

FDA-Industry GDUFA Reauthorization Meeting

August 24, 2016, 2:15 pm – 2:30 pm

FDA White Oak Campus, Silver Spring, MD

Building 51, Room 6144, with industry representatives participating by telephone

Purpose

To discuss statutory language for GDUFA II

Participants

FDA

Mary Beth Clarke

Keith Flanagan

Mike Jones

James Myers

Carter Beach

CDER

CDER

CDER

CDER

CDER

Industry

John DiLoreto

David Gaugh

Gil Roth

BPTF

GPhA

PBOA

Discussion

FDA and industry agreed on the terms of a GDUFA II reauthorization package.

Next Meeting

GDUFA II negotiations have concluded.