

GDUFA II Fees: What To Expect

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FDA | CDER

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Outline

- Refresher on GDUFA II fee structure
 - What stays the same
 - What is new and different
- Preparations for GDUFA II fees
 - Data clean up effort
- Timeline for next steps

Where We End GDUFA I

Fee Type	Target Percentage	Total Target Revenue
ANDA / PAS	24%	\$77,523,000
API Facility	14%	\$45,221,000
FDF Facility	56%	\$180,886,000
DMF	<u>6%</u>	<u>\$19,381,000</u>
Total:	<u>100%</u>	<u>\$323,011,000</u>

Where We Begin 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>

Where We Begin GDUFA II

Fee Type		Target Percentage		Total Target Revenue	
GDUFA I	GDUFA II	GDUFA I	GDUFA II	GDUFA I	GDUFA II
ANDA / PAS	ANDA				000
	Program				00
API Fac	API Fac				00
FDF Fac	FDF Fac				00
DMF	DMF				00
Total:		<u>100%</u>	<u>100%</u>	<u>\$323,011,000</u>	<u>\$493,600,000</u>

- Fee is due upon submission of an ANDA
- Withdraw before filing eligible for 75% refund
- State entities exempt from fee

Where We Begin 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	48%			\$24,552,000
FDF Fac	FDF Fac	56%			\$8,720,000
DMF	DMF	<u>6%</u>			<u>\$4,680,000</u>
Total:		<u>100%</u>	<u>100%</u>	<u>\$323,011,000</u>	<u>\$493,600,000</u>

Annual fee for holders of approved ANDAs

Where We Begin 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
ADL Fee	ADL		7%	\$45,331,000	\$98,730,000
Total:		<u>100%</u>	<u>100%</u>	<u>\$323,011,000</u>	<u>\$493,600,000</u>

Together, the ANDA and Program fees under GDUFA II account for 68% of total revenue, up from 24% under GDUFA I

Where We Begin 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				
API Fac	API Fac				
FDF Fac	FDF Fac	56%			
DMF	DMF	<u>6%</u>			
Total:		<u>100%</u>			

- Fee due if referenced in approved application as of beginning of fiscal year
- Foreign facility fee differential of \$15,000
- Only one fee assessed
- Introduction of CMO fee

Where We Begin 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%	\$77,520	
	Program		35%		
API Fac	API Fac	14%	7%		
FDF Fac	FDF Fac	56%	20%	\$18,480	
DMF	DMF	<u>6%</u>	<u>5%</u>	<u>\$1,680</u>	
Total:		<u>100%</u>	<u>100%</u>	<u>\$32,680</u>	

Together, facility fees under GDUFA II account for 27% of total revenue, down from 70% under GDUFA I

Where We Begin 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
			35%		\$172,760,000
API			7%	\$45,221,000	\$34,552,000
FDF Fac	FDF Fac		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>

DMF fee due on first reference or request for CA

Where We Begin 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%	\$77,522,000	\$162,888,000
	Program		35%		
API Fac	API Fac	14%	7%		
FDF Fac	FDF Fac	56%	20%	\$180,886,000	\$
DMF	DMF	<u>6%</u>	<u>5%</u>	<u>\$19,381,000</u>	<u>\$</u>
Total:		<u>100%</u>	<u>100%</u>	<u>\$323,011,000</u>	<u>\$493,600,000</u>

Finally, notice that there was a slight uptick in the size of the program

ANDA Holder Program Fee

Each person and its affiliates will be assessed an annual fee depending on the number of approved ANDAs in its (their) combined portfolio.

