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JANUARY 26TH, 2017

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featuring Gisa Perez - Generics Branch Chief in the Division of User Fee Management and Budget Formulation

GDUFA Resources:

1. FY 2017 Generic Drug Research Public Workshop, May 3, 2017
2. GDUFA II Program Fee: List of ANDA Sponsors and Application Numbers; Request for Information and Comments
3. SBIA webinar recording: Overview of GDUFA II and Implementation of GDUFA II User Fees
4. GDUFA II Fee Structure Summary
5. Generic Drug User Fee Amendments of 2012: Questions and Answers Related to User Fee Assessments; Guidance for Industry
6. GDUFA webpage

FDA Addresses Small Business Concerns in GDUFA II

The FDA and the Generic Drug Industry have completed negotiations for the reauthorization of the Generic Drug User Fee Amendments (GDUFA II). The agreement is now with Congress, which must write it into legislation in order for it to become effective. When GDUFA II takes effect, it will be great news for both the FDA and industry, as it will address questions that arose with the implementation of GDUFA I. In this issue, we are interviewing Gisa Perez, Generics Branch Chief in the Division of User Fee Management and Budget Formulation, regarding the GDUFA II enhancements.

Gisa Perez

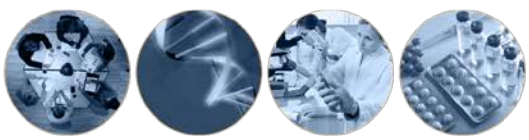
Q: What are some of the primary regulatory enhancements in GDUFA II?

A: One of the primary concerns with GDUFA I was that it did not provide any relief for small business. Under GDUFA II, we will address this by including three elements aimed directly at small business:

1. Under GDUFA I, a facility incurred an annual facility fee if it was referenced in a *pending or approved* Abbreviated New Drug Application (ANDA). As a result, a facility referenced only in pending submissions would incur an annual GDUFA facility fee even though it had no generic drug revenue stream. Under GDUFA II, a facility will be assessed an annual fee **only** once it is identified in an *approved* submission.

2. Under the GDUFA II user fee structure, there will be three tiers for the annual program fee based on the number of approved ANDAs owned by a firm and its affiliates: (1) Large (20 or more approved ANDAs); (2) Medium (between 6 and 19 approved ANDAs); and (3) Small (5 or fewer approved ANDAs). The "large" tier will pay 100% of the annual program fee, while the "medium" and "small" will pay 40% and 10%, respectively. We believe this will be a major relief for small business.

3. Within the Finished Dosage Form (FDF) facility category, GDUFA II has carved out a subcategory for Contract Manufacturing Organizations (CMOs), which are independent facilities contracted by ANDA sponsors to manufacture their generic drugs. Under GDUFA II, CMOs will pay only one-third of the annual fee paid by firms that manufacture ANDA products at facilities which they themselves or their affiliates own.



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Q: These elements are really good news for small business! What are the major changes in user fees included in GDUFA II?

A: Under GDUFA II, there will be no annual fee for facilities identified only in pending submissions, and there will be no fee for prior approval supplements (PAS). Facilities manufacturing both active pharmaceutical ingredients (API) and FDF will **only** pay the FDF fee. There will be a new fee category for CMOs. The tiered generic drug applicant fee will feature a small tier (1-5 approved ANDAs) where the fee will be one-tenth of a full program fee. The small tier will be a major benefit to small business.

Q: Can you expand a bit on the differences between the fee structures between GDUFA I and GDUFA II?

A: GDUFA II will have a fee structure very different from GDUFA I. The distribution of user fee categories will show the shift from facilities to applications and the addition of two new user types. The table below displays the differences:

Fee Category	GDUFA I	GDUFA II
1st 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 Fee	One-third FDF fee
• ANDA Holder	---	35%
• Small (1-5 ANDAs)	---	One-tenth full fee
• Medium (6-19)	---	Four-tenths full fee
• Large (20+)	---	Full Fee

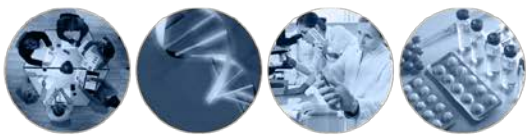
Q: So, to sum up what you're saying, all these changes are going to benefit small business?

A: Certainly, especially since the folks that really have the revenue stream are the ANDA holders. So this shift from facilities to ANDA applicants seems to be the right path to go right now.

- Facilities identified only in pending submissions will not incur an annual fee, which will relieve some of the financial burden faced by small businesses.
- CMOs will only pay one-third of the FDF fee. CMOs located outside of the U.S. and its territories will continue to also pay the $15,000 foreign fee differential.
- The tiered ANDA holder program fee will feature a small business tier which will incur a fee one-tenth that of the large tier.

Q: So, how will facilities be assessed user fees in GDUFA II?

A: Under GDUFA II, facilities, including FDF CMOs, will be assessed an annual fee only after the facility is identified in an approved submission as of October 1st of the applicable fiscal year.



Q: You had mentioned that facilities manufacturing both API and FDF will only pay the FDF fee. How will this work?

A: Facilities approved to produce only an API will continue to incur the API annual fee. Those facilities producing both API and FDF will no longer have to pay both API and FDF fees.

Q: Let's talk about refunds. Under GDUFA I, under certain circumstances where FDA refused to receive an ANDA or PAS, a partial refund was possible. If the reason that the application was refused was not related to failure to pay fees, then 75% of the fee paid will be refunded to the applicant. Are there any changes to refunds under GDUFA II?

A: Yes, under GDUFA I, there were no provisions for ANDA withdrawals once submitted to the Agency. Now, under GDUFA II, if you submit an ANDA, and for any reason decide to withdraw the ANDA before it is received for filing by the Office of Generic Drugs – then you're welcome to withdraw the ANDA and be entitled to a 75% refund.

Q: In the tiered ANDA holder program fees, are discontinued ANDAs included in the approved ANDA count for the program fee?

A: Yes, all approved ANDAs owned by the sponsors and its affiliates will be included in the program fee tiers. If sponsors wish to withdraw their discontinued ANDAs – which would remove those ANDAs from their counts - they should submit a withdrawal request to OGD.

Q: Are positron emission tomography (PET) drugs manufactured under 21 CFR 212 still exempt from GDUFA fees?

A: Yes, GDUFA II will have the same exemptions for PET drugs just as in GDUFA I.

Q: And do facilities still have to self-identify annually under GDUFA II?

A: Yes, just like under GDUFA I, facilities will have to submit or reconfirm by June of every fiscal year during GDUFA II. CMOs will be able to certify their CMO status during the self-identification open period.

Q: So will API manufacturers be able to self-identify and pay as CMOs?

A: That's a question we get a lot. No, unfortunately under GDUFA II, the CMO classification is carved out for the FDF manufacturers only. API manufacturers will incur an API fee when referenced in an approved submission. If you have questions about GDUFA II, please contact the Division of User Fees via email at: CDERCollections@fda.hhs.gov.

Clearly, GDUFA II is structured to allow FDA to continue on the path forward to improve patient access to quality and affordable generic drugs. We are looking forward to working with industry to address any concerns that may arise in the upcoming fiscal years. To hear answers to these frequently asked questions directly from FDA's Generics Branch Chief in the Division of User Fee Management and Budget Formulation, Gisa Perez, please check out our audio podcast.

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

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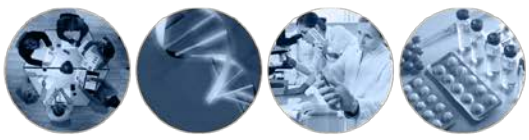

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