U.S. FOOD & DRUG ADMINISTRATION

FDA and Industry GDUFA III Implementation Quarterly Meetings – 2Qtr 2025 Meeting
June 4, 2025, 1:00 PM – 3:00 PM
White Oak Campus and Virtual Zoom Meeting

Agenda

- Industry Topics
    1. Current state of OGD and work impacted due to RIFs (e.g., PSGs)
    2. Nitrosamines
    3. AI pilot and impact/alignment with other tools currently in place (e.g., KASA and GDSA-BE)
    4. GDUFA logistics and QIMs going forward
- FDA Topics
    1. Late cycle IRs

Participants

FDA Participant	Center	Industry Participant	Affiliation
Jacqueline Corrigan-Curay	CDER/OCD	Giuseppe Randazzo	AAM
Dat Doan	CDER/OMP	Joel Carpenter	BPTF
Carter Beach	CDER/OCD	Gil Roth	PBOA
Ashley Boam	CDER/OPQ	Brian McCormick	AAM (Teva)
Ivy Sweeney	OII/OHADI	Kiran Krishnan	AAM (Apotex)
Kathleen Davies	CDER/OCD	Scott Kuzner	AAM
Kristin Davis	CDER/OGD	Rebecca Alcantara	BPTF
Kim Dettelbach	OCC	Jeff Robinson	BPTF
Francis Godwin	CDER/OC		
Michael Kopcha	CDER/OPQ		
Iilun Murphy	CDER/OGD		
Kendra Stewart	CDER/OGD		
Anastazjia Ray	CDER/OSP	-	-
Susan Rosencrance	CDER/OPQ	-	-
Malik Imam	CDER/OGD	-	-
Kim Taylor	CDER/OSP	-	-

Industry Topics

Industry posed questions to FDA related to current implementation activities.

1. Current state of OGD and work impacted due to RIFs (e.g., PSGs)

   Industry inquired about how RIFs have affected FDA and the generic drug program. FDA noted that we continue to move applications along.

2. Nitrosamines

   Industry noted challenges with meeting the August 2025 deadline regarding nitrosamines. FDA noted that this topic is not within scope of GDUFA implementation but that the Agency will consider the feedback provided by industry and understands the importance of this issue.

3. AI pilot and impact/alignment with other tools currently in place (e.g., KASA and GDSA-BE)

   Industry inquired on the use of AI in ANDA reviews and FDA indicated it is continuing to look at the use of AI for reviews, including to see how systems can interact with one another to improve efficiency.

4. GDUFA logistics and QIMs going forward

   Industry and FDA discussed planning related to upcoming GDUFA IV Negotiations.

FDA Topics

1. Late cycle IRs

   FDA provided information on how often goal dates are extended following responses to late cycle IRs.

Action Items*

1. Industry will provide names of negotiators by end of the week.
2. Industry will provide name of speaker(s) for July public meeting by the end of the week.
3. Industry will provide prioritization of data call questions by the end of the week.

*All action items were received as of June 6, 2025.