

**FDA-Industry GDUFA Reauthorization Meeting**  
**December 16, 2015, 10:00 am - 4:00 pm**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 71, Room 1208/1210**

---

**Purpose**

To discuss elements of the pre-ANDA process and the Federal budget formulation process as it applies to FDA.

**Participants**

FDA

Donald Beers  
Robert Berlin  
Ashley Boam  
Mary Beth Clarke  
Keith Flanagan  
Robert Lionberger  
Ann Marie Montemurro  
Edward Sherwood  
Martin Shimer  
David Skanchy  
Susan Zuk

OC/OCC  
OC/OPPLA  
CDER  
CDER  
CDER  
CDER  
ORA  
CDER  
CDER  
CDER  
CDER

Industry

John DiLoreto  
David Gaugh  
Steve Giuli  
Marcie McClintic Coates  
Alan Nicholls  
Christina Planellas  
Gil Roth  
Cornell Stamoran  
Elizabeth Stampa  
Tom Thorpe  
Scott Tomsky  
Keith Webber

BPTF  
GPhA  
GPhA (Apotex)  
GPhA (Mylan)  
BPTF  
EFCG (Medichem)  
PBOA  
PBOA (Catalent)  
EFCG (Medichem)  
PBOA (Afton Scientific)  
GPhA (Teva)  
GPhA (Perrigo)

**FDA Supporting Staff**

Carter Beach, Deborah Elliott, Derek Griffing, Michael Jones, Michael Neuenschwander, Martha Nguyen, Tawni Schwemer, Katie Stronati, Trang Tran, Lucie Yang

**Industry Supporting Staff**

Lisa Tan (GPhA), Mark Hendrickson (GPhA)

**Discussion**

FDA and Industry discussed complex generic drug products and the need for clarity in the pre-ANDA space. Additionally, meeting participants discussed controlled correspondence and regulatory science priorities for GDUFA II. Industry highlighted the importance of transparency and the timely publication of product-specific bioequivalence guidances.

FDA discussed Drug Master File (DMF) enhancements and potential improvements to the Inactive Ingredient Database (IID). FDA also explained the Federal budget formulation process as it applies to FDA. Further, FDA described the integrated IT platform and its contribution to FDA's enhanced productivity. FDA and Industry will continue the discussion with regards to all of these topics to further identify priorities to contribute to the program's overall success.

**Next Meeting**

The next negotiation meeting is planned for Wednesday, January 6, 2016.