FDA-Industry GDUFA Reauthorization Meeting
October 1, 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)
Susan Rosencrance	CDER	Scott Tomsky	AAM (Teva)
Edward Sherwood	CDER	Thomas Thorpe	PBOA (Afton Scientific)
Maryll Toufanian	CDER	Molly Ventrelli	AAM (Fresnius-Kabi)
		Brant Zell	BPTF (AmbioPharm)

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

Discussion
FDA and Industry shared proposals to advance earlier approvals of generic applications. Industry focused on proposals around the pre-submission of facility correspondence program, transparency and communication enhancements, and greater use of the information requests and other communications to move an application to approval in a single cycle. FDA focused on applications that are ready for assessment, timely responses to complete response letters raising minor issues, opportunities for more efficient review of amendments submitted in response to facility deficiencies, the pre-submission of facility correspondence program, applications with data reliability issues, and drug master files. FDA and Industry discussed the opportunities and challenges around the proposals, asked clarifying questions, and committed to continuing the discussion at the next negotiation meeting.

Next Meeting
The next negotiation meeting is planned for Thursday, October 15, 2020.