Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

November 13, 2025 | 1:00pm-3:00pm

Virtual Format (Teams)

MEETING PURPOSE

To continue discussion about FDA and Industry proposals on the operating reserve adjustment, triggers, and proposed patch test exemption.

PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Emily Ewing	CDER	Steve Berman	BIO
Angela Granum	CDER	Kelly Goldberg	PhRMA
Kate Greenwood	OCC	Kristy Lupejkis	PhRMA
Kristopher Hoover	CDER	Alison Maloney	PhRMA (Bayer)
Christine Hunt	OCC	Drew Sansone	BIO (Alkermes)
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Joshua Kirk	OO/OFBA		
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MEETING SUMMARY

FDA and Industry discussed three proposals: operating reserve adjustment, harmonizing triggers, and the patch test exemption.

Enhancing Operating Reserve Adjustment Flexibility (FDA Proposal)

FDA presented its operating reserve adjustment proposal, which aims to make the operating reserve adjustment floor discretionary. FDA's intent with this proposal is to mitigate the need for small adjustments to the fee revenue and fees when the operating reserve is below the 10-week minimum threshold.

FDA provided background on the current framework for the operating reserve adjustment, highlighting that any operating reserve adjustment made in setting PDUFA user fee rates for a given fiscal year is not included in the base revenue amount for subsequent fiscal years.

FDA provided historical data on the operating reserve from 2018 to 2026, highlighting the years in which an upward or downward adjustment was made and the reasons for these adjustments. FDA noted that in fiscal year 2025, a small upward adjustment was made when the operating reserve was estimated to be at 9.8 weeks. FDA noted that with this proposal, an adjustment in such an instance could be avoided, which would help mitigate increases in fees. FDA noted that the Generic Drug User Fee Amendment (GDUFA) has a discretionary floor which enabled that program to avoid an upward adjustment in fiscal year 2026, when that program was projecting a 9.8-week operating reserve.

Industry indicated that they have no concerns with incremental adjustments in such instances. Industry stated that changing to a discretionary floor without limitations on that discretion has no benefit and potentially introduces unnecessary risks for a user fee program as large as PDUFA.

Industry emphasized that their proposal is to manage the operating reserve to an amount equivalent to 10 weeks every year. Industry stated its view that the 14-week cap is too high and that funds in excess of 10 weeks should be returned to fee payers.

FDA noted that its financial system is complex and that it would be very challenging to manage the operating reserve to equal a specific amount at the end of every year. FDA stated that Industry's proposal would require an operating reserve adjustment every year. FDA emphasized that it would be much more efficient to manage the operating reserve within a range.

FDA noted recent years where PDUFA funds were under collected by as much as $100 million dollars. In such instances, under Industry's proposal, large upward adjustments would be required to increase the fee amounts to account for those under-collections. FDA noted that managing within a range has helped to mitigate some of those impacts.

FDA and Industry agreed to discuss further at a subsequent meeting.

Harmonizing Triggers for Efficiency and Resilience (FDA Proposal)

FDA noted that the first part of its proposal aims to simplify the appropriations and spending trigger calculations by writing the 2025 trigger amounts into statute while concurrently updating the adjustment factor. FDA noted that this would be a technical change to update the statute without changing the calculated trigger amounts in any subsequent year, compared with the current method.

FDA stated it is also proposing to standardize the spending trigger compliance threshold to match that of the Biosimilar User Fee Act (BsUFA) program. This proposal would mean changing the current PDUFA 3%–5% trigger compliance threshold to 15%.

FDA noted that it is trying to address two issues with its proposal. One issue is that the triggers vary considerably across user fee programs and more consistency would make the triggers easier to manage. The second issue is flexibility. In an uncertain budgetary environment, FDA would have limited options available to ensure triggers are met across all user fee programs. Missing the spending trigger would have catastrophic impacts. By updating the statutory language on the

compliance threshold, FDA can preserve the intent of the trigger – to ensure adequate appropriations spending towards the program – while improving flexibility and decreasing risk during difficult budget cycles.

Industry expressed concern that increasing the trigger threshold would enable a decrease in budget appropriations. Industry also expressed concern that a larger trigger threshold could enable a diversion of current budget appropriations supporting the PDUFA program to other programs. Industry also noted that given the difference in size of the PDUFA and BsUFA programs, the proposed approach to harmonize with the BsUFA trigger threshold may increase the risk of adverse impacts on the stability of the PDUFA program.

FDA and Industry agreed to revisit this proposal at subsequent meetings.

Patch Test Exemption (FDA Proposal)

FDA answered clarifying questions from Industry on its proposal to exempt patch tests for the diagnosis of allergic contact dermatitis from paying fees. FDA noted that no submissions have been received in a number of years and that this exemption would have no financial impact on the PDUFA program, as no fees have been paid by these products.

Industry asked how many submissions FDA might receive if this exemption were implemented. FDA noted that this market is very small.

Industry said it would follow up on this proposal in a subsequent meeting.

Other Topics

The FDA team shared that Agency leadership does not support Industry's proposal to eliminate the capacity planning adjustment (CPA) and to cap the inflation adjustment at 1.5%; therefore, FDA will not be able to engage in discussion on those two proposals. FDA did state that if Industry had any reasonable technical modifications regarding these adjustments to suggest, the Agency may be able to engage on those proposed modifications.

Industry indicated a concern about growth in the number of full time equivalents (FTEs) in the PDUFA program. FDA reiterated that the CPA is not expected to add any additional FTEs until review functions are re-staffed. FDA noted that these adjustments are important safeguards against growth in the workload of the program and inflation. FDA noted that if there were no growth in workload or inflation, there wouldn't be adjustments made as a result of the CPA or the inflation adjuster. FDA also asked about Industry's perspective on adjustments to the base revenue to reflect administrative efficiencies.

Industry noted that their proposals are a full package aimed at ensuring the stability and long-term sustainability of the program. Since FDA will not entertain the capacity planning adjustment and inflation adjustment proposals as currently proposed, further discussions are needed on any reasonable technical modifications regarding these adjustments.

FDA and Industry agreed to add planning time to next Tuesday's meeting to discuss topic schedules.

Next Steps

The goals for the next meeting on November 18th will be to begin detailed discussion on the fixing fee loopholes proposal and have planning time to review subsequent meeting schedules.