FDA and Industry GDUFA III Implementation Quarterly Meetings – 4Qtr 2024 Meeting
November 1, 2024, 1:00 PM – 3:00 PM
White Oak Campus and Virtual Zoom Meeting

Participants

FDA Participant	Center	Industry Participant	Affiliation
Tiana Barnes	CDER	David Gaugh	AAM
Carter Beach	CDER	Kiran Krishnan	AAM (Apotex)
Ashley Boam	CDER	Brian McCormick	AAM (Teva)
Alonza Cruse	OII	John Murphy	AAM
Kathleen Davies	CDER	Giuseppe Randazzo	AAM
Kristin Davis	CDER	Gil Roth	PBOA
Kim Dettelbach	OCC	Cornell Stamoran	PBOA (Catalent)
Edwin Echegoyen	CDER	Molly Ventrelli	AAM (Fresenius-Kabi)
Francis Godwin	CDER	Brant Zell	BPTF (AmbioPharm)
Michael Kopcha	CDER	-	-
Iilun Murphy	CDER	-	-
Susan Rosencrance	CDER	-	-
Edward Sherwood	CDER	-	-

AAM Introduction of new CEO
John Murphy introduced himself to the participants, discussed his background, and plans to participate in User Fee discussions.

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

Status of cGMP Inspections in China
Industry inquired about the status of CGMP inspections in China. FDA noted the increase in API inspections in recent years, noting substantial resources have been allocated to inspections in China and India. FDA has made a significant push in hiring to offset attrition and is working to improve training time for independent inspections.

Domestic Inspection Frequency
Industry discussed that the interval between inspections of domestic US facilities can sometimes lead to delays in action on applications for approval in other jurisdictions because certain foreign regulatory agencies who rely on those inspections expect more frequent inspections. FDA explained that it applies its risk-based framework to its inspections.

GDUFA Budget for Rent
Industry introduced this budget topic in anticipation of the upcoming data call prior to the next

round of negotiations. Industry made FDA aware of several data points around the budget they plan to inquire about.

GDUFA IV Process and Timing
Industry inquired on the timing and logistics of GDUFA IV negotiations. FDA discussed timing similar to the last round of negotiations, with a preference for in-person meetings and a hybrid option, if necessary.

FDA Topics
FDA provided updates and posed questions to Industry related to current implementation activities.

Transparency on Goal Dates
FDA has developed a pilot, which will run for six months, to address Industry's request around increased transparency on ANDAs past the goal date. The scope includes ANDAs that have missed or will miss a goal date by more than 60 days. FDA has requested feedback from Industry and member companies on whether they find the pilot helpful.

Labeling
FDA discussed Labeling assessments and the provisions related to this in the current commitment letter and industry raised some potential communication ideas.

Early DMF Assessment
FDA noted minimal use by Industry of the early DMF Assessment program. Industry discussed that the scope of the current program may limit applicability.

Shift in Applications
FDA discussed how we have seen a shift with more applications pending with Industry awaiting applicant action than pending with FDA. Industry noted some potential reasons for this and also asked for more information, including what cycle these applications are in.