

FDA-Industry GDUFA Reauthorization Meeting
November 12, 2020, 10:00 am – 3:00 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)
Beth Walls	BPTF (MilliporeSigma)

FDA Supporting Staff

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

Discussion

Industry and FDA continued discussions on advancing toward finalization the proposals to facilitate earlier approvals. FDA introduced a new set of proposals intended to set a sound foundation for continued programmatic success. These proposals focus on how to best predict resource needs for GDUFA III using data-driven models and time reporting. The Agency also discussed the importance of maintaining sufficient operating reserves to enable continuity of operations. Finally, there was discussion of how inflation adjustments may need to be tailored to the program.

Next Meeting

The next negotiation meeting is planned for Thursday, November 19, 2020.