

**FDA-Industry GDUFA Reauthorization Meeting**  
**September 17, 2020, 10:00 am – 3:00 pm**  
**Virtual Meeting**

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**Purpose**

To begin 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

Susan Rosencrance

CDER

Edward Sherwood

CDER

Maryll Toufanian

CDER

Industry

John DiLoreto

David Gaugh

Karin Hessler

Kiran Krishnan

Lisa Parks

Gil Roth

Scott Tomsky

Molly Ventrelli

Bethany Walls

Brant Zell

BPTF

AAM

AAM

AAM (Apotex)

AAM

PBOA

AAM (Teva)

AAM (Fresenius-Kabi)

BPTF (MilliporeSigma)

BPTF (AmbioPharm)

**FDA Supporting Staff**

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

**Ground Rules for Virtual Negotiations**

FDA and Industry negotiators adopted ground rules for all virtual negotiations.

**Discussion**

FDA and Industry introduced each member on the negotiating teams, including negotiators and support members. Industry and FDA both introduced topics of interest for negotiations. Members on each team discussed what is working well in GDUFA II and areas of interest for negotiations to set a sound foundation for GDUFA III. Among other topics, the negotiators expressed mutual interest in discussing opportunities to increase first cycle approvals as well as exploring transparency and communications between FDA and Industry.

**Next Meeting**

The next negotiation meeting is planned for Thursday, October 1, 2020.