

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

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

BPTF

David Gaugh

AAM

Karin Hessler

AAM

Kiran Krishnan

AAM (Apotex)

Lisa Parks

AAM

Gil Roth

PBOA

Scott Tomsky

AAM (Teva)

Molly Ventrelli

AAM (Fresenius-Kabi)

Bethany Walls

BPTF (MilliporeSigma)

Brant Zell

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.