

**FDA-Industry GDUFA Reauthorization Meeting**  
**July 1, 2021, 10:00 am – 11:15 am**  
**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
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 (Catalent)
Molly Ventrelli	AAM (Fresenius-Kabi)

FDA Supporting Staff

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

**Discussion**

FDA and Industry continued discussions around suitability petitions.

FDA shared a visual to show Industry the possible additive effects of goal dates when submitting post-midcycle meeting amendments.

Industry discussed a desire to continue to work on efficiencies around controlled correspondence.

**Next Meeting**

The next negotiation meeting will be Thursday, July 8, 2021.