**FDA-Industry GDUFA Reauthorization Meeting**
**April 6, 2016, 9:00 am – 1:20 pm**
**FDA White Oak Campus, Silver Spring, MD**
**Building 71, Room 1208/1210**

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**Purpose**
To discuss the pre-Abbreviated New Drug Application (pre-ANDA) process and review goals pertaining to ANDAs.

**Participants**

| FDA | | Industry | |
|---|---|---|---|
| Donald Beers | OC/OCC | David Gaugh | GPhA |
| Robert Berlin | OC/OPPLA | Kiran Krishnan | GPhA (Apotex) |
| Mary Beth Clarke | CDER | Marcie McClintic Coates | GPhA (Mylan) |
| Keith Flanagan | CDER | Molly Rapp | GPhA (Fresenius-Kabi) |
| Michael Jones | CDER | Gil Roth | PBOA |
| Robert Lionberger | CDER | Lisa Tan | GPhA |
| Edward Sherwood | CDER | Scott Tomsky | GPhA (Teva) |
| Martin Shimer | CDER | | |

FDA Supporting Staff
Carter Beach, Matt Defina, Derek Griffing, Martha Nguyen, Tawni Schwemer, Trang Tran, Lucie Yang

**Discussion**
FDA and Industry continued discussions from earlier negotiation meetings on a pre-ANDA process and review goals for ANDAs. Topics included controlled correspondence, product-specific guidance, pre-ANDA meetings, and review goals for standard and priority ANDAs.

**Next Meeting**
The next negotiation meeting is planned for Thursday, April 14, 2016.