

FDA-Industry GDUFA Reauthorization Meeting
July 29, 2021, 10:00 am – 11:45 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
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, and Tawni Schwemer

Discussion

FDA acknowledged that FDA and Industry have come to an initial agreement regarding allocation of revenues among fee categories and will continue to work toward an initial overall agreement as well as an initial agreement on the Commitment Letter.

FDA and Industry met to discuss the draft Commitment Letter.

Next Meeting

If needed, FDA and Industry may meet again to make further revisions to the draft Commitment Letter. Any further meeting(s) are to be determined.