



U.S. Food and Drug Administration

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PET Products and User Fees

Positron Emission Tomography (PET)
Drugs Public Meeting March 2, 2011

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What are User Fees?

- Application fee – at time of submission
 - 505(b)(1)s and 505(b)(2)s pay unless waived or exempted
 - **ANDAs (505(j)s) don't pay under current law**
 - Fees for supplements that require clinical data - 1/2 of full application fee
- Product and Establishment Fees
 - 505(b)(1)s and 505(b)(2)s pay unless waived or exempted or have generic competition
 - Yearly
 - Usually due October 1
- Fee amounts set annually and announced in FR Notice usually beginning of August for upcoming FY

Fiscal Year 2011 Fees

- Application: requires clinical data - \$1,542,000
- Application: clinical data not required - \$771,000
- Supplement: requires clinical data - \$771,000
- Product: \$86,520
- Establishment: \$497,200 (PET 1/6)



March 10, 2000, FR Notice

- FDG F-18, Ammonia N-13, NaF F 18
- Application fee can be waived if
 - Application submitted in accordance with March 10, 2000, FR notice
 - If different indications/usage not in the notice, then not waived unless meet other criteria for waiver
 - Only covers application fee
 - Applicant to waive any exclusivity

Reduced Establishment Fees

- If you are eligible for product fees you are eligible for establishment fees.
- PET establishment fees are 1/6 the regular establishment fee.
- If not-for-profit medical center that has only one establishment and at least 95% of total doses within the medical center, then exempt from establishment fee.
- There is no similar provision for product fees.

Waivers – General Information

- Case-by-case basis
- Generally request the waiver 3 to 4 months before you submit your application – details on requests later
- Waivers must be requested no later than 180 days after the fee is due
- Possible to pay the fee, request a waiver, and receive a refund

Waivers – Small Business

- First application for you and your affiliates
- Fewer than 500 employees for you and your affiliates
- You do not have a drug product approved under a human drug application and introduced or delivered for introduction into interstate commerce

Waivers – Public Health and Barrier to Innovation

- The waiver guidance sets out the criteria
- For products, establishments, or applications
- The 2000 FR notice makes a case for how some PET products are innovative; may be able to make a similar case for other PET products
- Financial test for both waivers
- Other things to consider
 - Not for profit
 - University based research center

Written Request

- Name and address, phone number, contact person
- Specify the fee & reason for request (e.g., statutory provision) and analysis
- Application, product, and/or establishment information
- Invoice number if applicable
- Details on PET Internet site

Contact Information

- Mailing Address
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Exemptions – Generic Competition

- You continue to pay product and establishment fees until your product is the same as another product
- In another words, if you have generic competition, no fee
- Competition is per strength
- No prorating

One FDG Product has Generic Competition

- Approved FDG 20-200 mCi/mL strength products have generic competition (AP rated) and will not be assessed annual product fees
- Feinstein NDA 21870 for the 20-200 mCi/mL strength is AP rated to the PETnet ANDA 79086
- If other strengths are approved in (b)(2) or (j) applications, and are AP rated, neither innovators nor generics will be assessed annual product fees

Exemptions – Orphan

- Application fee
- Designated for a rare disease or condition under section 526 of the Act
- Orphan only

Exemptions – Orphan

- Product and establishment fees
- Designated for a rare disease or condition under section 526 of the Act
- Meets the public health requirements
- Your company (including affiliates) under \$50 million in gross worldwide revenue for the 12 months prior to your request
- Need certification that you did not exceed \$50 million

Exemptions – State/Fed Gov Entity

- Product, establishment, or application fees
- The application holder is a state or federal government entity for a drug that is not distributed commercially
- Distributed commercially means: Any distribution in exchange for financial reimbursement, goods, or services, whether or not the amount of the charge covers the cost

Exemptions – Product Discontinued

- If you are no longer producing and marketing your product but the product is in the Orange Book, you pay
- Alert the Orange Book staff if you discontinue
- Still pay for the discontinued year and no prorating

How do you show you qualify for an exemption?

- Applications – If criteria met, enter on user fee cover sheet and note in cover letter
- Products – Send a letter (use previously supplied contact information)
- For generic competition – Should be automatic – monitor the Orange Book

Waivers – Fees Exceed the Cost

- Compares all the fees you have paid against all the submissions you have submitted
- If you have paid more than your costs you get a refund
- Costs are not known until after the FY ends
- Guidance on our Internet site

Internet Addresses

- Main Prescription Drug User Fee Act (PDUFA) page
 - <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>
- PET Q and A page
 - <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm193476.htm>