

FDA-Industry GDUFA Reauthorization Meeting
November 19, 2020, 10:00 am – 1:00 pm
Virtual Meeting

Purpose

To continue negotiations to reauthorize GDUFA (GDUFA III).

Participants

FDA

Ozan Aygun	CDER
Carter Beach	CDER
Donald Beers	OC/OCC
Lisa Berry	CDER
Ashley Boam	CDER
Joshua Brown	OC/OCC
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Robert Lionberger	CDER
Susan Rosencrance	CDER
Bethany Rue	CDER
Edward Sherwood	CDER
Maryll Toufanian	CDER

Industry

John DiLoreto	BPTF
David Gaugh	AAM
Karin Hessler	AAM
Kiran Krishnan	AAM (Apotex)
Lisa Parks	AAM
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent)
Scott Tomsky	AAM (Teva)
Molly Ventrelli	AAM (Fresenius-Kabi)
Brant Zell	BPTF (AmbioPharm)

FDA Supporting Staff

Tiana Barnes, Dat Doan, Andrew Fine, Tawni Schwemer, Scott Vehovic

Discussion

Industry and FDA continued to discuss the pre-submission facility correspondence program and imminent actions, as well as classifications of major amendments. Discussions continued on transparency and communication enhancements.

A significant portion of this session was dedicated to addressing Industry's questions around resource capacity planning, potential adjustment to operating reserve levels, alternative methods for calculating inflation to accurately account for program costs, and a pending limitation on allowable fee expenditures.

Next Meeting

Due to the upcoming holiday, the next negotiation meeting is planned for Thursday, December 3, 2020.