

GDUFA II: Update on Year One

Donal Parks, Director

Division of User Fee Management and Budget Formulation
Office of Management | CDER | US FDA

Outline

- Recap of changes in GDUFA II
- Where are we in the annual cycle?
- How did implementation go?
- Words to the wise...

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Recap of Changes in GDUFA II

- Introduction of program fee, CMO concept
- Removal of PAS fee
- No more pending facility fees
- Shifting reliance on fee types

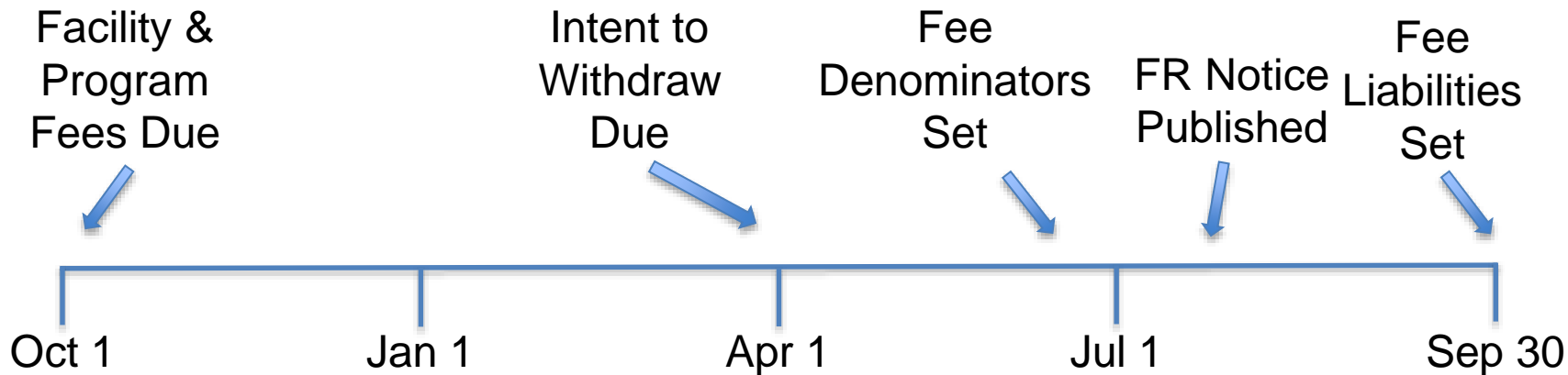
Changes to Fee Structure – GDUFA II

Fee Type		Target Percentage		Total Target Revenue	
GDUFA I	GDUFA II	GDUFA I	GDUFA II	GDUFA I	GDUFA II
ANDA / PAS	ANDA	24%	33%	\$77,523,000	\$162,888,000
	Program		35%		\$172,760,000
API Fac	API Fac	14%	7%	\$45,221,000	\$34,552,000
FDF Fac	FDF Fac	56%	20%	\$180,886,000	\$98,720,000
DMF	DMF	<u>6%</u>	<u>5%</u>	<u>\$19,381,000</u>	<u>\$24,680,000</u>
Total:		<u>100%</u>	<u>100%</u>	<u>\$323,011,000</u>	<u>\$493,600,000</u>

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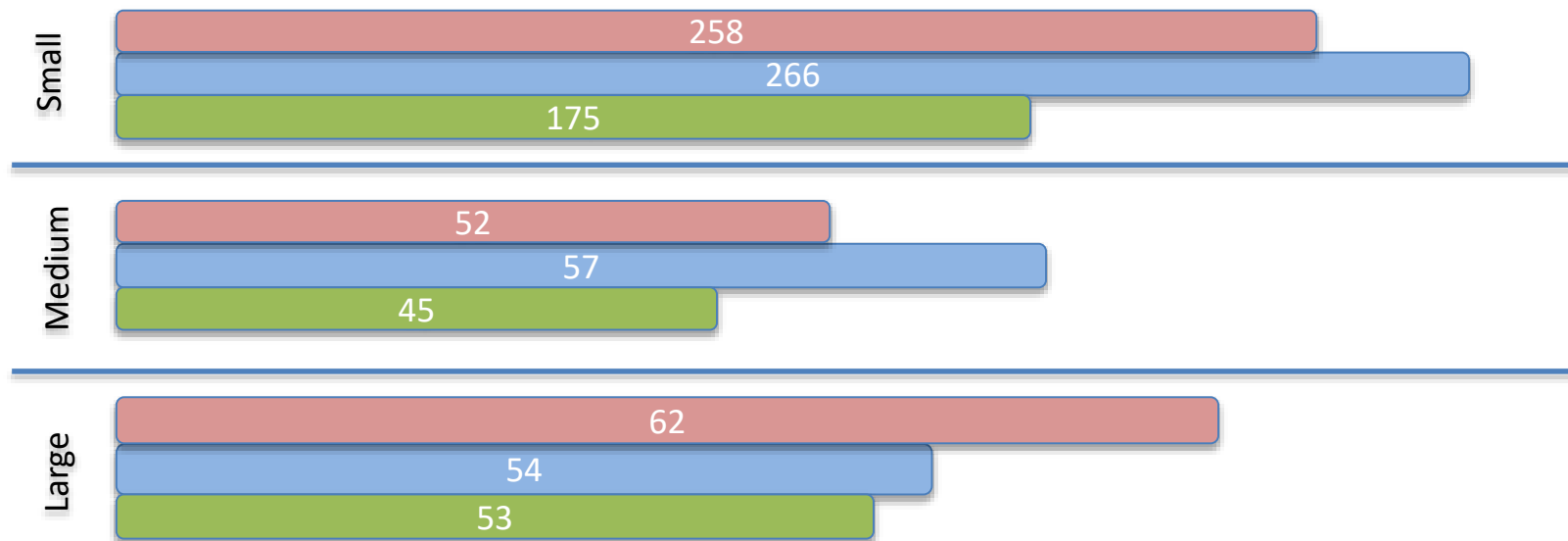
Deadlines To Watch



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Year One of Program Fee



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Things to Bear In Mind...

- Be proactive; monitor our website:
<https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm537822.htm>
- “Approved” vs “discontinued” vs “withdrawn”
- Self-ID ≠ fees

