

**FDA-Industry GDUFA Reauthorization Meeting**  
**January 28, 2021, 10:00 am – 1:00 pm**  
**Virtual Meeting**

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**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
Francis Godwin	CDER
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
Cornell Stamoran	PBOA (Catalant)
Molly Ventrelli	AAM (Fresenius-Kabi)
Beth Walls	BPTF (MilliporeSigma)
Brant Zell	BPTF (AmbioPharm)

FDA Supporting Staff

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

**Discussion**

Industry and FDA spent the session clarifying positions around the proposals to set a sound foundation for continued programmatic success, inspections, and Controlled Correspondence proposals. FDA and Industry also discussed the limitation of allowable GDUFA expenses that under FDARA Section 905 will take effect on October 1, 2023 and FDA highlighted the anticipated adverse impacts of this section on the program.

**Next Meeting**

The next negotiation meeting is planned for Thursday, February 4, 2021.