

**FDA-Industry GDUFA Reauthorization Meeting**  
**April 8, 2021, 10:00 am – 12:45 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
Ashley Boam	CDER
Joshua Brown	OC/OCC
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Robert Lionberger	CDER
Bethany Rue	CDER
Edward Sherwood	CDER
David Skanchy	CDER
Maryll Toufanian	CDER

Industry

John DiLoreto	BPTF
David Gaugh	AAM
Karin Hessler	AAM
Brian McCormick	AAM (Teva)
Kiran Krishnan	AAM (Apotex)
Lisa Parks	AAM
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent)
Molly Ventrelli	AAM (Fresenius-Kabi)
Bethany Walls	BPTF (MilliporeSigma)

FDA Supporting Staff

Tiana Barnes, Dat Doan, Andrew Fine, Scott Vehovic

**Discussion**

FDA and Industry continued to discuss proposals related to drug master files (DMFs) and streamlining annual reporting commitments.

FDA and Industry continued to draft the GDUFA III Commitment Letter.

FDA also presented further clarifying information around how a capacity planning adjuster (CPA) could work in GDUFA III.

**Next Meeting**

The next negotiation meeting will be Thursday, April 15, 2021.