

FDA-Industry GDUFA Reauthorization Meeting
October 22, 2020, 10:00 am – 1:00 pm
Virtual Meeting

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
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

Discussion

FDA and Industry continued clarifying the proposals to advance earlier approvals of generic applications. Industry will inform FDA of its position with the proposals in the coming weeks.

Next Meeting

The next negotiation meeting is planned for Thursday, October 29, 2020.