

FDA-Industry GDUFA Reauthorization Meeting- Fees Subgroup
July 22, 2016, 10:45 am – 12:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 6335

Purpose

Fees Subgroup to discuss financial issues for GDUFA II.

FDA

Don Beers

Mary Beth Clarke

Michael Jones

Gisa Perez

OC/OCC

CDER

CDER

CDER

Industry

John DiLoreto

David Gaugh

Gil Roth

Guy Villax

BPTF

GPhA

PBOA

EFCG (Hovione)

FDA Supporting Staff

Carter Beach, Tom Hinchliffe, Victor Ng, Katie Stronati

Discussion

FDA and Industry representatives continued to discuss possible approaches to GDUFA II fee models. FDA and Industry also discussed a proposed fee structure that involves annualized tiered fees. Industry agreed to further discuss the proposed structure.

Next Meeting

The next meeting has not yet been scheduled.