FDA-Industry GDUFA Reauthorization Meeting
December 17, 2020, 10:00 am – 11:30 am
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	Lisa Parks	AAM
Ashley Boam	CDER	Gil Roth	PBOA
Joshua Brown	OC/OCC	Cornell Stamoran	PBOA (Catalent)
Jacqueline Corrigan-Curay	CDER	Scott Tomsky	AAM (Teva)
Alonza Cruse	ORA	Molly Ventrelli	AAM (Fresenius-Kabi)
Robert Lionberger	CDER	Beth Walls	BPTF (MilleporeSigma)
Susan Rosencrance	CDER	Brian McCormick	AAM (Teva)
Bethany Rue	CDER	Karin Hessler	AAM
Edward Sherwood	CDER		
Maryll Toufanian	CDER		

FDA Supporting Staff
Dat Doan, Andrew Fine, Tawni Schwemer, Scott Vehovic

Discussion

FDA and industry ratified the December 10, 2020 negotiation meeting minutes.

Industry asked FDA to consider harmonizing some technical terminology related to the mid-cycle discipline review letters with a publicly facing policy document.

FDA described and provided data regarding the steady increase in post-marketing changes submitted through post-approval supplements (PASs) and changes being effected supplements (CBEs). FDA indicated if supplement volume continues to grow or other direct review work grows during GDUFA III, additional resources may be required.

The Agency shared similar information regarding the steady and continued annual increases in controlled correspondences. FDA indicated that a substantial percentage of these submissions are for complex generic drug products

Finally, FDA began an initial discussion of a possible proposal to resource more timely consideration of suitability petitions.

Next Meeting
In recognition of the holidays, the next negotiation meeting is planned for Thursday, January 14, 2021.