GDUFA II Fee Structure Summary

To achieve GDUFA II commitments, FDA must increase the overall capacity and capabilities of the generic drug application review program through a user fee structure that provides stable, predictable funding, is efficient in design and feasible to execute. FDA and industry agreed to jointly recommend these proposed changes for GDUFA II.

I. Agreed Upon Enhancements

A. Increased Funding

GDUFA I was built on the assumption that FDA would receive 750 Abbreviated New Drug Applications (ANDAs) per year. ANDAs are the primary workload driver of the program. Over the first 4 years of GDUFA I, ANDA receipts have averaged approximately 1000 per year. To address the increased workload, FDA hired additional staff and is projected to spend about $430 million in the final year of GDUFA I. In order to maintain FDA's current productivity and implement negotiated improvements, Industry and FDA agreed that user fees should total $493.6 million annually adjusted each year for inflation.

B. Modifications to the User Fee Structure

1. Introduction of GDUFA Program Fees

In order to maintain its generic drug review program, FDA's user fee collections must be predictable. Whereas application volume can fluctuate from year to year, there is a relatively stable universe of generic drug facilities and ANDA sponsors. Therefore, in order to improve the predictability of the fee base and to more closely align fee responsibility with program costs and fee-paying ability, FDA and industry have agreed to shift the burden more toward annual program fees.

Firms that sponsor one or more approved ANDAs will pay an annual fee. Finished Dosage Form (FDF) and Active Pharmaceutical Ingredient (API) facilities will continue to pay annual fees as they did under GDUFA I.

2. Elimination of Supplement Fees

In GDUFA I, ANDA sponsors making changes to an already approved ANDA through a Prior Approval Supplement (PAS) were required to pay a fee. Because the number of annual PAS submissions is unpredictable, FDA was unable to accurately project fee collections. In addition, collecting those fees required administrative resources. Moreover, some PAS submissions were solicited by FDA. In those instances, it seemed unwarranted to charge the filer a fee. Finally, the new ANDA program fee is meant to be an investment in the program, and encompasses what were supplement fees. For those reasons, industry and FDA agree that the PAS fee should be eliminated.

3. Small Business Considerations

As part of the negotiations, FDA and industry convened a working group to discuss small business considerations. The group did extensive research on the issues confronted by small businesses and others under GDUFA I. Pursuant to its conclusions and other lessons learned through GDUFA I and the negotiation process, FDA and industry have agreed to three distinct small business considerations:

1. Under GDUFA I, a facility would pay an annual fee if it was listed in an ANDA, regardless of whether it was listed in any approved ANDAs. As a result, a facility that is listed only in pending applications could be charged an annual GDUFA fee even though it had no generic drug revenue stream. Under GDUFA II, no facility or ANDA sponsor would be charged an annual fee until an ANDA in which it is listed is approved.
2. The ANDA sponsor landscape varies dramatically from firms that own hundreds of approved ANDAs to new market entrants that own only one approved ANDA. Under the GDUFA II fee structure, a firm and its affiliates will pay one program fee commensurate with the number of approved ANDAs that the firm and its affiliates collectively own. Firms will not pay a per-ANDA fee, but will be split into three tiers that represent different positions held by the firms and their affiliates within the market. Industry's negotiation representatives consulted with ANDA sponsors to determine the parameters for each tier.
3. Within the FDF facility category, there are two distinct business types. Contract Manufacturing Organizations (CMOs) are hired by ANDA sponsors to manufacture their generic drugs. Alternatively, some ANDA sponsors manufacture their own drugs. Under the GDUFA II fee structure, CMOs will pay one third the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own. The foreign fee differential will still apply.

GDUFA I v. GDUFA II Fee Structure

Fee Category	GDUFA I		GDUFA II	
1-time Fees:				
• **ANDA Application**	✓	**24%**	✓	**33%**
• **DMF Application**	✓	**6%**	✓	**5%**
Annual Program Fees:				
• **API Facility**	✓	**14%**	✓	**7%**
• **FDF Facility**	✓	**56%**	✓	**20%**
• **CMO Facility**	**Same as FDF**		✓	**One-third FDF**
• **ANDA Holder**	**N/A**		✓	**35%**
• **Small (1-5 ANDAs)**	**N/A**		✓	**One-tenth Large**
• **Medium (6-19)**	**N/A**		✓	**Four-tenths Large**
• **Large (20+)**	**N/A**		✓	**Full Fee**

Small business considerations

II. Other Technical Improvements

1. Fee relief for non-commercial drug distribution

State or Federal Government entities which sponsor or manufacture drugs but do not distribute them commercially will not be assessed user fees.

2. Refund for Withdrawal

Currently, there exists a disincentive for an ANDA sponsor to withdraw an application that it knows will not be received by FDA for some fatal flaw. GDUFA II will allow a sponsor to receive a partial refund if it withdraws an ANDA voluntarily before FDA makes a decision on whether the ANDA may be received. This will save FDA work and the sponsor time.

3. One fee per Facility

Under GDUFA I, a facility that qualified as both API and FDF would pay both fees. Such a facility will pay just the FDF fee under GDUFA II.

4. Foreign Fee Differential

Under GDUFA I, FDA could charge foreign facilities anywhere from $15,000 to $30,000 more per facility than domestic facilities, depending on FDA's calculations each year concerning relative costs of foreign and domestic inspections. For each year under GDUFA I FDA determined that the differential would be $15,000. Under GDUFA II, the foreign fee differential will be set at $15,000.