

FDA-Industry GDUFA Reauthorization Meeting
July 8, 2021, 10:00 am – 10:45 am
Virtual Meeting

Purpose

To continue negotiations to reauthorize GDUFA (GDUFA III).

Participants

FDA

Carter Beach	CDER
Donald Beers	OC/OCC
Ashley Boam	CDER
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Susan Rosencrance	CDER
Bethany Rue	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)

FDA Supporting Staff

Dat Doan, Andrew Fine, and Tawni Schwemer

Discussion

FDA and Industry continued discussions around a proposal for suitability petitions.

Next Meeting

The next negotiation meeting is tentatively scheduled for next Thursday, July 15, 2021.