Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
February 19, 2026, 12:30pm – 4:30pm
Hybrid Meeting | FDA White Oak Campus, Silver Spring, MD

PURPOSE

To continue discussions to reauthorize GDUFA (GDUFA IV).

PARTICIPANTS

FDA		Industry	
Kathleen Davies	CDER	Giuseppe Randazzo	AAM
Kimberly Taylor	CDER	Scott Kuzner	AAM
Tasha Ray	CDER	Andrew Zacher	AAM (Amneal)
Alison Lyndaker	CDER	Kiran Krishnan	AAM (Apotex)
Jonathan Collins	CDER	Nimi Chhina	AAM (Teva)
Kristin Davis	CDER	Jess Greenbaum	AAM (Sandoz)
Rob Lionberger	CDER	Gil Roth	PBOA
Kendra Stewart	CDER	Joel Carpenter	BPTF
Malik Imam	CDER	Beth Mihalek	BPTF (Veranova)
Martha Nguyen	CDER	Brant Zell	BPTF (AmbioPharm)
Susan Rosencrance	CDER		
Ashley Boam	CDER		
Erin Skoda	CDER		
Rebecca Dowd	OII		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Drug Master Files (DMFs)

FDA presented a counter proposal addressing both industry and FDA's initial proposals related to DMFs. FDA acknowledged industry's prior request to expand the DMF prior assessment enhancement to all DMFs and explained why this is not feasible. FDA restated its proposal that the agency would clarify and standardize the process by creating a prior assessment cover letter template, presenting to industry on the process at least once per fiscal year, and by instructing DMF holders to request prior assessments using FDA Form 3938. FDA also proposed expanding the criteria based on feedback from industry. Under this proposal, prior assessment eligibility would expand to include assessment of DMFs that have not previously been reviewed in advance of the following types of ANDA submissions: planned ANDA submissions for which all patents and exclusivities will expire within 18

months of the planned submission date; planned PASs including reference to a DMF in which a new domestic API source is added; and planned submissions for complex APIs. FDA also proposed some limitations on the maximum number of submissions that would be accepted in certain categories to ensure FDA's ability to manage the workload. Specifically, and considering resource constraints, on an annual basis, FDA proposed to review a maximum of 12 PAS-referenced DMFs in which a new domestic API source is added, and a maximum of 10 complex APIs that are submitted in DMFs that have never had substantive review; Prior Assessment requests would be granted on a first-come basis. FDA also proposed changes to the timelines to allow for earlier IRs to be sent following a DMF prior assessment.

Industry asked clarifying questions regarding implementation of the limit on the number of submissions that would be accepted in certain categories, including how FDA could ensure equity across ANDA applicants, and provided some additional considerations. FDA stated they would be willing to consider changes to the proposed language.

Industry agreed to bring a response on this topic at a future date.

No agreements were made at this time.

Structured Review

FDA presented a response to industry's proposal for changes to certain procedural aspects of ANDA review.

Regarding filing timelines, FDA proposed that they would strive to make a receipt decision within 45 days of ANDA submission provided the applicant's timeline to respond to filing information requests was shortened from 10 to 7 calendar days. Industry expressed that 7 calendar days could be challenging to respond in the case of holidays and asked whether FDA would consider 7 business days. FDA indicated the agency would consider that. Industry asked whether IT improvements could help save FTE hours. FDA indicated potential IT improvements would be anticipated to help industry identify missing items before submitting their ANDAs but are not currently anticipated to meaningfully reduce FTE hours.

