

FDA-Industry GDUFA Reauthorization Meeting
June 3, 2021, 10:00 am – 2:00 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
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Robert Lionberger	CDER
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
Tom Thorpe	PBOA (Afton Scientific)
Molly Ventrelli	AAM (Fresenius-Kabi)

FDA Supporting Staff

Tiana Barnes, Dat Doan, Tawni Schwemer, Scott Vehovic

Discussion

Industry members provided thoughts on the proposals for setting a sound foundation for continued programmatic success.

FDA and Industry continued discussions and clarifications around the complex generic proposals that primarily consist of enhancing meeting options.

FDA presented a few proposals on ANDAs that miss a goal date which include creating transparency around senior management awareness and an annual reporting option.

Next Meeting

The next negotiation meeting will be Thursday, June 10, 2021.