Money, Money, Money, Always Sunny: FDA Issues Updated Draft Guidance on User Fee Waivers, Reductions, and Refunds

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On June 21, 2018, the Food and Drug Administration issued new guidance related to the Prescription Drug User Fee Act.[1] The document, "Guidance for Industry: Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products," updates and supersedes previous guidance issued in September 2011.[2] Industry should carefully review the guidance document, as it contains a number of significant changes to and clarifications of the now outdated 2011 guidance. FDA recommends that electronic or written comments be submitted by August 20, 2018.

In this Bulletin, we focus on changes to the small business fee waiver, which includes the following:

- The new guidance reaffirms that FDA, not the Small Business Administration, reviews user fee waivers, reductions, and refund requests.

- In contrast to the 2011 guidance, the new guidance states that, if the human drug or biological application is not submitted within a year from issuance of the waiver, the small business should request a new small business waiver.
  - this is to confirm that the business remains qualified as "small:" if it (1) employs fewer than 500 employees, including employees of affiliates, (2) does not have a drug product that has been approved under a human drug application and introduced or delivered into interstate commerce, and (3) is submitting its first human drug application (including affiliates)

- Previously, an applicant remained eligible for a small business fee waiver only if the applicant did not submit the drug application for which it was granted a small business fee waiver. The new guidance clarifies that an applicant remains eligible for a small business fee waiver if a drug application was submitted but was later refused for filing or withdrawn.
  - if the applicant resubmits the same application that was previously refused for filing or withdrawn, it may also renew its request for the small business fee waiver

- For fee waivers submitted after a human drug application has already been submitted, the applicant is given 180 days from the date when the invoice is due to request a waiver.
  - the new guidance clarifies that it is 180 calendar days
  - the new guidance notes that any request for reconsideration or appeal of a fee waiver determination must be submitted within 30 calendar days

- The new guidance includes a separate section regarding the content and format of the request for a small business fee waiver, to promote consistency and address frequent problems with waiver submissions.
  - it states: "To qualify for a small business waiver of the application fee, an entity must submit to FDA a written request for such a waiver and a certification that the entity meets the requirements for the waiver. Applicants should submit requests

1 https://www.federalregister.gov/documents/2018/06/21/2018-13295/prescription-drug-user-fee-act-waivers-reductions-and-refunds-for-drug-and-biological-products-draft.

2 For a copy of the guidance, see https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm611183.pdf.

for a small business waiver of the application fee and refund due to the small business waiver via Form FDA 3971, attached as Appendix 1"[3]

- Important to the small business fee waiver request is FDA's analysis of what entities are "affiliates" of the applicant.
  - AGG has seen "affiliate" issues (i.e., who is correctly identified as an affiliate of the fee waiver applicant) cause confusion, delay, and added scrutiny in FDA's review of small business fee waiver requests.
  - in the new guidance, FDA clarifies that:

    Occasionally, FDA finds entities to be affiliated with the applicant that the applicant did not identify as one of its affiliates in its initial waiver or exemption submission. When determining whether parties are affiliated for purposes of user fee assessment under PDUFA, the critical factor is whether one party controls or has the power to control another entity, or if a third party has the power to control both entities. In such cases, FDA recommends that the applicant submit copies of any agreements between an applicant and the other entities that demonstrate the nature of the relationship the applicant has with the entity. If the requested supporting documentation is not submitted, FDA may deny the small business waiver request because there 651 is insufficient evidence that the applicant meets the requirements in section 736(d)(1)(C) of the FD&C Act.

- The new guidance adds that no new information or analyses should be included in an appeal of an FDA fee waiver determination by stating: "If new information and/or analyses are presented in the appeal request, the appeal will not be accepted and the matter will be referred back to the original deciding official to consider the new information or analyses"

3 The form is available at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM584476.pdf.

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