FDA-Industry GDUFA Reauthorization Meeting- Fee Modeling Subgroup
June 30, 2016, 10:00 pm – 2:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1300

Purpose
To discuss potential fee models for GDUFA II.

FDA		Industry	
Robert Berlin	OC/OPPLA	John DiLoreto	BPTF
Mary Beth Clarke	CDER	David Gaugh	GphA
Michael Jones	CDER	Gil Roth	PBOA
		Guy Villax	EFCG (Hovione)

FDA Supporting Staff
Carter Beach, Katie Stronati

Discussion
FDA and Industry representatives discussed possible approaches to GDUFA II fee models. One proposed fee model involved annual fees, one time fees, and a tiered fee structure. Industry agreed to take the proposed fee model back to their prospective groups for evaluation and discussion.

Next Meeting
The next meeting is planned for Wednesday, July 6, 2016.