

FDA-Industry GDUFA Reauthorization Meeting- Fees Modeling Subgroup
June 28, 2016, 1:00 pm – 3:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 6157

Purpose

Kickoff meeting for the Fees Subgroup to discuss financial issues for GDUFA II.

FDA

Robert Berlin
Mary Beth Clarke
Michael Jones

OC/OPPLA
CDER
CDER

Industry

John DiLoreto
David Gaugh
Gil Roth
Guy Villax

BPTF
GphA
PBOA
EFCG (Hovione)

FDA Supporting Staff

Carter Beach, Katie Stronati

Discussion

FDA and Industry representatives agreed that the objective of the workgroup is to conceptually align on a fee model for GDUFA II and present options back to the GDUFA II negotiators. The subgroup discussed each trade association's concerns and statements of position.

Next Meeting

The next meeting is planned for Thursday, June 30, 2016.