Regarding consults, FDA indicated that, as industry requested, the review team will begin their assessment as soon as the receipt determination is made, and will strive to promptly send necessary consults that can be identified based on a threshold review of the ANDA, with a request that consult responses be provided within a timeframe that allows for incorporation of issues identified in the consult response into the DRL. FDA also explained why it is not possible to identify all needed consults from a threshold review, including because some of the information that is the subject of consults is only submitted by applicants after IRs or DRLs are sent, and because the need for some consults can only be identified once assessors have the opportunity to substantively review relevant portions of the ANDA. Recognizing Industry's goal of making consults more efficient and timely, FDA

proposed developing draft guidance on good ANDA submission practices to allow for earlier consults. Industry agreed that a guidance could be helpful in this area but suggested that FDA also consider other methods of providing information that may allow for more regular updates, e.g., recurring training for industry or a website. FDA indicated it would consider this suggestion but noted that FDA's Good Guidance Practice regulations require that information constituting guidance under the regulations would need to be disseminated through formal agency guidance rather than through means such as website postings. FDA also explained that the controlled correspondence process could be leveraged pre-submission to aid Industry in identifying information to provide in original ANDA submissions to allow for earlier consults. Finally, FDA stated that it would not be willing to negotiate consult timeline reporting because this involves internal processes that are outside the scope of negotiations.

Regarding industry's proposal to provide for only a single 90-day goal date extension in situations addressed by section II.B.1.c.i of the GDUFA III commitment letter, FDA noted that the agency was open to this, but also explained why it believed this could result in more minor Complete Response letters (CRLs). As an alternative to industry's proposal, FDA proposed leaving the current process (under which multiple 90-day goal date extensions may occur) available as an option while also adding a provision that would provide for applicants to specify upon submission whether they are instead only amenable to a single 90-day goal date extension for that submission. Industry asked clarifying questions regarding how this alternative that would provide an opportunity for applicants to choose an option could be implemented and indicated they would consider FDA's proposal. Industry also asked FDA to consider whether the concern about an increase in minor CRLs could be addressed if the single 90-day extension was from the goal date instead of from the date of the applicant's response to the IR or DRL. FDA agreed to consider this.

Regarding Imminent Action (IA), FDA requested additional information on what specific questions industry has that they suggest be clarified in a MAPP or guidance under their proposal. Industry agreed to provide more information at a later date. With respect to industry's proposal to create a separate category for IA to be used when a facility's surveillance inspection is pending classification, FDA indicated that it believes the agency's separate proposal to address pOAI alerts is the better option for addressing this issue. Industry asked FDA to consider whether a 90-day extension from the goal date, with the use of IA if appropriate, could address pOAI alert issues as well.

Regarding missed goal dates, FDA proposed that the agency would assign a new goal date of six months after the missed goal date for original ANDAs if the goal date will be missed by more than 60 days, and highlighted that this will only result in a single new goal date (i.e., no subsequent new goal date will be applied if this goal date is missed). Industry asked if FDA would be willing to meet with applicants if the second goal date is missed, and FDA indicated that they would consider this and that it is consistent with current practice for

missed goal date ANDAs. In response to industry's requests related to reporting on missed goal date ANDAs, FDA proposed that the agency would report on the overall outcome of this second goal date. With respect to industry's request for more information about missed goal date ANDAs, FDA indicated that the agency would provide the applicant a description of the issue causing the agency to miss the goal by the goal date and also agreed to continue to work with the applicant to resolve other unrelated outstanding issues in the applicant's ANDA, including through the issuance of IRs. Industry asked whether a communication could be sent by the goal date outlining other unrelated outstanding issues to increase efficiencies by enabling applicants to continue working on these issues while the ANDA remains pending with FDA, and the agency indicated it would consider this.

Regarding labeling review, FDA agreed to complete an initial labeling review by the midpoint of the cycle and to issue a DRL with any labeling comments/deficiencies. FDA also agreed to generally provide labeling feedback in track changes for differences in the Prescribing Information and package labeling but noted that narrative descriptions would continue to be provided for carton/container labeling. FDA noted that when there are RLD labeling changes, FDA would aim to review revised labeling before the goal date when possible (depending on the timing of the RLD labeling update), and noted that if labeling is the only discipline pending, the agency would commit to reviewing revised labeling within 30 days of receipt. Industry expressed appreciation for the agreement to provide labeling comments in tracked changes and asked clarifying questions about the labeling review process.

Regarding industry's communications and transparency proposals, FDA indicated it was open to feedback on its standard format for communicating ANDA review status updates, and industry indicated it would provide examples of inconsistent approaches in FDA's current communications and illustrating what industry is seeking to change. With respect to industry's request for FDA to report some performance metrics separately for complex and non-complex generics, FDA agreed to report monthly and quarterly approval and tentative approval activities separately by complex vs. non-complex generics.

