Coming Down the Home Stretch:

GDUFA I Enters Its Final Year

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Agenda

I. Quick recap of the basics

II. What if I don't like the Agency's decision?

III. Why do fees go up or down each year?

IV. Looking forward to GDUFA II

V. Helpful resources / Q&A

Quick Recap

I. Types of fees

II. Types of consequences

III. Types of forms

IV. Types of lists

Types of GDUFA Fees

I. DMF (and the (a)(3)(f)…)

II. Facility (four types, plus a wrinkle)

III. Application (two kinds)

IV. Backlog

Consequences – what can happen

I. Best case?
   a) Filing review
   b) Completeness Assessment

II. Required fee not paid?
   a) Letter from my office
   b) RTR
      i. Refund after RTR
   c) Loss of receipt date
   d) Misbranding

Paperwork…

I. User fee cover sheet
   a) Available on the web:

      http://www.fda.gov/ForIndustry/UserFees/default.htm

II. 356h
   a) Available on the web:
      http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm082348.pdf


DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE
(Title 21, Code of Federal Regulations, Parts 314 & 601)

Lists – how to get on (or off) them

I. Facility arrears list
(http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM346165.pdf)

II. Facility not-on-arrears list
(http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM416640.pdf)

III. Paid facility list
(http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm351219.htm)

IV. Self-identified facilities list
(http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM445412.xls)

V. DMF available for reference list
(http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM332875.xls)

Reconsiderations and Appeals (Fees)

I. Basic process
   a) Contact my office
   b) Request reconsideration
   c) Request appeal (§10.75)

II. Statistics so far
   a) Over 18,000 transactions since go-live
   b) 17 requests for reconsiderations
      i. 13 upheld
      ii. 4 reversed
   c) 1 appeal (underway)

Why do fees go up or down?

Basic Process

- Determine target revenue
- Allocate to types of fees
- Determine denominators
- Calculate

Timeline

Determine Target Revenue (TR)

Base target revenue of $299M in FY2013 is inflated each year:

Fiscal Year	Base TR	Inflation factor	Actual TR
2013	$299,000,000	1.000000	$299,000,000
2014	$299,000,000	1.022270	$305,659,000
2015	$299,000,000	1.044228	$312,224,000
2016	$299,000,000	1.064759	$318,363,000
2017	$299,000,000	??	??

Allocate to Types of Fees

Target revenue (TR) of $318,363,000.

Allocate to fee types:

ANDA / PAS:	24%	X TR	=	$76,407,000
DMF:	6%	X TR	=	$19,102,000
FDF facility:	56%	X TR	=	$178,283,000
API facility:	14%	X TR	=	$44,571,000

Determine Denominators

ANDA / PAS: Concept of “full application equivalents” or FAEs – 1,005 in FY2016

DMF: Number of newly-referenced DMFs – 453 in FY2016

FDF Facility: Number of fee-liable FDF facilities – 283 domestic, 422 foreign in FY2016 (705 total)

API Facility: Number of fee-liable API facilities – 105 domestic, 721 foreign in FY2016 (826 total)

Break Out the Calculators

Fee Type	Target Revenue	Denominator	Fee
ANDA / PAS	$76,407,000	1,005	$76,030
DMF	$19,102,000	453	$42,170
FDF Facility	$178,283,000	Domestic - 283	$243,905
		Foreign - 422	$258,905
API Facility	$44,571,000	Domestic - 105	$40,867
		Foreign - 721	$55,867

Timeline

- Statutory requirement to publish in *Federal Register* no later than early August each year: https://federalregister.gov/a/2015-18915 for FY2016 notice.
- Process begins in April / May with analysis of historical data for ANDA/PAS and DMF
- Self-identification data used for facilities in early June

Looking Forward to GDUFA II

Negotiations are currently underway to reauthorize GDUFA

Kicked off with public meeting in June 2015, started face-to-face meetings in October 2015

Congress directed stakeholders to consider relief for small businesses; sub-group formed to discuss issues

Looking Forward to GDUFA II (cont'd)

- Statute requires the Agency to submit a package to Congress by January 15, 2017
- Will have another public meeting beforehand to present recommendations
- Meeting minutes available on web: http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm256662.htm

Helpful Resources

Main GDUFA website: www.fda.gov/gdufa

Cover sheet and payment information:
http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm322629.htm

Reauthorization website:
http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm476940.htm

Reconsiderations & appeals:

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/ucm444092.htm

Thank You!

Questions?

surveymonkey.com/r/GDF-D2S5