FDA-Industry GDUFA Reauthorization Meeting
April 1, 2021, 10:00 am – 2:45 pm
Virtual Meeting

Purpose

To continue negotiations to reauthorize GDUFA (GDUFA III)

Participants

FDA		Industry	
Carter Beach	CDER	John DiLoreto	BPTF
Donald Beers	OC/OCC	David Gaugh	AAM
Lisa Berry	CDER	Karin Hessler	AAM
Ashley Boam	CDER	Brian McCormick	AAM (Teva)
Joshua Brown	OC/OCC	Kiran Krishnan	AAM (Apotex)
Jacqueline Corrigan-Curay	CDER	Lisa Parks	AAM
Alonza Cruse	ORA	Gil Roth	PBOA
Robert Lionberger	CDER	Dave Schoneker	IPEC (Black Diamond)
Susan Rosencrance	CDER	Cornell Stamoran	PBOA (Catalent)
Bethany Rue	CDER	Katherine Ulman	IPEC (KLU)
Edward Sherwood	CDER	Molly Ventrelli	AAM (Fresenius-Kabi)
Maryll Toufanian	CDER	Bethany Walls	BPTF (MilliporeSigma)
Susan Zuk	CDER	Priscilla Zawislak	IPEC (IFF)

FDA Supporting Staff
Tiana Barnes, Dat Doan, Andrew Fine, Scott Vehovic

Discussion

FDA and Industry continued discussions around the implementation of the Inactive Ingredient Database (IID).

FDA also discussed the role of inspections in meeting the requirements for a complete review under GDUFA and the impact of current restrictions on travel in meeting these requirements. A complete review is required to meet a goal date.

FDA and Industry continued discussions around streamlining annual reporting commitments while maintaining key and meaningful categories of interest for Industry.

FDA presented further clarifying information around the set of proposals intended to set a sound foundation for continued programmatic success, including how a capacity planning adjuster (CPA) could work in GDUFA III.

Next Meeting

The next negotiation meeting will be Thursday, April 8, 2021.