

**FDA-Industry GDUFA Reauthorization Meeting- Fees Modeling Subgroup**  
**August 4, 2016, 11:30 am – 1:30 pm**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 71, Room 4032, with industry representatives participating by telephone**

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**Purpose**

Fees Subgroup to discuss financial issues for GDUFA II.

**Participants**

FDA

Donald Beers

Robert Berlin

Mary Beth Clarke

OC/OCC

OC/OPPLA

CDER

Industry

John DiLoreto

David Gaugh

Gil Roth

BPTF

GPhA

PBOA

FDA Supporting Staff

Carter Beach, Thomas Hinchliffe, Victor Ng, Gisa Perez, Katie Stronati

Industry Supporting Staff

Mark Hendrickson (GPhA), Lisa Tan (GPhA)

**Discussion**

Industry proposed modifications to the suggested fee model. FDA and Industry continue to review and consider proposed GDUFA II fee models.

**Next Meeting**

The date of the next negotiation meeting is under discussion.