

FDA-Industry GDUFA Reauthorization Meeting
August 12, 2021, 10:00 am – 1:00 pm
Virtual Meeting

Purpose

To continue negotiations to reauthorize GDUFA (GDUFA III).

Participants

FDA

Carter Beach	CDER
Donald Beers	OC/OCC
Lisa Berry	CDER
Ashley Boam	CDER
Joshua Brown	OC/OCC
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Robert Lionberger	CDER
Bethany Rue	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

FDA Supporting Staff

Tiana Barnes and Dat Doan

Discussion

FDA and Industry met to continue working toward agreement on the Draft Commitment Letter and other components of the package.

Next Meeting

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