FDA-Industry GDUFA Reauthorization Meeting
December 3, 2020, 10:00 am – 3:00 pm
Virtual Meeting

Purpose
To continue negotiations to reauthorize GDUFA (GDUFA III).

Participants

FDA		Industry	
Ozan Aygun	CDER	John DiLoreto	BPTF
Carter Beach	CDER	David Gaugh	AAM
Donald Beers	OC/OCC	Kiran Krishnan	AAM (Apotex)
Lisa Berry	CDER	Lisa Parks	AAM
Ashley Boam	CDER	Gil Roth	PBOA
Joshua Brown	OC/OCC	Cornell Stamoran	PBOA (Catalent)
Jacqueline Corrigan-Curay	CDER	Scott Tomsky	AAM (Teva)
Alonza Cruse	ORA	Molly Ventrelli	AAM (Fresenius-Kabi)
Robert Lionberger	CDER		
Susan Rosencrance	CDER		
Bethany Rue	CDER		
Edward Sherwood	CDER		
Maryll Toufanian	CDER		
Benjamin Walworth	CDER		

FDA Supporting Staff
Tiana Barnes, Dat Doan, Andrew Fine, Tawni Schwemer, Scott Vehovic

Discussion

FDA and Industry continued discussions on advancing earlier approvals and the Pre-submission Facility Correspondence (PFC) program.

FDA described how the foundation for a capacity planning adjustment (CPA) methodology was developed during GDUFA II and how the proposed CPA methodology could continue to be developed and refined. FDA explained how the CPA methodology can be used to translate the predicted ANDA original and ANDA original amendment submissions into full-time equivalent (FTE) needs.

FDA provided more information regarding the inflation adjustment proposal, to more accurately account for program costs, as well as the proposed operating reserve adjustment and the proposed elimination of a limitation on allowable fee expenditures.

Industry will consider these further details and provide the Agency with further questions to continue discussions around these issues in an upcoming session.

Next Meeting
The next negotiation meeting is planned for Thursday, December 10, 2020.