FDA and Industry GDUFA III Implementation Quarterly Meetings – 1Qtr 2024 Meeting
January 18, 2024, 2:00 PM – 4:00 PM
Virtual Zoom Meeting

Agenda

- Industry Inquiries
  - ❖ PLAIR Pilot Process
  - ❖ Facility Reclassification Evaluations and Process
  - ❖ OPQ Reorganization
  - ❖ Missed GDUFA Goal Dates
  - ❖ Update on State of Foreign Inspections

Participants

FDA:		Industry:	
Tiana Barnes	CDER	Joel Carpenter	BPTF
Carter Beach	CDER	David Gaugh	AAM
Ashley Boam	CDER	Kiran Krishnan	AAM (Apotex)
Jacqueline Corrigan-Curay	CDER	Scott Kuzner	AAM
Alonza Cruse	ORA	Brian McCormick	AAM (Teva)
Kristin Davis	CDER	Giuseppe Randazzo	AAM
Francis Godwin	CDER	Jeff Robinson	SKPharmTeco (BPTF)
Michael Kopcha	CDER	Gil Roth	PBOA
Iilun Murphy	CDER		
Susan Rosencrance	CDER		
Edward Sherwood	CDER		

Industry Inquiries on Implementation
Industry and FDA discussed several topics relating to current implementation activities.

PLAIR Pilot Process
Industry posed questions regarding the disparity in FDA response time to a PLAIR under the new process. FDA explained the pilot process of delaying decisions in the "major" space if a decision is expected soon, while implementing a default grant decision in the "minor" space, absent an identified issue. Industry noted the new process as a positive one.

Facility Reclassification Evaluations and Process
FDA noted among the accepted requests for reclassification, 95% received response on time. Industry acknowledged the January 2024 MAPP on this process to address instances when the applicant requests to withdraw the facility in question.

OPQ Reorganization
FDA provided an overview of the OPQ reorganization, effective January 14, 2024.

Missed GDUFA Goal Dates

Industry expressed a desire for increased transparency around missed GDUFA goal dates. FDA explained that it is our practice to share what information we can about potential issues delaying action on an ANDA, but that there can be limitations on what we can disclose while we are internally deliberating an issue.

Update on State of Foreign Inspections

FDA is working aggressively to conduct foreign inspections more efficiently. Foreign inspection numbers are currently trending higher than this time last year.