FDA-Industry GDUFA Reauthorization Meeting
March 25, 2021, 10:00 am – 11:45 am
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	Brian McCormick	AAM (Teva)
Jacqueline Corrigan-Curay	CDER	Lisa Parks	AAM
Alonza Cruse	ORA	Gil Roth	PBOA
Robert Lionberger	CDER	Cornell Stamoran	PBOA (Catalent)
Susan Rosencrance	CDER	Molly Ventrelli	AAM (Fresenius-Kabi)
David Skanchy	CDER		
Edward Sherwood	CDER		
Maryll Toufanian	CDER		

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

Discussion

FDA and Industry continued clarifying discussions around a few of the shared proposals related to drug master files (DMFs), including potential outreach on considerations for the timing of unsolicited DMF amendments.

FDA also proposed changes to streamline annual reporting commitments while maintaining key and meaningful categories of interest for Industry.

FDA also discussed the role of inspections in meeting the requirements for a complete review under GDUFA and the impact of current restrictions on travel in meeting these requirements. A complete review is required to meet a goal date.

Industry provided initial thoughts on FDA's resource needs proposals.

Next Meeting

The next negotiation meeting will be Thursday, April 1, 2021.