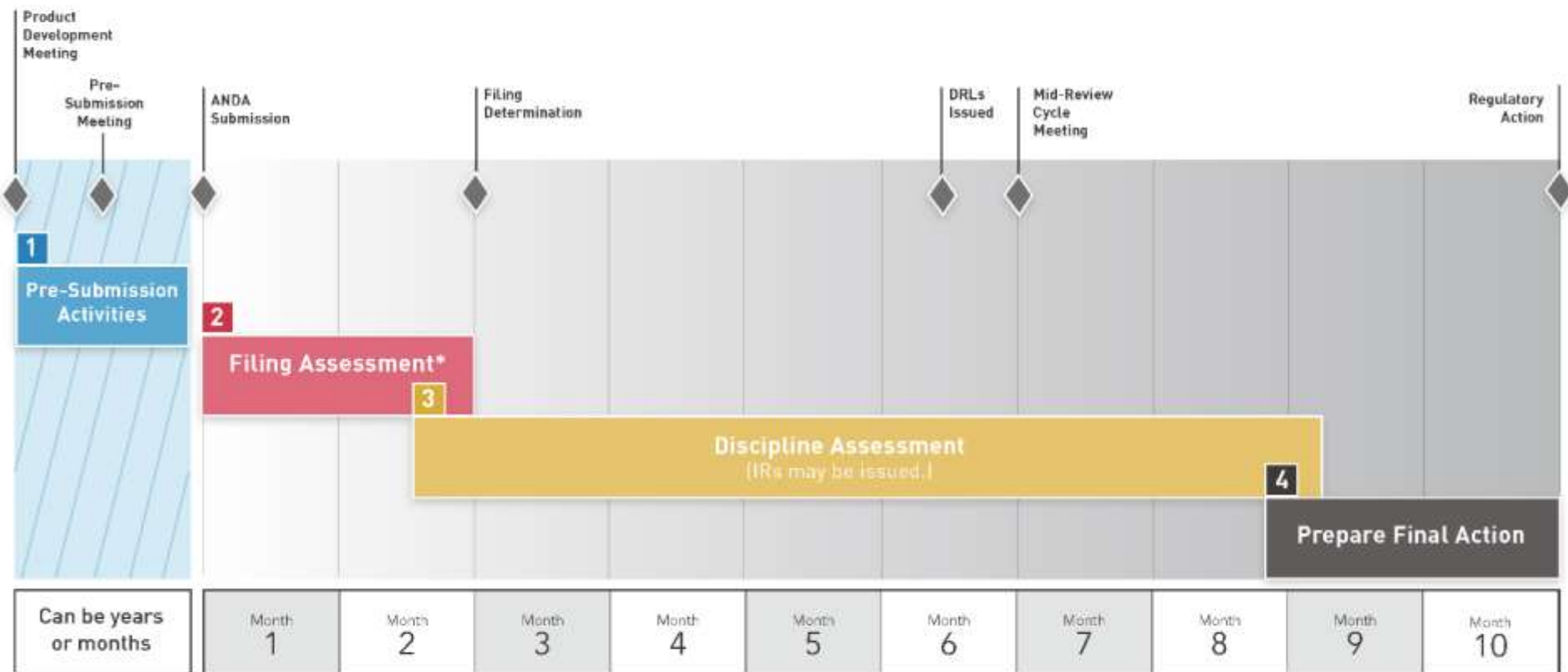
⁺ Each ANDA assessment progresses in a unique and iterative way. This is one example and is not reflective of every ANDA assessment.

^{*} [Good ANDA Assessment MAPP](#)

^{**} Under GDUFA II, for an ANDA to be eligible to receive the priority review goal (8-months), the facility information [PFC](#) shall be submitted no later than 60 days prior to ANDA submission.

Abbreviated New Drug Application (ANDA) Review Timeline*

Pre-ANDA Program 10-Month Goal



+ Each ANDA assessment progresses in a unique and iterative way. This is one example and is not reflective of every ANDA assessment.

* Good ANDA Assessment MAPP

Direct from the GDUFA II Commitment Letter Supplements



	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 to receive earlier goal dates
- More predictable actions and communications timeline
- Increased business certainty

What is the Impact for Applicants?

- Opportunity for applicants doing it right to pull ahead of their competitors
- Opportunity for applicants doing it right to make minor updates, corrections, etc. & gain a first cycle approval - *win for FDA & applicant*

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](#)
- [ANDA Submissions - Amendments to Abbreviated New Drug Applications Under GDUFA](#)
- [MAPP 5240.3: Prioritization of the Review of Original ANDAs, Amendments, and Supplements](#)
- [ANDAs: Pre- Submission of Facility Information Related to Prioritized Generic Drug Applicants \(Pre-Submission Facility Correspondence\)](#)

