

FDA-Industry GDUFA Reauthorization Meeting
February 25, 2021, 10:00 am – 12:00 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
Kennerly Chapman	CDER
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
Brian McCormick	AAM (Teva)
Lisa Parks	AAM
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent)
Molly Ventrelli	AAM (Fresenius-Kabi)

FDA Supporting Staff

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

Discussion

FDA and Industry continued to discuss inspection proposals and taking into account business days when setting calendar day goal dates for certain responses.

Next Meeting

The next negotiation meeting will either be Thursday March 4, 2021 or Thursday, March 11, 2021.