

FDA-Industry GDUFA Reauthorization Meeting
April 22, 2021, 10:00 am – 11:30 am
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
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
Kiran 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 presented a final set of slides clarifying the proposals for setting a sound foundation for maintaining programmatic success and continued clarifying proposals around inspections and streamlining annual reporting requirements. Industry and FDA agreed to not move forward with the Site Engagement Program. In addition, FDA discussed with Industry the Inactive Ingredient Data base.

Next Meeting

The next negotiation meeting will be Thursday, May 6, 2021.