FDA-Industry GDUFA Reauthorization Meeting
October 15, 2020, 10:00 am – 3:00 pm
Virtual Meeting

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

Participants

FDA		Industry	
Carter Beach	CDER	John DiLoreto	BPTF
Donald Beers	OC/OCC	David Gaugh	AAM
Ashley Boam	CDER	Karin Hessler	AAM
Joshua Brown	OC/OCC	Kiran Krishnan	AAM (Apotex)
Jacqueline Corrigan-Curay	CDER	Lisa Parks	AAM
Alonza Cruse	ORA	Gil Roth	PBOA
Robert Lionberger	CDER	Cornell Stamoran	PBOA (Catalent)
CDR Mahesh Ramanadham	CDER	Scott Tomsky	AAM (Teva)
Susan Rosencrance	CDER	Molly Ventrelli	AAM (Fresenius-Kabi)
Edward Sherwood	CDER	Beth Walls	BPTF (MilliporeSigma)
Maryll Toufanian	CDER	Brant Zell	BPTF (AmbioPharm)

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

Discussion
FDA and Industry spent the day clarifying the proposals to advance earlier approvals of generic applications. Considerable time was spent on the pre-submission facility correspondence program to ensure FDA and Industry gained a better understanding of the current program, how the information submitted enables FDA to make a determination of whether or not an inspection is needed, and which information is most critical and Industry's challenges with meeting these needs. FDA and Industry had a productive discussion and will continue fleshing out the details, opportunities and challenges with these proposals at the next meeting.

Next Meeting
The next negotiation meeting is planned for Thursday, October 22, 2020.