

**FDA-Industry GDUFA Reauthorization Meeting**  
**January 21, 2021, 10:00 am – 2:45 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
Francis Godwin	CDER
Robert Lionberger	CDER
Susan Rosencrance	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
Molly Ventrelli	AAM (Fresenius-Kabi)

FDA Supporting Staff

Tiana Barnes, Dat Doan, Andrew Fine, Tawni Schwemer

**Discussion**

FDA and Industry continued discussions around the set of proposals regarding inspections that were introduced last week. FDA and Industry had a productive discussion and will continue discussions to ensure there is a good understanding around the issues on both sides.

FDA and Industry also spent time clarifying some details around the Controlled Correspondence proposals.

**Next Meeting**

The next negotiation meeting is planned for Thursday, January 28, 2021.