Generic Drug User Fee Amendments (GDUFA) Reauthorization

FDA-Industry Negotiation Meeting
March 11, 2026, 9:00am – 2:00pm
Virtual Meeting

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	Cornell Stamoran	PBOA (Catalent Pharma Solutions)
Malik Imam	CDER	Joel Carpenter	BPTF
Martha Nguyen	CDER		
Susan Rosencrance	CDER		
Ashley Boam	CDER		
Bhagwant Rege	CDER		
Derek Smith	CDER		
Rebecca Dowd	OII		
Ivy Sweeney	OII		
Angela Granum	OC		
Gisa Perez	OC		
Josh Brown	OC		
Mingham Ji	OC		

MEETING SUMMARY

Prioritization MAPP Commitment Letter (CL) Language

FDA presented proposed CL language outlining that FDA would revise the Prioritization MAPP to reflect previously agreed upon proposals. Industry asked if it could be documented that FDA agreed to provide data on this at the quarterly implementation meetings (QIM) and FDA indicated the meeting minutes outlining this would be available for reference. Industry re-raised previously expressed questions and concerns about how this proposal was in scope as in their view, certain Industry proposals were previously determined to be beyond the scope of GDUFA negotiations. Industry also explained that this proposal could be considered to set a precedent for future negotiations. FDA again explained why the agency

considered this proposal to be in scope but indicated that the agency would pull this proposal from negotiations as the repeatedly raised issues around scope were becoming a distraction to negotiations. Following this discussion, Industry clarified that they were not objecting to the draft commitment letter language nor was Industry recommending removal of the proposal. FDA reiterated that, considering the continued issues raised regarding scope, the agency was removing this proposal from negotiations. The agency also noted that the onshoring prioritization pilot remained available to industry and that FDA would consider the feedback provided by industry during negotiations over this proposal in shaping any future version of the pilot. Industry reiterated its appreciation for the progress made on this proposal to date as well as the importance of onshoring, ultimately recommending that the proposed language be retained in the CL.

Classification of REMS Deficiencies

Industry shared concerns around delays in generic approvals as a result of issues encountered when generic applicants are working with the RLD holder to form or join shared system REMS, including late REMS modifications, and asked whether there are tools that industry can work with FDA to use to prevent brand drug REMS modifications from slowing down generic drug approvals. Industry cited an ongoing GAO study on REMS that could provide recommendations on this topic. FDA acknowledged Industry's concerns and indicated it would continue to work with Industry to avoid delays caused by REMS for generic applications, but outside of the negotiation process.

Industry agreed to no longer pursue their proposal on this topic.

Controlled Correspondence

Industry shared their perspective on the types of controlled correspondence that could be addressed on a proposed 90-day timeline. FDA indicated that some of the categories industry presented are currently typically responded to under a 60-day timeline. Industry clarified that they were not seeking to move any level 1 control to the proposed 90-day timeline and shared that they have seen inconsistencies in timelines for those types of inquiries. FDA indicated that typically these are addressed as level 1 controls on a 60-day timeline but that some could be level 2 controls on a 120-day timeline if they called for consultations with multiple disciplines, consistent with current guidance.

FDA also indicated that one of these categories of requests would be better addressed in a meeting and had been incorporated into the meeting structure proposal. Industry acknowledged FDA's response but expressed concerns that there may be circumstances in which FDA converts those meeting requests into a controlled correspondence with a longer timeframe, undermining necessary predictability. FDA indicated they could explore language to indicate that if FDA determined a meeting was not necessary the agency would provide a written response only under the same timeline as applies to the meeting request instead of converting the meeting request to a controlled correspondence.

FDA indicated internal discussions would be needed on the remaining types of controls industry was proposing for a 90-day timeline. Industry also indicated they would have additional internal discussion on this.

Meetings Commitment Letter Language

FDA provided two counter proposals for language related to meeting format conversions in response to language industry had earlier provided. Industry indicated their preference among the two options presented and FDA agreed. FDA also provided a counter proposal for language related to "novel" issues in response to language industry had previously provided. Industry asked whether FDA would be willing to include additional text to put guardrails around the meetings that would be on a longer timeframe and provided some alternative suggested text. FDA indicated no concerns with the alternative text. FDA also noted the agency would draft CL language to capture the other agreed upon goals around meetings.

Industry also indicated their view that the changes being made related to the GDUFA meeting framework in these negotiations would necessitate revisions to the guidance on this topic, and suggested a commitment be drafted around the timeframe for revising the guidance.

Structured Review

Industry provided a response to FDA's counter on the structured review proposal. Industry indicated they prefer to keep the 60-day filing timeline so that industry can maintain the 10-day response timeline for filing information requests (IRs).

Industry indicated several aspects of the proposal they would like to be captured in the commitment letter. FDA agreed and indicated they would draft language to share at an upcoming meeting.

Industry indicated they are interested in adding guardrails around when IRs can result in a goal date extension. FDA indicated this seems to be a new proposal and it would not be possible to outline the universe of scenarios where this could be appropriate to include in the commitment letter. Industry indicated it was not meant to be new, referencing its initial Structured Review proposal, and explained they were seeking to include more general guardrails around when FDA may extend the goal date to limit the use of extensions. FDA indicated it would consider language.

Industry asked if imminent action (IA) can be used for pOAI alerts (together with a 90-day goal date extension). FDA explained that IA could not be used unless the final facility classification was available and indicated the classification was VAI or NAI, as IA is only used when in FDA's judgment it may be possible to approve or tentatively approve the ANDA, limiting the ability to use IA if the pOAI alert occurs when the 90-day goal date extension has already been taken and the classification status is not yet resolved at the end of this extension. Industry indicated they would discuss this.

Industry indicated they are largely aligned with FDA's proposal for a second goal date 6 months after a missed goal date but indicated it would be helpful to have information on deficiencies that are unrelated to the issue causing the goal date to be missed by the goal date. FDA indicated this was generally possible for some deficiencies but posed issues for deficiencies that would be the basis of a Complete Response letter, and that FDA would not be able to review a response to any such deficiencies within the current review cycle. Industry explained that their objective was for FDA to provide this information to applicants so applicants could begin the work to address these deficiencies while the ANDA was pending past the goal date and suggested language could be included in the CL to clarify this. FDA indicated they would consider this.

Industry provided additional clarity for how the discipline assessments could be broken out in the review status update. FDA noted that some of the listed areas were not assessment disciplines and indicated the agency would provide a revised response.

Industry indicated alignment on the complex and non-complex reporting metrics proposed by FDA.

FDA indicated they would propose CL language that reflects the agreed-upon areas of the structured review proposal.

Drug Master Files (DMFs)

In response to a previously-presented FDA counter-proposal on DMF review prior to ANDA submission for which there was a question pending with industry on whether industry would prefer a shorter review timeframe for one category of DMFs or would prefer a higher cap on the number of prior assessment requests that would be considered under the category, Industry noted that after discussing internally they prefer the shorter timeframe to better align with development timelines. Industry asked FDA to consider what impact that would have on the cap. FDA noted they would consider this and provide further information at a future meeting.

Closing

FDA and industry confirmed topics to be discussed at the next meeting.

NEXT MEETING

The next meeting is scheduled for Friday, March 13 and the goal will be to continue discussion on proposals related to improving program efficiency and increasing first cycle approvals.