

FDA-Industry GDUFA Reauthorization Meeting
March 18, 2021, 10:00 am – 1:15 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
Bethany Rue	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
Cornell Stamoran	PBOA (Catalent)
Molly Ventrelli	AAM (Fresenius-Kabi)
Brandt Zell	BPTF (AmbioPharm)

FDA Supporting Staff

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

Discussion

FDA presented further clarifying information around the set of proposals intended to set a sound foundation for continued programmatic success, including how a capacity planning adjuster (CPA) could work in GDUFA III to support the program and Industry's needs.

FDA and Industry continued clarifying discussions around the shared proposals related to drug master files (DMFs).

Next Meeting

The next negotiation meeting will be Thursday, March 25, 2021.