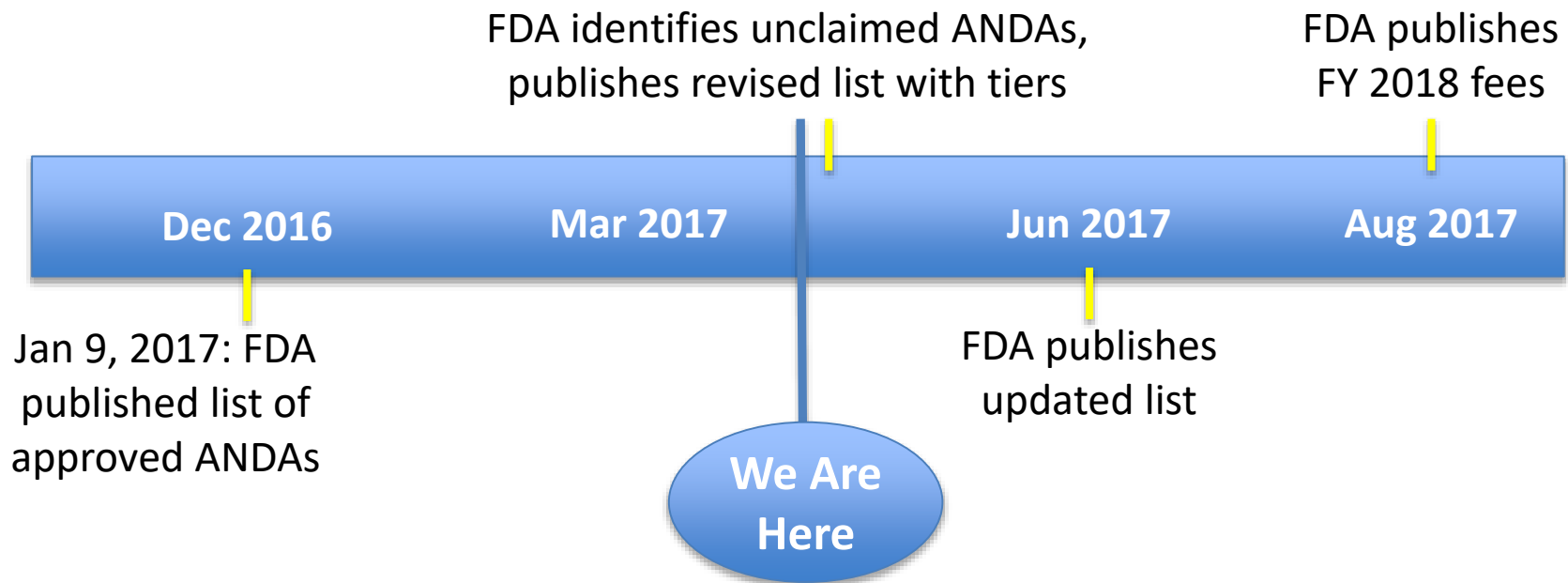
- There are three tiers:
 - Large: 20 or more approved ANDAs
 - Medium: Between 6 and 19 approved ANDAs
 - Small: Five or fewer approved ANDAs
- The fee for each tier differs:
 - Large: Full fee
 - Medium: 40% of the 'large' fee
 - Small: 10% of the 'large' fee

Notice that several entries may actually represent one company. Separately, these entities would owe 1 medium fee and four small fees. Together, these entities would owe only 1 medium fee.

3	Sponsor Name	Number of Approved ANDAs
136	⊕ BRECKENRIDGE PHARMACEUTICALS INC	4
137	⊕ BRIGHAM AND WOMENS HOSP	1
138	⊕ BRIGHAM AND WOMENS HOSP INC	1
39	⊕ BRISTOL ALPHA CORP SUB BRISTOL MYERS CO	2
40	⊕ BRISTOL LABORATORIES INC DIV BRISTOL MYERS CO	7
41	⊕ BRISTOL MYERS PRODUCTS INC	2
42	⊕ BRISTOL-MYERS CO INTERNATIONAL DIV	1
43	⊕ BRISTOL-MYERS SQUIBB CO	1
144	⊕ C AND M PHARMACAL INC	1
145	⊕ CADILA PHARMACEUTICALS LTD	6
146	⊕ CADISTA PHARMACEUTICALS INC	5
147	⊕ CALL INC DBA ROCHESTER PHARMACEUTICALS	2
148	⊕ CAMALL CO INC	4
149	⊕ CARACO PHARMACEUTICAL LABORATORIES LTD	2
150	⊕ CARDINAL HEALTH 414 LLC	1
151	⊕ CARDINAL HEALTH 414 LLC CARDINAL HEALTH NUCLEAR PHARMACY SERVICES	3
152	⊕ CARLSBAD TECHNOLOGY INC	10
153	⊕ CAROLINA MEDICAL PRODUCTS CO	6
154	⊕ CATALENT PHARMA SOLUTIONS LLC	1
155	⊕ CEDAR PHARMACEUTICALS LLC	2
156	⊕ CENTRAL RADIOPHARMACEUTICAL SERVICES INC	1

