



U.S. Food and Drug Administration

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# CDER Small Business Webinar on PDUFA

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# Internet Address

- We post PDUFA documents at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>
- Documents include:
  - FR Notices
  - Annual reports
  - Guidance documents

# Why is PDUFA important?

- Pre-PDUFA – Review times were an issue.
- PDUFA – More resources to eliminate the backlog and improve timeliness.
- PDUFA II – Focus on review times (increase in goal commitments, meeting requests, dispute resolution).
- PDUFA III – Sound financial footing with significant increase in base funding and new, but limited, support for postmarket risk management activities.
- PDUFA IV – Further increase in base funding and increased fee funding for drug safety.

# Importance (cont.)

- Increased patient access to new drugs and biologics (from FY 1993 to 2010, nearly 1500 NDAs and BLAs).
  - More than 90 new cancer drugs
  - More than 140 drugs for metabolic and endocrine disorders
  - More than 125 anti-infective drugs
  - More than 140 drugs for neurologic and psychiatric disorders
  - More than 110 drugs for cardiovascular and renal disease

# PDUFA Fee Structure

- Total fee amounts are collected equally from 3 sources.
- Fees are set by statute, but adjusted for inflation, etc. See FR notice for details.
- Fee revenue amounts for FY 2012
  - Application Fees           \$234,057,000 (\$1,841,500)
  - Product Fees               \$234,057,000 (\$98,970)
  - Establishment Fees       \$234,057,000 (\$520,100)
  - Total                       \$702,172,000

# Application Fees

- Full fee for original NDA/BLA that requires clinical data for approval
- Half fee for original NDA/BLA that does not require clinical data for approval
- Half fee for supplement that requires clinical data for approval
- No fee for INDs
- No fee for DMFs

# Only Certain Applications Pay

- “Human drug applications” defined to carve out:
  - Generic drugs
  - Government applications IF not for commercial use
  - Biologic carve outs (e.g., whole blood, allergenic extract products)
- Orphan drugs may be exempt.

# Supplements

- Fees only for supplements to “human drug applications”
- Fees for supplements that require clinical data for approval
- Exemptions
  - Orphan drug indications – yes
  - Pediatric uses – no!
  - Geriatric uses – no!



# Costs and Fees

<b><u>App Type</u></b>	<b><u>2010 Cost</u></b>	<b><u>2012 Fee</u></b>
• <b>IND</b>	<b>\$362,100</b>	<b>0</b>
• <b>NDA:NME</b>	<b>\$4,316,600</b>	<b>\$1,841,500</b>
• <b>NDA:Non NME</b>	<b>\$1,863,600</b>	<b>\$1,841,500</b>
• <b>NDA: No CD</b>	<b>\$502,100</b>	<b>\$920,750</b>
• <b>Supp w CD</b>	<b>\$615,700</b>	<b>\$920,750</b>
• <b>Supp No CD</b>	<b>\$31,400</b>	<b>0</b>

# Collection of Fees

- Application Fees
  - Pay entire amount, up front, to
    - US Bank in St. Louis
    - pay.gov
    - Wire transfer
    - Details in yearly FR notice
- Product and Establishment Fees
  - Invoices sent twice a year (pre- and post-FY).

# Waivers and Reductions

## section 736(d) of the Act

New waiver guidance finalized September 2011  
– on our Internet site.

- Small Business
- Public Health
- Barrier to Innovation
- Fees Exceed the Cost

# Small Business

- Applicant employs fewer than 500 employees, including employees of affiliates.
- Applicant does not have a drug product approved under a human drug application and introduced or delivered for introduction into interstate commerce.
- Applicant, including its affiliates, is submitting its first human drug application.

# Small Business (cont.)

- Generally submit request 3 to 4 months before submitting your application.
- FDA consults with the SBA.
- Waiver expires one year after the effective date of the small business determination.
- Small business waiver is not applicable to the annual product and establishment fees.

# Public Health

- Does the product protect the public health?
  - For example, is it fast track? NME? priority?
  - Treatment alternatives?
- The applicant needs to show that a waiver or reduction is **NECESSARY** to continue an activity that protects the public health.
  - FDA considers “limited resources.”

# Barrier to Innovation

- Is the product innovative, or is the applicant developing other products or technologies that are innovative?
  - Demonstrate advanced breakthrough research? Forefront of new medical technology? Federal grant for innovation?
- Is the fee a significant barrier to the applicant's ability to develop, manufacture, or market innovative products or to pursue innovative technology?
  - FDA considers gross revenues and other financial resources of the applicant and its affiliates.

# Financial Resources

- For both public health and barrier-to-innovation waivers
- FDA considers total gross annual revenue of the applicant and its affiliates
- Other financial assets (e.g., cash, results of recent issuances of stock).
- “An applicant with \$20 million or more in financial resources, including the financial resources of affiliates, generally will not be considered to have limited resources for user fee purposes.”

# Fees Exceed The Cost

- Separate guidance on fees exceed the cost waivers.
- FDA considers all the fees you and your affiliates have paid since PDUFA began.
- Compares what you have paid to total of standard costs FDA has incurred on your behalf from the beginning of PDUFA.
- Not a single submission consideration — a cumulative review.

# PDUFA Goals

- Many goals – See goals letter on the Internet for a full description.
- Some examples
  - Standard NDA/efficacy supp. – 90% in 10 months
  - Priority NDA/efficacy supp. – 90% in 6 months
  - Prior approval manufacturing supp. – 90% in 4 months
  - Manufacturing supp., prior approval not required – 90% in 4 months
  - Meeting management goals
  - Responses to clinical holds within 30 days

## Bundling Policy and Definition of Clinical Data

- Guidance on Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004)
  - what should be submitted in separate applications
  - what may be submitted in an application
  - what may be submitted as a supplement
  - provides a uniform definition of the term “clinical data” for user fees
  - provides a level playing field for industry

# Product Fees

- The applicant must have an application or supplement pending after 9/1/1992
- The product must be
  - Subject to an approved human drug application
  - In the active portion of the Orange Book or, if a biologic product, on a list created and maintained by the Secretary
  - For NDAs, not the same as another product.
- OTCs under NDAs don't pay product fees.

# Establishment Fees

- The applicant — not the establishment owner — is responsible for the establishment fee.
- The applicant must have had an application or supplement pending after 9/1/1992.
- The product is manufactured in final dosage form, during the FY.

# Failure to Pay Fees

## section 736(e)

- All fees owed must be paid.
- If no application fee received, the application is incomplete.
- If in arrears for nonpayment of product and/or establishment fees, any application or supplement you submit is incomplete.

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