U.S. FOOD & DRUG ADMINISTRATION

# GDUFA II Overview

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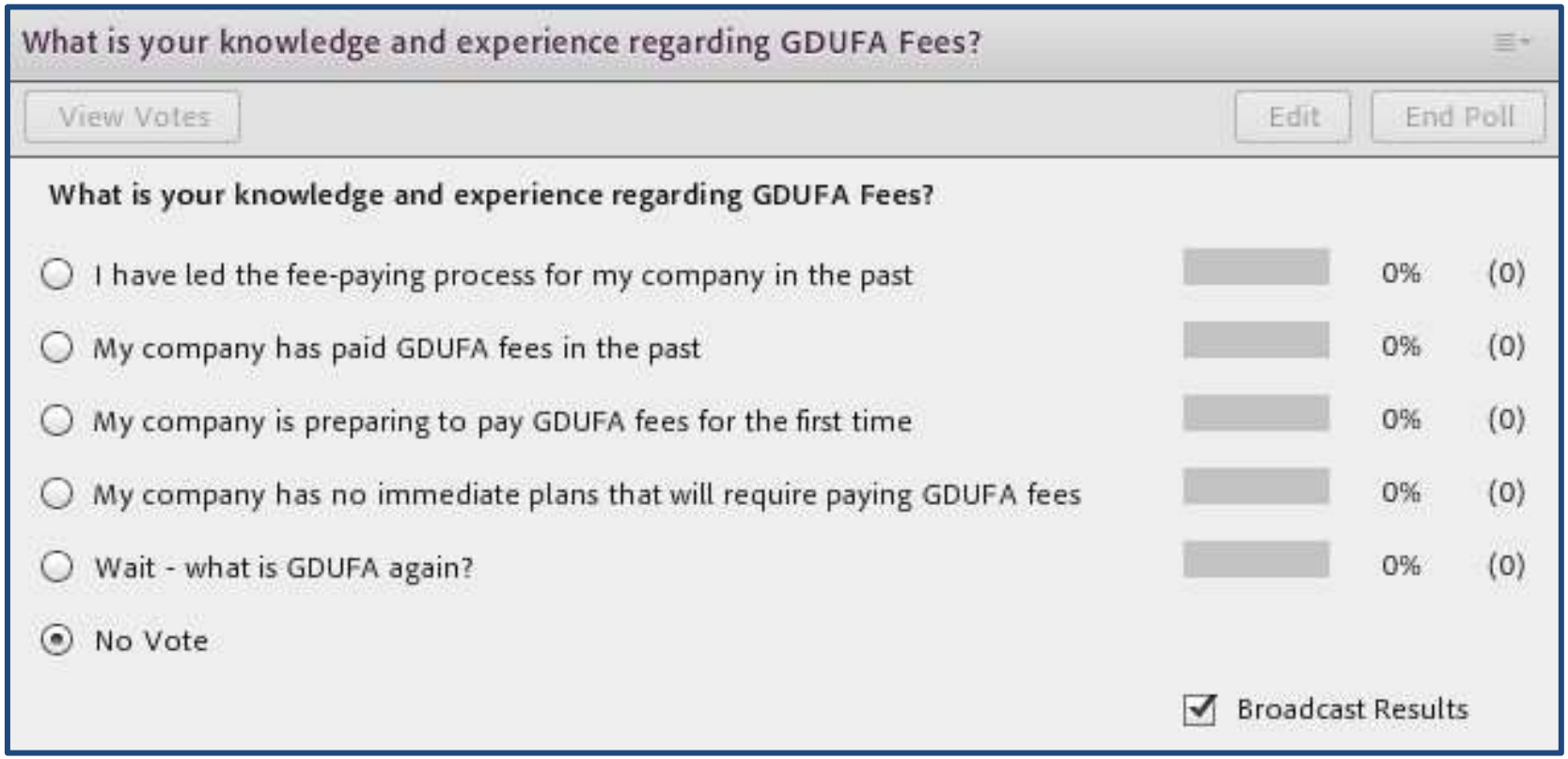
October 28, 2016

