



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

March 20, 2026, 1:00pm – 2:00pm

Virtual Meeting

PURPOSE

To continue discussions to reauthorize GDUFA related to finance.

PARTICIPANTS

FDA

Kathleen Davies	CDER
Kimberly Taylor	CDER
Tasha Ray	CDER
Alison Lyndaker	CDER
Jonathan Collins	CDER
Angela Granum	OC
Gisa Perez	OC
Josh Brown	OC
Mingham Ji	OC

Industry

Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Andrew Zacher	AAM (Amneal)
Jess Greenbaum	AAM (Sandoz)
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent Pharma Solutions)

MEETING SUMMARY

Industry provided a counterproposal following their last finance proposal presented in February. Industry reiterated the progress on proposals that address FDA’s goals so far, including moving the program fee liability date and adjusting the foreign facility fee differential from \$15k to \$25k (without any increase to the differential amount for inflation). Industry explained that this new counterproposal was prompted by clarification from FDA regarding its priority of lowering application fees. Industry reiterated its prior concerns with significantly lowering the application fee and corresponding increase in program fees including challenges to industry sustainability. Industry indicated that this counterproposal was intended to find a middle ground that reflected the principles of financial predictability; the preservation of incentives for high quality complete ANDAs; minimal disruption to the existing fee structure; and avoidance of disproportionately burdening any one tier of payer.

Industry proposed two options for a shift in the allocation percentages: a decrease of the ANDA application fee allocation from 33% of target revenue to 29%, which would decrease the ANDA application fee by 12%, or a decrease of the ANDA application fee allocation to 26% which would decrease the ANDA application fee by 21%. Industry indicated they believe these options would support FDA and industry’s needs. Industry also proposed that additional FTE transparency and hiring accountability, guardrails to encourage high quality submissions and fee collections, and deploying resources to maximize public health impact be discussed further.

FDA queried whether industry was proposing the shift would be made all at once in the first year of GDUFA IV. Industry confirmed they were proposing that, and they believe that timing would make the most impact. FDA queried whether industry was proposing the percentage would move to the program fee. Industry confirmed they were proposing that, consistent with FDA's previously shared examples as outlined in their proposal. FDA queried whether industry was proposing to keep the weighting and number of program fee tiers the same. Industry confirmed they were.

FDA asked industry to provide more details on the other two topics raised. Regarding transparency and hiring, industry indicated they want to ensure generic user fee money is being sufficiently spent on FTEs focused on human generic drug activities. Industry shared that appropriate staffing levels are of paramount importance to them and suggested quarterly hiring updates similar to what is done for PDUFA and BsUFA. FDA indicated that the updates for those programs are only done as overall, Center-wide net hiring figures that don't reflect specific programs and for new FTEs added as the result of the recommended negotiated enhancements. Industry acknowledged this and said that beyond reporting they are interested in ensuring fees support sufficient hiring of staff.

FDA asked for clarification on what industry meant by identifying guardrails to encourage high quality submissions and ensure FDA collects fees. Industry commented that the administration is committed to addressing fraud, waste, and abuse and industry may be exploring other potential ideas related to this work that is done out of the Office of Inspector General's (OIG). FDA indicated they would need to see more details on any proposal to be able to respond and industry stated they would provide additional details at a subsequent meeting.

FDA further queried what industry meant by ensure resources are deployed to activities that maximize public health. Industry stated that not all ANDAs are the same, for example a generic where there is only one or two of a certain product versus where there are 50, noted that public health impact was brought up in a recent public stakeholder meeting, and suggested there is more value in looking at the higher impact applications. FDA indicated that, in its view, it wasn't a financial topic and should be discussed at the broader negotiation group.

FDA and industry agreed to further discuss finances next week.