



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

March 17, 2026 | 3:30pm-5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To discuss the changes to statute proposed by FDA around program eligibility date and treatment of “affiliates” for purposes of orphan exemption from program fees and small business waiver.

PARTICIPANTS

FDA

Joshua Barton	CDER
Angela Granum	CDER
Kate Greenwood	OCC
Kristopher Hoover	CDER
Christine Hunt	OCC
Rebecca Kemp	CBER
Andrew Kish	CDER

Industry

Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Drew Sansone	BIO (Alkermes)

MEETING SUMMARY

FDA and Industry discussed the changes to statute proposed by FDA: to adjust the program fee eligibility date, clarify the inclusion of affiliates in the program fee orphan exemption financial threshold, and clarify the inclusion of affiliates for the small business waiver criteria.

Industry stated they could not accept FDA’s proposal to adjust the program fee eligibility date; however, Industry accepted FDA’s proposals for inclusion of affiliates in the program fee orphan exemption financial threshold and the small business affiliate term.

Adjust the Program Fee Eligibility Date

Under this FDA proposal, previously discussed by Industry and FDA (see minutes from the 11/20/25 meeting), approved products would be eligible for the program fee based on their status as of April 1st rather than October 1st, which is the start of the fiscal year. FDA noted that invoices must be sent in advance and when there are then changes to product status or if there are waiver requests, the sponsor may have to pay the original invoice and then request a refund. According to FDA, this change from October 1st to April 1st would reduce unnecessary and inefficient

administrative processes for both Industry and FDA and improve the predictability of program fee collections.

Industry expressed concern that if the eligibility date was changed, due to the gap between April 1st and October 1st, there could be instances of companies paying fees in a fiscal year for a product that was discontinued in the previous fiscal year or not paying fees for a product that was approved in the previous fiscal year. Industry stated their belief that FDA will receive complaints from companies regarding this situation and suggested that any efficiencies realized from changing the eligibility date will then be unrealized due to responding to Industry feedback. FDA explained that processing requests that invoices be cancelled or refunds be granted, which it has to do now, is more significant from a workload perspective than responding to questions from Industry about the eligibility date would be. FDA also asserted that there are examples where fee obligations depend on actions sponsors take before the fiscal year of the fee in other user fee programs. Industry stated their apprehension to making further changes to the PDUFA program given the significant changes already being implemented.

Industry ultimately stated they could not agree to this proposal.

Clarify Inclusion of Affiliates in Program Fee Orphan Exemption Financial Threshold

FDA presented the second change: to clarify in statute that revenue from affiliates should be included in the calculation of the applicant's gross worldwide revenue when evaluating requests for orphan exemptions from PDUFA program fees. FDA explained that some firms have disputed whether affiliate revenue should be included in the evaluation of requests for orphan exemptions. FDA explained that disputes on requests for waivers or exemptions from companies can take significant resources from the Agency to adjudicate and can lead to uncertainty for companies while they wait for the adjudication to be completed.

Industry asked about the use of the term 'person'. FDA explained that the Federal Food, Drug, and Cosmetic Act defines 'person' to include an individual, partnership, corporation, and association, and that the definition of 'person' for purposes of PDUFA includes affiliates. Industry inquired about the frequency of this issue. FDA observed that even if only a few instances arise, they take significant time and resources for the Agency to evaluate.

Industry agreed to FDA's proposal to clarify that the finances of an applicant and its affiliates are to be included in the calculation of the applicant's gross worldwide revenue.

Clarify Inclusion of Affiliates in Small Business

The final proposed change from FDA is to clarify that the term "affiliates" in the relevant section of statute applies to both criteria for the small business waiver. Some firms have sought small business waivers even when their affiliates have been marketing prescription drug products. FDA proposed a solution of modifying the statutory language to consistently apply the term "affiliate" to both criteria for the definition of "small business". FDA asserted that, while the issue

addressed by this change is relatively infrequent, waivers in general are a driver of the application fee increase. FDA addressed Industry's clarifying questions.

Industry agreed to FDA's proposal to clarify the inclusion of affiliates in the criteria for the small business waiver.

Next Steps

The goal for the next meeting is for FDA and Industry to discuss the PDUFA VIII ledger, the draft of the finance section of the commitment letter, and the outstanding costs (time reporting licenses and third-party assessments).