

**FDA-Industry GDUFA Reauthorization Meeting**  
**December 10, 2020, 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
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
Scott Tomsky	AAM (Teva)
Molly Ventrelli	AAM (Fresenius-Kabi)

FDA Supporting Staff

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

**Discussion**

FDA and Industry ratified the December 3, 2020 negotiation meeting minutes.

FDA presented a revised proposal regarding mid-cycle discipline review letters. FDA also discussed the current inflation adjustment and a proposed refinement to better capture GDUFA specific costs. Discussions also touched on the impact of potential limitations on allowable fee expenditures.

FDA and Industry discussed agenda items for upcoming sessions and agreed to share proposals in advance of related initial discussions, when possible.

**Next Meeting**

The next negotiation meeting is planned for Thursday, December 17, 2020.