

FDA-Industry GDUFA Reauthorization Meeting
January 14, 2021, 10:00 am – 2:00 pm
Virtual Meeting

Purpose

To continue negotiations to reauthorize GDUFA (GDUFA III).

Participants

FDA

Carter Beach	CDER
Donald Beers	OC/OCC
Ashley Boam	CDER
Joshua Brown	OC/OCC
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Francis Godwin	CDER
Robert Lionberger	CDER
Susan Rosencrance	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
Cornell Stamoran	PBOA (Catalent)
Molly Ventrelli	AAM (Fresenius-Kabi)
Beth Walls	BPTF (MilleporeSigma)
Brant Zell	BPTF (AmbioPharm)

FDA Supporting Staff

Tiana Barnes, Dat Doan, Andrew Fine, Tawni Schwemer

Discussion

Industry introduced a set of proposals around inspections, including follow-up activities after FDA has issued a final classification letter.

FDA agreed to harmonize some technical terminology related to the mid-cycle discipline review letters.

Next Meeting

The next negotiation meeting is planned for Thursday, January 21, 2021.