

FDA-Industry GDUFA Reauthorization Meeting- Fees Modeling Subgroup
July 26, 2016, 10:00 am – 12:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1417

Purpose

Fees Subgroup to discuss financial issues for GDUFA II.

Participants

<u>FDA</u>		<u>Industry</u>	
Donald Beers	OC/OCC	John DiLoreto	BPTF
Robert Berlin	OC/OPPLA	David Gaugh	GPhA
Mary Beth Clarke	CDER	Gil Roth	PBOA
Michael Jones	CDER		

FDA Supporting Staff

Carter Beach, Tom Hinchliffe, Dianoda Lewis, Victor Ng, Hanah Pham, Katie Stronati

Industry Supporting Staff

Mark Hendrickson (GPhA) Lisa Tan (GPhA)

Discussion

FDA and Industry representatives continued to discuss possible approaches to GDUFA II fee models. FDA and Industry agreed that further discussion is needed.

Next Meeting

The date of the next negotiation meeting is under discussion.