

FDA-Industry GDUFA Reauthorization Meeting
March 11, 2021, 10:00 am – 1:00 pm
Virtual Meeting

Purpose

To continue negotiations to reauthorize GDUFA (GDUFA III).

Participants

FDA

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
David Skanchy	CDER
Edward Sherwood	CDER
Maryll Toufanian	CDER

Industry

John DiLoreto	BPTF
David Gaugh	AAM
Karin Hessler	AAM
Kiran Krishnan	AAM (Apotex)
Brian McCormick	AAM (Teva)
Lisa Parks	AAM
Gil Roth	PBOA
Molly Ventrelli	AAM (Fresenius-Kabi)
Beth Walls	BPTF (MilliporeSigma)
Brandt Zell	BPTF (AmbioPharm)

FDA Supporting Staff

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

Discussion

FDA and Industry discussed inspection proposals and taking into account business days when setting certain goal dates for responses. The goal dates will continue to be in calendar days.

Industry shared proposals around drug master files (DMFs) and provided initial thoughts on FDA's DMF proposals that were previously shared.

Next Meeting

The next negotiation meeting will be Thursday, March 18, 2021.