U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Frequently Asked Questions on Prescription Drug User Fees (PDUFA)

INTRODUCTION

1. What is PDUFA?

The Prescription Drug User Fee Act (PDUFA), enacted in 1992 and renewed in 1997 (PDUFA II) and 2002 (PDUFA III) authorizes FDA to collect fees from companies that produce certain human drug and biological products. PDUFA established three types of user fees - application fees, establishment fees, and product fees. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process.

APPLICATION FEES

2. What is a human drug application?

PDUFA levies a user fee on certain human drug applications. Under PDUFA, the term human drug application means an application for

- approval of a new drug submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) after September 1, 1992

- approval of a new drug submitted under section 505(b)(2) of the FD&C Act after September 30, 1992, which requests approval of
  - a molecular entity which is an active ingredient (including any salt or ester of an active ingredient), or
  - an indication for a use that had not been approved under an application submitted under section 505(b), or
- licensure of certain biological products under section 351 of the Public Health Service Act (PHS Act) submitted after September 1, 1992

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3. What is a 505(b)(1) application?

A 505(b)(1) application is an application that contains full reports of investigations of safety and effectiveness.

The investigations the applicant relied on for approval were conducted by or for the applicant or the applicant has obtained a right of reference or use for the investigations.

4. What is a 505(b)(2) application?

A 505(b)(2) application is an application submitted under section 505(b)(1) for which

- the investigations the applicant relied on for approval were not conducted by or for the applicant and
- the applicant has not obtained a right of reference or use for the investigations (21 U.S.C. 355(b)(2)).

Section 505(b)(2) expressly permits FDA to rely, for approval of an NDA, on data not developed by the applicant - such as published literature or the agency's finding of safety and/or effectiveness of a previously approved drug product.

5. What is a supplement?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) says, "The term supplement means a request to the Secretary to approve a change in a human drug application which has been approved." Each indication or claim is considered a separate change for which a separate supplement should be submitted. This policy allows FDA to approve each indication or claim as it is ready for approval rather than delaying approval until the last of a group of indications or claims is ready to be approved.

6. What are application fees?

Each person that submits a human drug application or supplement after September 1, 1992, is assessed an application fee as follows.

- A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed a full application fee.
- A human drug application for which clinical data with respect to safety or effectiveness are not required for approval is assessed one-half of a full fee.
- A supplement to a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed one-

half of a full fee.

Human drug application fees are due when the application or supplement is submitted.

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ESTABLISHMENT FEES

7. What are establishment fees?

Establishment fees are assessed annually of each person who

- is named as the applicant in a human drug application and
- had a human drug application or supplement pending after September 1, 1992.

An establishment fee is assessed for each prescription drug establishment listed in the approved human drug application as an establishment that manufactures the prescription drug product.

- The establishment fee is assessed for each prescription drug product that is assessed a product fee - unless the establishment listed in the application does not manufacture the product during the fiscal year.
- Each establishment is assessed only one establishment fee for a fiscal year.
- If more than one applicant lists an establishment in a human drug application, the establishment fee for the fiscal year is divided equally among the applicants whose prescription drug products are manufactured at the establishment.

8. What is a prescription drug establishment?

The term prescription drug establishment means a foreign or domestic place of business

- which is at one general physical location consisting of one or more buildings, all of which are within 5 miles of each other, and
- at which one or more prescription drug products are manufactured in final dosage form.

For purposes of user fees, the term manufactured does not include packaging.

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9. What does final dosage form mean?

Final dosage form means a finished dosage form which is approved for administration to a patient without substantial further manufacturing.

PRODUCT FEES

10. What are product fees?

For Fiscal Year 2002 and before:

Prescription drug product fees are assessed annually for eligible products. The product fees are assessed on products for each person who

- is named as the applicant in a human drug application for a prescription drug product that has been submitted for listing under section 510 of the FD&C Act, and
- had a human drug application or supplement pending after September 1, 1992.

For FY 2003 and after:

Prescription drug product fees are assessed annually for eligible products. The product fees are assessed on products for each person who

- is named as the applicant in a human drug application, and
- had a human drug application or supplement pending after September 1, 1992.

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11. What is the definition of a prescription drug product?

Prescription drug product means a specific strength or potency of a drug in final dosage form for which a human drug application has been approved and which may be dispensed only by prescription under section 503(b) of the FD&C Act, and, after October 1, 2002, is also on the list of products described in section 505(j)(7)(A) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act. (Section 351 of the PHS Act provides the authority for regulating biological products. Biological products are regulated by the Center for Biologics Evaluation and Research.)

12. What does "listing under section 510 of the FD&C Act" mean?

For user fee assessments, this applies only to FY 2002 and before:

Section 510 of the FD&C Act requires manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding or processing of human or veterinary products to register their establishments and submit a list of every product in commercial distribution with the FDA. Additional information can be found on the **Drug Registration and Listing System (/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm)** web page.

13. Are there drugs that are not included in the term prescription drug product?

Yes. The term prescription drug product does not include the following drugs.

- Whole blood or a blood component for transfusion
- A bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the PHS Act (Section 351 of the PHS Act provides the authority for regulating biological products. Biological products are regulated by the Center for Biologics Evaluation and Research.)

- A biological product that is licensed for further manufacturing use only
- A drug that is not distributed commercially AND is the subject of an application or supplement submitted by a State or Federal Government entity
- A large volume parenteral drug product approved before September 1, 1992
- After October 1, 2002, any large volume parenteral drug product regardless of when it was submitted (unless it is a large volume biological product intended for single dose injection for intravenous use or infusion)

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EXCEPTIONS TO FEE REQUIREMENTS

14. Are there any exceptions to the fee requirements?

Yes, there are exceptions.

For Application Fees

- Previously Filed Applications or Supplements. If an application or supplement
  - was submitted by a person that paid the fee for the application or supplement,
  - was accepted for filing, and
  - was not approved or was withdrawn (without a waiver),

The resubmission of the application or supplement for the same product (by the same person) does not require an application fee.

- Designated Orphan Drug or Indication
  - An application for a prescription drug product that has been designated as a drug for a rare disease or condition under section 526 of the Act is not subject to an application fee unless the application includes an indication for other than a rare disease or condition.
  - A supplement proposing to include a new indication for a rare disease or condition is not subject to an application fee if the drug has been designated a drug for a rare disease or condition with regard to the indication proposed in the supplement.

For Establishment Fees

- If the establishment listed in the human drug application does not engage in the manufacture of the prescription drug product during the fiscal year, the applicant is not assessed an establishment fee.
- When the manufacture of a prescription drug is started during the year and after the establishment fee has already been assessed, the applicant is not assessed an establishment fee for that year. The product must not have been manufactured at the establishment in the previous fiscal year to be exempt.

For Product Fees

Applies only to FY 2002 and before:

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