# Agenda

- Outline of the Agreement
- Fee Types
- CMO Evaluation
- Changes from GDUFA I to GDUFA II
- Target Revenue for FY 2018
- ANDA Holder Program Fee Clean-Up Process
- Helpful Resources

# A Quick Poll


What is your knowledge and experience regarding GDUFA Fees?
View Votes
Edit
End Poll
What is your knowledge and experience regarding GDUFA Fees?
I have led the fee-paying process for my company in the past 0% (0)
My company has paid GDUFA fees in the past 0% (0)
My company is preparing to pay GDUFA fees for the first time 0% (0)
My company has no immediate plans that will require paying GDUFA fees 0% (0)
Wait - what is GDUFA again? 0% (0)
No Vote
Broadcast Results

# Outline of the Agreement

**Program Size**

- $493.6M in FY 2018 (FY 2017 was $323M)
- Adjustments made for inflation, FY 2019 - FY 2022

**New Exemptions and Refunds**

NEW • Drugs manufactured by State or Federal entities not intended for commercial use

NEW • 75% refund for submissions that have been withdrawn prior to being received

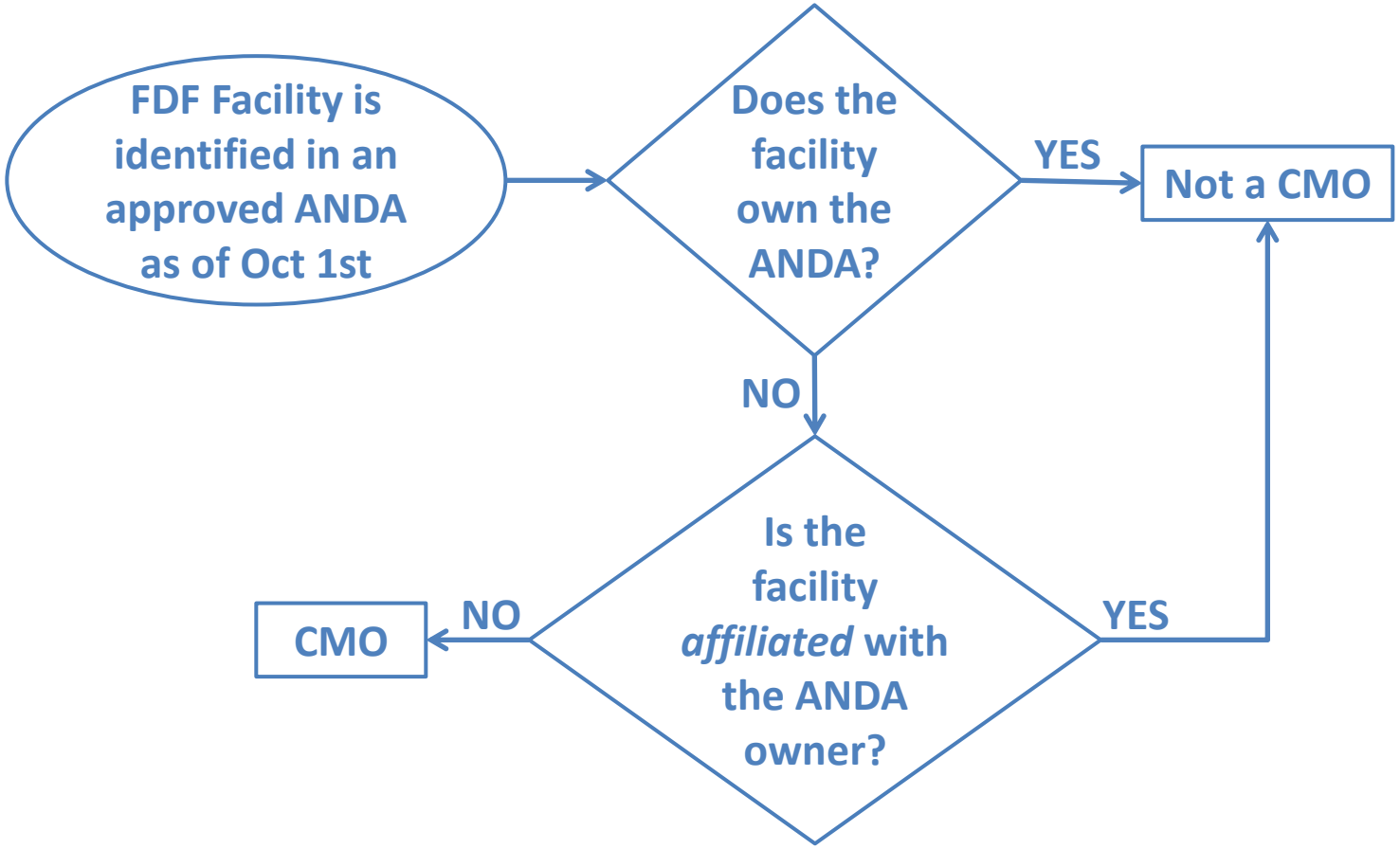
# Fee Types - Applications

- Abbreviated New Drug Application (ANDA) filing fee
- Drug Master File (DMF) fee
- NEW No more Prior Approval Supplement (PAS) fee
- Fee still due upon submission – same as in GDUFA I

# Fee Types - Facilities

- NEW • API and FDF facilities will only incur a fee once identified in an ***approved*** ANDA
- • $15K for facilities located outside of the U.S. and its territories
- NEW • Facilities manufacturing both API and FDF will pay **only** the FDF fee
- • Fee still due at the beginning of each fiscal year – same as in GDUFA I
- NEW • Contract Manufacturing Organization (CMO) fee – one-third the FDF fee
  - A CMO is a facility that provides contract manufacturing for ANDA sponsors
  - A CMO does not hold the ANDAs and is not affiliated with the ANDA holders

# 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.**

# Fee Types - ANDA Holder Program Fee

**Generic Drug Applicant Program Fee** (the "ANDA Holder Program Fee")

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

