

FDA-Industry GDUFA Reauthorization Meeting
August 26, 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
Joshua Brown	OC/OCC
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Robert Lionberger	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
Molly Ventrelli	AAM (Fresenius-Kabi)

FDA Supporting Staff

Tiana Barnes, Dat Doan, Tawni Schwemer, and Scott Vehovic

Discussion

FDA and Industry met to continue working toward agreement on the Draft Commitment Letter. FDA agreed to make additional edits as discussed and provide a revised Draft Commitment Letter to Industry. FDA and Industry anticipate that no further negotiation meetings will be necessary to resolve the remaining edits.

Next Meeting

No further negotiations are planned.