FDA/CDER
SMALL BUSINESS CHRONICLES
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GDUFA

Inside This Issue

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Questions about GDUFA? Contact us!

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On Oct. 1, 2012, FDA implemented the Generic Drug User Fee Amendments of 2012 (GDUFA) to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Under GDUFA, certain facilities, sites, and organizations must self-identify and may be subject to user fees. This month's issue provides a brief overview of these requirements.

Self-Identification Self-identification is necessary to determine the universe of facilities required to pay user fees, and is a central component of an effort to promote global supply chain transparency. This information will enable quick, accurate, and reliable surveillance of generic drugs and facilitate inspections and compliance.

FDA issued a self-identification requirement notice in the Federal Register that lists the information that must be submitted. FDA has also provided guidance about the types of generic entities who are required to self-identify with FDA. Please refer to the Step-by-Step Instructions for Electronic Self-Identification of Facilities, Sites, and Organizations for information on how to get started.

Although most facilities that are required to self-identify will also be required to pay an annual facility user fee, certain types of generic facilities, sites and organizations will not be required to pay the fee. These include generic entities that solely manufacture positron emission tomography (PET) drugs; clinical bioequivalence or bioavailability study sites; in vitro bioequivalence testing or bioanalytical testing sites; active pharmaceutical ingredient (API)/finished dosage form (FDF) analytical testing sites; packagers; and repackagers.

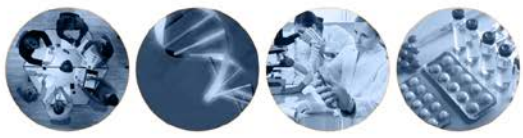
Note that entities that are required to register and list, and those being required to self-identify under GDUFA, will submit information separately to the respective systems. Each system will populate its own database to meet unique requirements and deadlines. The new GDUFA system uses the same platform and technical standards already familiar to manufacturers required to register and list.

For fiscal year 2013, identification information must be submitted by 12/03/12. If a facility fails to self-identify, all FDF or API products manufactured at the facility and all FDFs containing APIs manufactured at the facility will be deemed misbranded. It is a violation of federal law to ship misbranded products in interstate commerce or to import them into the U.S. Such violations can result in prosecution of those responsible, injunctions, or seizures of the misbranded products. Products that are deemed misbranded because of failure of the facility to self-identify are subject to being denied entry into the U.S.

GDUFA Fees Now let's take a closer look at GDUFA fee requirements, which started on 10/1/12.

Backlog Fee Each person that owns an original abbreviated new drug application (ANDA) that is pending on 10/1/12 and that has not been tentatively approved on that date will be required to pay a backlog fee for that ANDA. Any original ANDA that has not been withdrawn, tentatively approved, or approved by 9/28/12, is considered pending and is subject to a backlog fee. FDA calculates the backlog to be $17,434. The backlog fee is assessed only once, for FY 2013, and no backlog fee will be assessed in subsequent years. Once incurred, the backlog fee obligation can only be discharged by payment in full. Backlog fees are due on or before 11/26/12.

DMF Fee Each person that owns a type II active pharmaceutical ingredient (API) DMF that is referenced, on or after Oct. 1, 2012, in a generic drug submission by an initial letter of authorization (LOA) must pay a DMF fee.



The DMF can only be referenced if it is placed on FDA's publicly available list of DMFs. Inclusion on this list is a function of (a) paying the DMF fee and (b) not failing an initial completeness assessment.

The DMF fee for FY 2012 is $21,340. This fee is not incurred every time a DMF is referenced. Rather, it is a one-time fee for each individual DMF, incurred on first reference of the DMF on or after 10/1/12. Note that an ANDA applicant can pay the DMF fee for an API referenced in its submission**.** Type II DMF fees are due on or before the later of 11/26/12, or the date on which the first ANDA is submitted that references the DMF via an initial LOA on or after 10/1/12. However, DMF holders can pay the fee before a LOA is requested if they wish for their DMF to be placed on the publicly available list.

ANDA and PAS Fees Each applicant that submits, on or after 10/1/12, an ANDA or a PAS must pay the ANDA/PAS fee. The ANDA and PAS fees for FY 2012 are $51,520 and $25,760, respectively. The ANDA or PAS will not be received unless the fee is paid within 20 calendar days of the due date. ANDA or PAS fees are due on or before the later of 11/26/12, or the date the ANDA or PAS is submitted to the Agency on or after 10/01/12.

Facility Fees Any person that owns a facility that is identified or intended to be identified in at least one ANDA submission that is pending or approved to produce one or more generic drug FDFs and/or APIs is required to pay facility fees. If a facility manufactures both generic FDFs and APIs**,** such a facility will incur annual FDF AND annual API facility fees. FDA will publish the facility fee amounts, along with due dates, in a Jan 2013 *Federal Register* notice. Because of the differential in the costs of inspections, the facility fee for a facility located outside the U.S. and its territories will be higher than the amount of the fee for a domestic facility. This fee will be due annually.

If the same company's two locations manufacture a U.S. generic product and they are in different geographic locations, each has to pay an annual facility fee. However, separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are closely related to the same business enterprise, if they are under the supervision of the same local management and if they are capable of being inspected by the FDA during a single inspection. An annual facility fee will be due for each facility assigned a unique Facility Establishment Identifier (FEI).

Exclusions: As mentioned earlier, PET drug manufacturers are the only human generic drug manufacturers excluded from GDUFA fees. However, they are required to self-identify. FDA requests that all drug manufacturers, including generic PET manufacturers, submit a user fee cover sheet with any new FDA submissions. GDUFA fees are not reduced or waived for small business. The majority of generic companies are small companies that are expected to benefit significantly from reductions in the review time needed to commercialize their products and from the certainty associated with performance review metrics and program efficiencies.

Payment Process and Penalties To pay GDUFA fees, one must complete a generic drug user fee cover sheet and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, or wire transfer. Payment details are for backlog fees, and DMF and ANDA/PAS fees are detailed in the *Federal Register* notices. Penalties for failure to pay are outlined in the statute and summarized in the Questions and Answers Guidance document.

I encourage you to carefully read the GDUFA guidance documents and *Federal Register* Notices posted on the FDA website. In addition stay up-to-date by signing up to receive GDUFA email alerts.

We will be taking a holiday hiatus, and will publish our next issue in January. Have a safe and wonderful holiday season!

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

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