MULTIPLE NAMES = MULTIPLE FEES

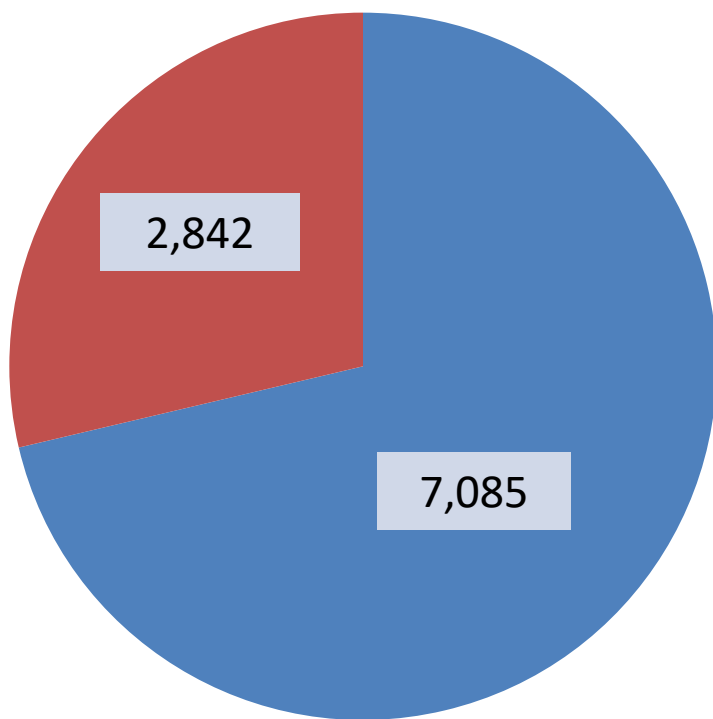
ANDA Holder Program Fee: Clean-up Effort



ANDA Holder Program Fee: Clean-up Status*

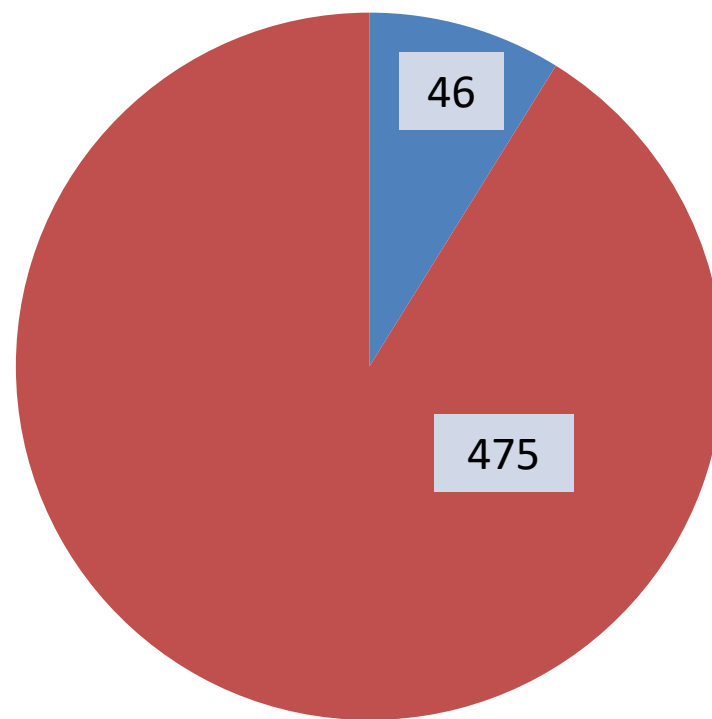


ANDAs



■ Claimed ■ Unclaimed

Sponsors



■ Claimed ■ Unclaimed



ANDA Holder Program Fee: Issues We Are Seeing

- Responses coming in differently than we expected - screen shots, PDF files, narrative descriptions
- Things we appreciate - Excel sheets, contact info
- Data problems – withdrawal requests that haven't been reflected in our systems, transfers of ownership that aren't showing up right
 - My team is forwarding to the appropriate party
 - Sponsor may want to reach out as well



