GDUFA User Fee Structural Changes

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	6%	5%	$19,381,000	$24,680,000
Total:		100%	100%	$323,011,000	$493,600,000

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GDUFA II Implementation – Industry Negotiators Perspective on the First Month

November 8, 2017

GDUFA REAUTHORIZATION GOALS & ENHANCEMENTS - 2018-2022

I. SUBMISSION REVIEW PERFORMANCE GOALS

- A. Original ANDAs and ANDA Amendments
- B. PASs and PAS Amendments
- C. Unsolicited ANDA and PAS Amendments
- D. DMFs
- E. Controlled Correspondence
- F. GDUFA I Bridging

II. ORIGINAL ANDA REVIEW PROGRAM ENHANCEMENTS

- A. ANDA Receipt
- B. ANDA Review Transparency and Communications Enhancements
- C. Review Classification Changes During the Review Cycle
- D. ANDA Approval and Tentative Approval
- E. Dispute Resolution
- F. Other ANDA Review Program Aspirations

GDUFA REAUTHORIZATION GOALS & ENHANCEMENTS - 2018-2022

III. PRE-ANDA PROGRAM AND SUBSEQUENT MID-REVIEW-CYCLE MEETINGS FOR COMPLEX PRODUCTS

- A. Rationale for Pre-ANDA Program, Guidance on Enhanced Pathway for Complex Products
- B. Controlled Correspondence
- C. Product-Specific Guidance
- D. Product Development Meetings
- E. Pre-Submission Meetings
- F. Inactive Ingredient Database Enhancements
- G. Regulatory Science Enhancements
- H. Safety Determination Letters
- I. Other Pre-ANDA Program Aspirations

IV. DMF REVIEW PROGRAM ENHANCEMENTS

- A. Communication of DMF Review Comments
- B. Teleconferences to Clarify DMF First Cycle Review Deficiencies
- C. DMF First Adequate Letters
- D. DMF No Further Comment Letters
- E. Guidance on Post-Approval Changes to Type II API DMFs

GDUFA REAUTHORIZATION GOALS & ENHANCEMENTS - 2018-2022

V. FACILITIES

- A. Guidance on Risk-Based Site Selection Model
- B. Outreach to Foreign Regulators on Risk-Based Site Selection Model
- C. Export Support and Education of Other Health Authorities
- D. Communications to Foreign Regulators
- E. Communication Regarding Inspections
- F. GDUFA II Facility Compliance Status Database

VI. ENHANCED ACCOUNTABILITY AND REPORTING

- A. Resource Management Planning and Modernized Time Reporting
- B. Financial Transparency and Efficiency
- C. Performance Reporting

FDARA Title VIII (Improving Generic Drug Access)

- Sec. 801. Priority review of generic drugs.
- Sec. 802. Enhancing regulatory transparency to enhance generic competition.
- Sec. 803. Competitive generic therapies.
- Sec. 804. Accurate information about drugs with limited competition.
- Sec. 805. Suitability petitions.
- Sec. 806. Inspections.
- Sec. 807. Reporting on pending generic drug applications and priority review applications.
- Sec. 808. Incentivizing competitive generic drug development.
- Sec. 809. GAO study of issues regarding first cycle approvals of generic medicines.

Review Under GDUFA II – Original and Amendments

Table for Section I(A)(1) and (2): Original ANDAs

Submission Type	Goal
Standard Original ANDAs	90% within 10 months of submission date.
Priority Original ANDAs	90% within 8 months of submission date if applicant meets requirements under I(A)(2)(a).
	90% within 10 months of submission date if applicant does not meet requirements as described under I(A)(2)(b).

Table for Section I(A)(3) – (5): ANDA Amendments

Submission Type	Goal
Standard Major ANDA Amendments	90% within 8 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
Priority Major ANDA Amendments	90% within 6 months of submission date if preapproval inspection not required.
	90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(A)(4)(b).
	90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(A)(4)(c).
Standard and Priority Minor ANDA Amendments	90% within 3 months of submission date.

Review Under GDUFA II - PASs

Table for Section I(B)(1) and (2): PASs

Submission Type	Goal
Standard PASs	90% within 6 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
Priority PASs	90% within 4 months of submission date if preapproval inspection not required.
	90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(B)(2)(b).
	90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(B)(2)(c)

Review Under GDUFA II – PAS Major/Minor

Table for Section I(B)(3) – (5): PAS Amendments

Submission Type	Goal
Standard PAS Major Amendments	90% within 6 months of submission date if preapproval inspection not required.
	90% within 10 months of submission date if preapproval inspection required.
Priority PAS Amendments	90% within 4 months of submission date if preapproval inspection not required.
	90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(B)(4)(b).
	90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(B)(4)(c).
Standard and Priority Minor PAS Amendments	90% within 3 months of submission date.

Review Under GDUFA II – Unsolicited Amendments

C. Unsolicited ANDA Amendments and PAS Amendments

1. Review and act on unsolicited ANDA amendments and PAS amendments submitted during the review cycle by the later of the goal date for the original submission/solicited amendment or the goal date assigned in accordance with Sections (I)(A)(3), (4) and (5) and (I)(B)(3), (4) and (5), respectively, for the unsolicited amendment.

2. Review and act on unsolicited ANDA amendments and PAS amendments submitted between review cycles by the later of the goal date for the subsequent solicited amendment or the goal date assigned in accordance with Sections (I)(A)(3), (4) and (5) and (I)(B)(3), (4) and (5), respectively, for the unsolicited amendment.

Thank You

The AAM GDUFA II Negotiating Team

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