– There will be 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 will differ:
  - Large: Full fee
  - Medium: 40% of the 'large' fee
  - Small: 10% of the 'large' fee

– The Agency will be offering sponsors an opportunity to clean up their data in preparation for FY2018 (more on this later)

# Changes from GDUFA I to GDUFA II

| GDUFA I Revenue Structure | | GDUFA II Revenue Structure | |
|---|---|---|---|
| Backlog (FY 2013 only) | | Generic Drug Applicant Program (3 tiers) | 35% |
| ANDA/PAS | 24% | ANDA | 33% |
| DMF | 6% | DMF | 5% |
| API Facility | 14% | API Facility | 7% |
| FDF Facility | 56% | FDF Facility | 20% |

# Target Revenue For FY 2018

| | | |
|---|---|---|
| **Target Revenue:** | | **$493,600,000** |
| **ANDA Program Holder** | **35%** | **$172,760,000** |
| **ANDA** | **33%** | **$162,888,000** |
| **DMF** | **5%** | **$24,680,000** |
| **API Facility** | **7%** | **$34,552,000** |
| **FDF Facility** | **20%** | **$98,720,000** |

# ANDA Holder Fee Clean-Up Process

- The Agency will be making available on its web site a list of all the approved ANDAs along with the holder of record for that ANDA. All of this information will already be in the public record.
- We expect to post this list in early December 2016.
- These approved ANDAs will be grouped by the name of the holder of record according to our systems.
- Because each of the sponsors shown on this list will owe a program holder fee as of October 1, 2017, one company could wind up owing several fees if our records show multiple company names for what is really the same corporate entity.

**MULTIPLE NAMES = MULTIPLE FEES**

# ANDA Holder Fee Clean-Up Process (cont.)

Here is what the file will look like:

| 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 |
| 139 | BRISTOL ALPHA CORP SUB BRISTOL MYERS CO | 2 |
| 140 | BRISTOL LABORATORIES INC DIV BRISTOL MYERS CO | 7 |
| 141 | BRISTOL MYERS PRODUCTS INC | 2 |
| 142 | BRISTOL-MYERS CO INTERNATIONAL DIV | 1 |
| 143 | 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 |

# ANDA Holder Fee Clean-Up Process (cont.)

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.

