**FDA and Industry GDUFA III Implementation Quarterly Meetings – 1Qtr 2025 Meeting**
**February 26, 2025, 1:00 PM – 3:00 PM**
**White Oak Campus and Virtual Zoom Meeting**

**Agenda**

- Industry Topics
  - ❖ Current State of the Pilot Program
  - ❖ Goal Date Assignment and Revisions
  - ❖ Major CRs and Impacts to Goal Dates
  - ❖ Labeling Reviews and Avoiding Goal Extensions
  - ❖ Trends in the Timing of DRLs
  - ❖ Clarification of Goal Date Changes with Late-Cycle IRs
  - ❖ GDUFA IV Planning
- FDA Topics
  - ❖ Trend in Original Submissions

**Participants**

| FDA Participant | Center | Industry Participant | Affiliation |
|---|---|---|---|
| Jacqueline Corrigan-Curay | CDER/OCD | Giuseppe Randazzo | AAM |
| Tiana Barnes | CDER/OEP | Joel Carpenter | BPTF |
| Carter Beach | CDER/OEP | Gil Roth | PBOA |
| Ashley Boam | CDER/OPQ | Brian McCormick | AAM (Teva) |
| Alonza Cruse | 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 | Cornell Stamoran | PBOA (Catalent) |
| Michael Kopcha | CDER/OPQ | | |
| Iilun Murphy | CDER/OGD | | |
| Anastazjia Ray | CDER/OSP | - | - |
| Susan Rosencrance | CDER/OPQ | - | - |
| Edward Sherwood | CDER/OGD | - | - |
| Kim Taylor | CDER/OSP | - | - |

**Industry Topics**

Industry posed questions to FDA related to current implementation activities.

*Current State of the Pilot Program*

Industry inquired about the status of pilot program launched by FDA to increase transparency around ANDAs that are past the goal date. FDA provided information on the pilot, including the generally positive feedback the Agency has received about it.

*Goal Date Assignment and Revisions*
Industry discussed receiving two goal dates after the issuance of a major amendment (one that would apply if no inspection is needed and the other that would apply if an inspection is needed), and asked about FDA's practice for determining the ultimate goal date if a response to an information request is received within three months of the earlier goal date. FDA explained that if an applicant responds to minor deficiencies in an information request, FDA may extend the goal date by 90 days from date of that response.

*Major CRs and Impacts to Goal Dates*
Industry inquired about cases where a surveillance inspection of a facility coincides with an ANDA under review, occurring close to the ANDA goal date. In these situations, the compliance determination may extend beyond the goal date due to time constraints. Industry asked whether the goal date could be extended to finalize the compliance determination before issuing the ANDA action. Further details will be provided in a follow-up submission.

*Labeling Reviews and Avoiding Goal Extensions*
Industry inquired on the timing of labeling reviews and if FDA is observing an increase in CRLs that contain only labeling deficiencies. FDA indicated that the Agency very rarely issues labeling only CRLs, and instead generally works with applicants through the imminent action process if late labeling issues arise.

*Trends in the Timing of DRLs*
Industry questioned if FDA is observing that DRLs are being sent later in the review cycle to applicants than in past years. FDA stated there was no marked change in trends in the timing of DRL issuance between FY2021 and FY2024.

*Clarification of Goal Date Changes with Late-Cycle IRs*
Industry asked FDA to clarify the process and practice of extending the goal date when Industry responds to late-cycle IRs in a timely manner. FDA explained factors it considers in determining whether the goal date will be extended and indicated it could provide more information if Industry wished to provide specific examples.

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

**FDA Topics**
FDA posed questions to Industry related to current implementation activities.

*Trend in Original Submissions*
FDA inquired on the recent downward trend in original submissions from Industry, and Industry indicated it would take this issue to its members to get further information.