Money for Nothin': FDA's PDUFA Fee Waivers and Exemptions

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Lately, we have received a number of client inquiries about prescription user fee waivers. The Prescription Drug User Fee Act (PDUFA), enacted in 1992, authorizes FDA to collect fees from companies that produce certain human drug and biological products.[1] Under PDUFA, there are three types of "user fees": application fees, establishment fees, and product fees. PDUFA also established a fee waiver program. Given the substantial savings resulting from a fee waiver, we are often asked to review applicability of the waiver to certain products. Below are answers to some of the most common questions we receive regarding fee waivers.

Fee Waiver Background

There are four primary methods of waiver:

- a waiver or reduction to protect the public health;
- the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;
- the fees to be paid will exceed the anticipated present and future costs incurred by the Food and Drug Administration in conducting the process for the review of human drug applications; or
- the applicant is involved in a small business and is submitting its first human drug application to FDA for review.[2]

The small business exception is by far the most common fee waiver we see requested. The small business fee waiver is designed to permit new companies that may not have the capital to afford application fees a chance at a one-time waiver of the application fees.

In addition to the waivers listed above, under certain conditions PDUFA also permits an exemption from product and establishment fees for orphan drugs, which are designed to treat rare diseases and conditions. We will discuss this provision in greater detail below.

Common Questions

- **What is a small business?**
  - A small business is defined to mean "an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce."[3]

- **How long does it take to obtain a small business application fee waiver?**
  - The current timeframe, even for businesses that appear to clearly fit within the "small business" definition, is 3-5 months. FDA's review could take longer if there are complicating factors.

1 https://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069943.htm
2 21 U.S.C. § 379h(d).
3 21 U.S.C. § 379h(d).

- In order to receive a small business fee waiver, FDA will review the waiver applicant to determine if the company "has fewer than 500 employees, including employees of affiliates, and [has no] drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce."[4]
- FDA will carefully review and scrutinize the request for waiver, including a detailed analysis of whether the company has "affiliates" that would cause the company to fall outside the definition of a small business.
- "Affiliate" is defined to mean "a business entity that has a relationship with a second business entity if, directly or indirectly--(A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has power to control, both of the business entities."[5]

- **Are application fee waivers available for biologics?**
  - Yes. FDA may grant a fee waiver to:
    - a person who is named as the applicant in a human drug application . . . [to include the licensure of a biological product under subsection (a) of section 262 of Title 42.]
  - The referenced subsection (42 U.S.C. § 262(a)) describes the approval process for biologics licenses.[6]
  - FDA guidance also confirms that BLAs are eligible for the small business fee waiver (assuming the other conditions to obtain the waiver are met).[7]

- **If a pharmaceutical manufacturer is too big to qualify for the small business application fee waiver, can it acquire a company that meets "small business" requirements immediately after the small company uses its fee waiver?**

  - Yes. There is no prohibition on a small business applying, receiving, and then using a fee waiver immediately before acquisition by another company, even if that other company would not qualify for a fee waiver.
  - However, if the application product and its waiver are transferred before NDA approval, the waiver would be void, based on our experience. The small business that applied for, and received, the waiver must be the entity to use it. The fee waiver is attached to the applicant and, if the applicant changes, the fee waiver would no longer be valid.

- **Is the orphan drug product and establishment fee exemption only permitted during the orphan drug's seven year exclusivity period?**
  - No. The law states that "[an orphan] drug . . . shall be exempt from product and establishment fees under this section, if the drug meets all of the following conditions:
    - (A) The drug meets the public health requirements contained in this chapter as such requirements are applied to requests for waivers for product and establishment fees [and]
    - The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue during the previous year."[8]
  - The statute does not directly speak to fee exemption being tied to the seven-year exclusivity.
  - FDA's guidance on the topic states that the orphan drug will continue to be exempt from product and establishment fees, as long as the applicant "submit[s] a certification that its gross worldwide revenues, including affiliates, did not exceed $50 million for the 12 months before the request."[9] The establishment and product fee exemptions are still available if the conditions described in the above paragraph are met.

4 21 U.S.C. § 379(h)(d)(4)(A).
5 21 U.S.C. § 379g.
6 21 U.S.C. §§ 379h(d) and 379g(1).
7 *Guidance for Industry: User Fee Waivers, Reductions, and Refunds for Drug and Biological Products*, U.S. FOOD AND DRUG ADMINISTRATION (September 2011), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079298.pdf.
8 21 U.S.C. § 379h(k).
9 *Guidance for Industry: User Fee Waivers, Reductions, and Refunds for Drug and Biological Products*, U.S. FOOD AND DRUG ADMINISTRATION (September 2011), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079298.pdf.

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