



## **Generic Drug User Fee Amendments (GDUFA) Reauthorization**

### **FDA-Industry Negotiation Meeting**

**December 10, 2025, 10:00am – 2:00pm**

**Hybrid Meeting | FDA White Oak Campus, Silver Spring, MD**

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#### **PURPOSE**

To continue negotiations 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
Erin Skoda	CDER
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
Beth Mihalek	BPTF (Veranova)
Kristen Pierpoint	BPTF (Curia Global)
Brant Zell	BPTF (AmbioPharm)

#### **MEETING SUMMARY**

##### **Drug Master Files (DMF)**

Both FDA and industry presented proposals related to DMFs. FDA proposed changes to the DMF Prior Assessment process including use of a fillable cover letter template and FDA Form 3938 to request a prior assessment and a shortened timeline to complete assessments to give industry more time to submit requests.

Industry proposed further modifications including expansion of the DMF prior assessment eligibility criteria as well as a more structured timeline.

FDA and industry asked clarifying questions, and industry noted that it looks forward to aligning the expansion concepts.

No agreements were made at this time.

### **Current Good Manufacturing Practice (cGMP) Compliance Communication Tools**

Industry presented two proposals to make information on current CGMP status available to finished dosage form purchasing agents for domestic sites that have not been recently inspected because they have not been prioritized for inspection low-risk under FDA's risk-based inspection site selection model. The first proposal would provide a mechanism for a manufacturer to request a surveillance inspection when there are no new generic products to be manufactured at that facility (i.e., no ANDAs under review) and the second proposal was related to FDA providing close out documentation to the facility when it conducts non-inspection CGMP assessments (e.g., Remote Regulatory Assessments).

FDA asked clarifying questions.

No agreements were made at this time.

### **Standardize Information in ANDA Submissions**

FDA presented a proposal to standardize information in four areas of ANDA submissions to improve reviewers' ability to quickly identify issues during review and increase the possibility of machine readability. FDA also proposed providing guidance on Clinical Data Interchange Standards Consortium (CDISC) implementation to help industry understand the optimal way to submit data from ANDA bioequivalence studies.

Industry asked clarifying questions.

No agreements were made at this time.

### **Closing**

FDA and industry summarized the proposals presented during this meeting and confirmed that no agreements were made.

FDA reported that a stakeholder meeting occurred on December 9 and will summarize and present feedback to industry at a later date.

### **NEXT MEETING**

The next negotiation meeting is planned for Wednesday, December 17, 2025. The goal of the meeting will be to discuss details of proposals relating to revenue.