ANDA Holder Program Fee: Upcoming Posting

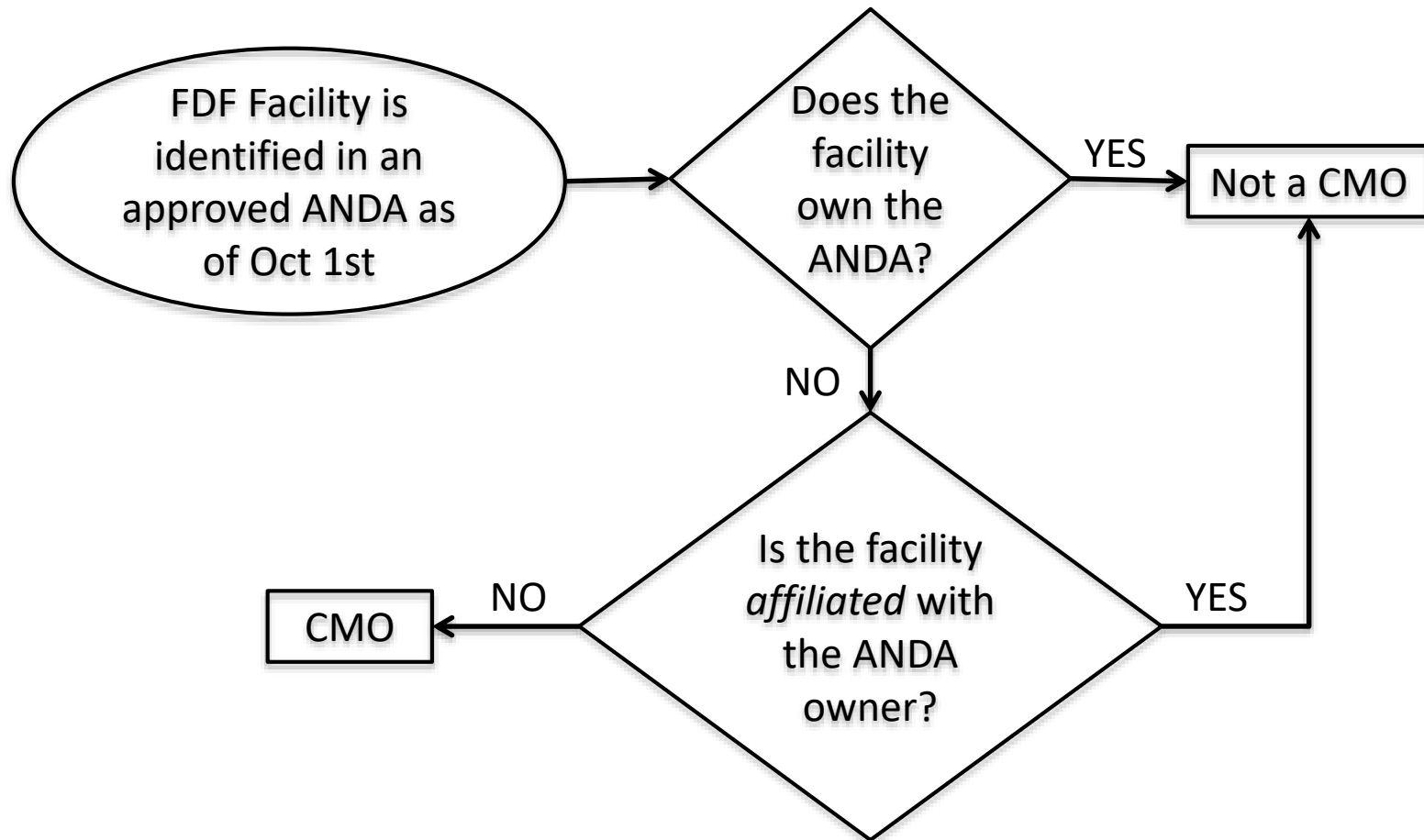
Will contain four tabs:

- Approved ANDAs that someone has claimed
- Approved ANDAs that nobody has claimed
- Look-up table from January posting
- List of all 9,927 ANDAs approved as of 3/10/2017

CMO Fee

- A contract manufacturing organization is a facility that provides FDF manufacturing services under contract to ANDA holders with which it is not affiliated.
- The CMO fee is one-third the fee assessed to an FDF facility.

CMO Evaluation



The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

- (A) one business entity controls, or has the power to control, the other business entity; or
- (B) a third party controls, or has power to control, both of the business entities.

Timeline for Next Steps

- Early April 2017 – Publish second list
- May 1, 2017 - June 1, 2017 - Open period for FY2018 GDUFA Facility Self-Identification.
- June 2017 – FDA to determine denominators for calculating FY 2018 fees
- August 2017 – FDA to publish FY 2018 fees
- User fee reauthorization – spring / summer
- October 1, 2017 – FY 2018 user fees kick in



Helpful Resources

Link to FDA site where program fee data are posted:

www.fda.gov/gdufa.

Link to a webinar we gave in October going over this information: <http://sbiaevents.com/sbia-files/GDUFA-II-Webinar-FULL-Oct-28-2016.mp4>

Contact my office at:

CDERCollections@fda.hhs.gov

301.796.7900

Thank You!

**Donal Parks will be back for Q&A
in the **2:00 Panel Discussion****

Please complete the session survey:
surveymonkey.com/r/GDF-D1S07