



Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting

January 28, 2026, 9:30am – 12:30pm

Virtual Meeting

PURPOSE

To continue discussions to reauthorize GDUFA (GDUFA IV).

PARTICIPANTS

FDA

Kathleen Davies	CDER
Kimberly Taylor	CDER
Tasha Ray	CDER
Alison Lyndaker	CDER
Jonathan Collins	CDER
Kristin Davis	CDER
Rob Lionberger	CDER
Kendra Stewart	CDER
Malik Imam	CDER
Martha Nguyen	CDER
Susan Rosencrance	CDER
Ashley Boam	CDER
Bhagwant Rege	CDER
Partha Roy	CDER
Rebecca Dowd	OII
Ivy Sweeney	OII
Angela Granum	OC
Gisa Perez	OC
Josh Brown	OC
Mingham Ji	OC

Industry

Giuseppe Randazzo	AAM
Scott Kuzner	AAM
Andrew Zacher	AAM (Amneal)
Kiran Krishnan	AAM (Apotex)
Nimi Chhina	AAM (Teva)
Jess Greenbaum	AAM (Sandoz)
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent Pharma Solutions)
Joel Carpenter	BPTF
Kari Abboud	BPTF (BASF)
Elizabeth White	BPTF (Evonik)

MEETING SUMMARY

Maximum Daily Dosage (MDD)

FDA presented a counter proposal to industry's proposal to make MDD values publicly available. FDA proposed that the agency would begin to pilot the public availability of a subset of validated MDD values with initial availability before the end of year 1 of GDUFA IV, seek yearly feedback on the utility of the piloted approach, and evaluate the resources needed to make available and keep updated more comprehensive information about MDD values during GDUFA IV.

Industry asked questions regarding how the subset of values to be made available would be defined and the scope of the pilot. FDA agreed to draft proposed commitment letter language that captures the counter proposal.

No agreements were made at this time.

Inactive Ingredient Database (IID)

FDA presented a counter proposal to industry's proposal to expand the IID. FDA proposed that, following the first approval of a drug containing an excipient that does not appear in the IID but that is accurately identified in the FDA-approved labeling of that drug, the agency would add the excipient name along with the route of administration and dosage form to the IID. FDA also plans to continue quarterly updates to the IID consistent with GDUFA III commitments and to continue to enhance and update the IID, including by populating additional MDE values when appropriate, posting information on flavors under the compound/group name, hyperlinking additional information, and engaging with industry by making improvements based on targeted questions received via email. FDA proposed no changes to the commitment letter, suggesting the current language covers these proposed enhancements.

Industry expressed appreciation for FDA looking into improvements to the IID and asked questions regarding expected timelines for MDE updates and IT improvements that may support further enhancing the IID. Industry also indicated they would prefer to make changes to the commitment letter to better specify the types of enhancements and updates to be made to the IID and will propose language at a later date.

No agreements were made at this time.

Filing Language Fix

Industry presented a counter proposal to FDA's proposal to update filing language in the commitment letter to align with current practice. Industry suggested additional clarifying language. FDA suggested one additional clarification after seeing industry's suggested edits and noted this language could be subject to further change if parts of industry's structured review proposal are accepted.

FDA and industry agreed on draft commitment letter language pending further discussion of the structured review proposal.

Finance

Industry presented initial counters to FDA's finance related proposals. Industry indicated their position that predictability and sustainability of GDUFA is a priority that benefits FDA, industry, and patients and also described challenges the generic industry is currently facing. Industry also raised questions about current and projected staffing levels.

Industry indicated that they are interested in the program fee liability date occurring as close to the fee due date as possible, suggesting a May or June date instead of FDA's proposed April date. FDA asked questions to understand why May or June is preferable and indicated they would assess whether this is possible. FDA and industry also discussed how to partially incorporate moving the facility fee liability date in this proposal to promote similar treatment for facilities referenced in newly approved ANDAs.

Industry indicated that updating the revenue allocation percentages to reduce the ANDA allocation percentage as proposed by FDA is not feasible for industry and that they do not support the floating allocation percentage model due to concerns about the uncertainty it could create in planning for future fee obligations. FDA indicated that they are open to discussing other options for a change in allocation percentages. FDA and industry agreed not to pursue the floating allocation model any further in these negotiations.

Industry expressed that a per ANDA program fee model is not feasible as proposed by FDA, highlighting their view that this proposal would disproportionately concentrate the highest fees on companies that supply the majority of the generic drug supply, potentially leading to drug shortages and undermining sustainability of an already fragile industry. FDA asked industry to explain how it is measuring proportionality and FDA explained its perspective on proportionality, considering factors such as fee burden per approved ANDA or the fee burden relative to supplement submission volumes. FDA recognized there could be additional ways to measure proportionality and asked industry to provide data on how they are measuring proportionality. FDA and industry agreed that additional discussion would be helpful.

In response to FDA's concern that arrears contributed to its under-collection, Industry conveyed their view that compliant applicants should not incur increased fees to compensate for the shortfall from firms in arrears. Instead, Industry proposed amending the statute to provide mechanisms to strengthen statutory consequences for non-payment. FDA indicated that industry's proposed changes to statutory provisions in this manner are beyond FDA's GDUFA user fee authority and would fall outside the scope of negotiations, while Industry's view was that amending section 744B in this manner was within scope. FDA expressed that arrears are only one factor that leads to under collection, while Industry emphasized that failing to collect from applicants in arrears unnecessarily contributed to under-collections. FDA indicated that they are open to discussing other options related to the program fee such as a different cap on the per ANDA model or additional tiers. FDA also noted that, in addition to the stated concerns, in its view, penalties proposed would require significant additional resources not provided for in current GDUFA agreements that would raise fees for all fee payers and may not be successful in recouping fees.

Industry also requested clarity on whether FDA still wishes to pursue proposals to reset base year triggers to the 2025 dollar amount and increase the spending trigger threshold, expressing concern that raising the spending trigger threshold could weaken a safeguard

designed to ensure that FDA maintains an adequate level of non-fee appropriations dedicated to the generic drug program. FDA agreed not to discuss these proposals further.

Industry closed by sharing that they are considering options that maintain the current program fee structure and, potentially, incremental changes (e.g., expanding program tiers from 3 to 5) as well as exploring other changes. Industry also emphasized that additional data that FDA has agreed to provide is needed to continue developing their counter proposals and FDA committed to providing data as quickly as possible.

FDA emphasized the importance of understanding the scope of what financial changes industry is considering for their counter proposal in order to continue to consider what enhancements they could agree to. Industry indicated that this is its initial, high-level financial presentation, that it will present additional details as more data and information become available, and that it does not intend to propose novel changes beyond the financial topics FDA introduced.

FDA and industry agreed that an additional finance subgroup meeting would be helpful.

Prior Negotiation Topic Updates

FDA indicated that they do not intend to further counter industry's response to the foreign fee differential and fee waiver for new domestic manufacturers proposals.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, February 4, 2026. The goal of the meeting will be to continue discussions on program efficiency, onshoring, and finance proposals.