

FDA-Industry GDUFA Reauthorization Meeting
April 15, 2021, 10:00 am – 3:00 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
Susan Rosencrance	CDER
Bethany Rue	CDER
Edward Sherwood	CDER
Maryll Toufanian	CDER

Industry

John DiLoreto	BPTF
David Gaugh	AAM
Karin Hessler	AAM
Kirin 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

Tiana Barnes, Dat Doan, Andrew Fine, Tawni Schwemer, Scott Vehovic

Discussion

FDA and Industry continued clarifying information around the proposals for setting a sound foundation for continued programmatic success, drug master files, criteria for a complete response when an inspection is not feasible due to a public health emergency or restrictions on travel and streamlining reporting requirements.

Industry presented a new set of proposals around process improvements to increase earlier approvals of complex products.

Next Meeting

The next negotiation meeting will be Thursday, April 22, 2021.