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| 138 | BRIGHAM AND WOMENS HOSP INC | 1 |
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| 140 | BRISTOL LABORATORIES INC DIV BRISTOL MYERS CO | 7 |
| 141 | BRISTOL MYERS PRODUCTS INC | 2 |
| 142 | BRISTOL-MYERS CO INTERNATIONAL DIV | 1 |
| 143 | BRISTOL-MYERS SQUIBB CO | 1 |
| 144 | C AND M PHARMACAL INC | 1 |
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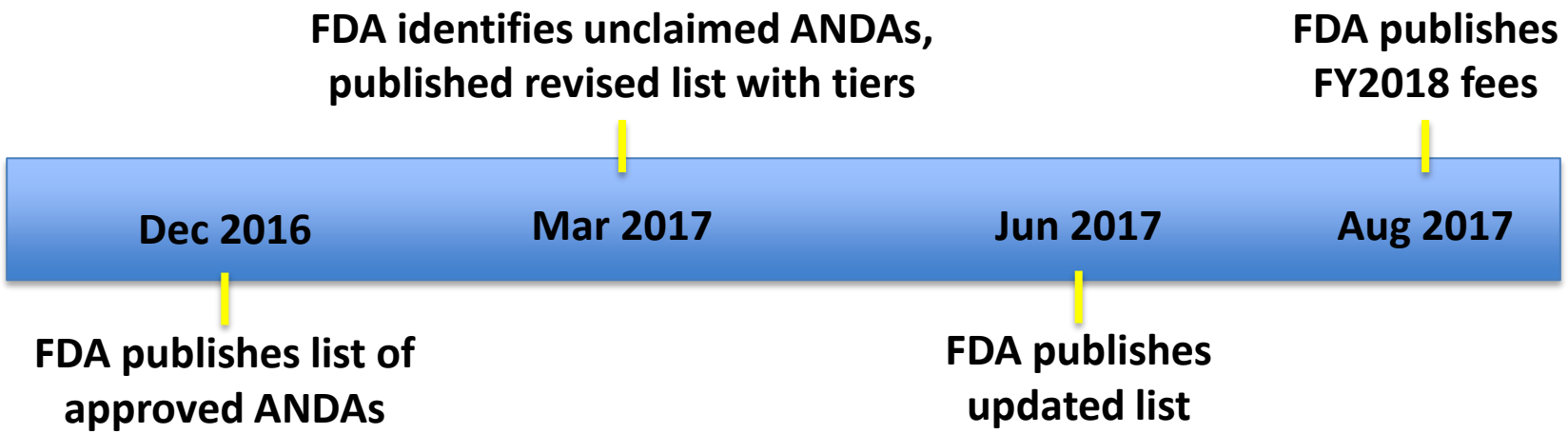
Once we publish the list in December 2016, industry will be able to let us know if corporate entities need to be consolidated.

# ANDA Holder Fee Clean-Up Process: **Tentative Timeline**



# And now for a demo…

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- Recording of this webinar is coming soon
- We are creating a “How-To Guide”
- Spreadsheet will be ***available in early December***

# Summary & Key Points

- No PAS fee
- Facility fee only once the ANDA is approved
- If both API and FDF, only pay the FDF fee
- New CMO fee
- New ANDA holder program fee
- Stay tuned for the list  (Early December!!)

# Helpful Resources

Click for:

- Cover sheet and payment information
- Reconsiderations and appeals
- PDF of today's slides
- Main GDUFA website:

**www.fda.gov/gdufa**

(where the spreadsheet will be in early December)

*Recording of this webinar will be on SBIA's website within one week*

*Questions about material presented during this webinar?*
CDERCollections@fda.hhs.gov

**Open Q&A begins shortly – type in your questions now.**

***Click for Evaluation and Certificate***