No agreements were made at this time.

Standardized Information for ANDA Submission

Industry presented a counterproposal to FDA's proposal to standardize certain information in ANDA submissions. Industry indicated they support efforts to improve review efficiency but suggested a change to the commitment letter is not warranted as these efficiency initiatives could be implemented at FDA's discretion. Industry asked questions regarding FTE savings and the process for implementing use of standard templates. FDA explained that the proposal is intended to make the ANDA process more efficient by aiding industry in providing more complete and readily identifiable information in their submissions, which can help reduce information requests and allow for identification of needed consults earlier and noted that this is expected to translate to faster time to approval but would not necessarily

translate to FTE savings. FDA also answered other process questions, including how FDA would approach outliers, and emphasized the value the agency sees in building a shared commitment around this.

No agreements were made at this time.

Postmarketing Commitments

FDA provided a response to industry's proposal to include a process for communications regarding postmarketing commitments (also called quality postmarket agreements (QPAs)) in the commitment letter and commit to revising relevant guidance. FDA noted that, from its perspective, industry's proposal did not address cases other than an urgent public health need (e.g., drug shortage, public health emergency) in which the benefit of the proposed generic product would outweigh the potential risks of an unresolved quality issue or obstacles to applying such an approach fairly given the competitive nature of the generics market. FDA stated that, in its view, industry's proposal is not consistent with application of the quality benefit-risk framework.

Industry explained that in its view, post-marketing commitments would be consistent with the quality benefit-risk framework and referenced the use of QPAs in other application types, including biosimilars, which have a similar benefit-risk framework, and asked questions. FDA noted differences across product types in potential benefits, particularly those offered by certain innovator products. Separate from the benefit-risk framework, FDA observed that while multiple ANDA applicants commonly submit applications for the same product on the same date, this has not occurred to-date for biosimilar applications. For example, FDA noted the concerns that could arise about treating similarly situated entities fairly if an applicant requested use of a QPA in lieu of providing certain information for their proposed drug product pre-approval when other applicants with pending ANDAs for the same drug product had provided that information pre-approval.

Industry agreed to no longer pursue this proposal.

Forfeiture Determinations and Timelines

FDA provided a response to industry's proposal for FDA to assess whether a first applicant has forfeited eligibility for 180-day exclusivity under the failure to obtain tentative approval forfeiture provision by 90 days after the 30-month period provided in statute for the first applicant to obtain tentative approval, and to post all forfeiture analyses (redacted for confidential commercial information) and provide other related information on the PIV Certifications List webpage.

FDA explained the important considerations informing the agency's current practice to make forfeiture decisions under the failure-to-obtain-tentative approval (FTOTA) provision only in the context of specific ANDAs that are otherwise eligible for approval, including the unreliability of earlier analyses given the constantly changing landscape. FDA also explained

that industry's proposal would require a substantial increase in resources for these activities and would divert resources from ANDA assessment activities. FDA also explained some resource- and disclosure-related considerations that could pose obstacles to aspects of industry's proposal related to posting more information about forfeiture analyses.

Industry explained that the information asymmetry in FTOTA determinations means subsequent applicants lack adequate information to effectively assess forfeiture. Industry acknowledged the resource concerns and asked whether FDA would consider conducting forfeiture analyses upon industry's request for a narrower subset of applications for which the forfeiture determination could minimize launch delays and expedite patient access, such as when there is a tentatively approved subsequent ANDA. FDA noted that if industry provides a counter proposal in this area the agency will consider it.

No agreements were made at this time.

Closing/Next Steps

FDA and industry discussed potentially increasing the frequency of meetings and agreed to go back and assess availability. FDA and industry determined who is responsible for next steps for topics discussed during this meeting.

NEXT MEETING

The next negotiation meeting is planned for Wednesday, March 4, 2026. The goal of that meeting will be to continue discussions on program efficiency, reducing number of review cycles, and finance proposals.