

**FDA-Industry PDUFA V Reauthorization Meeting**  
**March 31, 2011, 2:00pm - 4:30pm**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 31, Room 2442**

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**Purpose**

To conduct a final review of the draft PDUFA V commitment letter, draft statutory changes to reflect financial agreements, and the draft justifications for those proposed statutory changes

**Participants**

FDA

Jane Axelrad	CDER
Ed Cox	CDER
Patrick Frey	CDER
Debbie Henderson	CDER
John Jenkins	CDER
Chris Joneckis	CBER
Brian Kehoe	OL
Theresa Mullin	CDER
Donal Parks	CDER
Bob Yetter	CBER

Industry

Annetta Beauregard	EMD Serono
Paul Eisenberg	Amgen
Andrew Emmett	BIO
Jeffrey Francer	PhRMA
Sascha Haverfield	PhRMA
Rob Kowalski	Novartis
Mark Mayer	Eli Lilly
Bob Meyer	Merck
Sara Radcliffe	BIO
Mark Taisey	Eisai
Helen Thackray	GlycoMimetics
David Wheadon	PhRMA

FDA and Industry conducted a final review and made minor clarifying edits to the draft PDUFA V commitment letter to reflect tentative agreements on the following proposed enhancement initiatives for PDUFA V:

- Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs
- Enhancing Regulatory Science and Expediting Drug Development
  - Advancing the Science of Meta-Analysis Methodologies
  - Advancing the Use of Biomarkers and Pharmacogenomics
  - Advancing Development of Patient-Reported Outcomes (PROs) and Other Endpoint Assessment Tools
  - Advancing Development of Drugs for Rare Diseases
- Enhancing Benefit-Risk Assessment in Regulatory Decision-Making (including Patient-Focused Drug Development)
- Enhancement and Modernization of the FDA Drug Safety System
  - Measure the Effectiveness of REMS and Standardize and Better Integrate REMS into the Healthcare System
  - Sentinel as a Tool for Evaluating Drug Safety Issues That May Require Regulatory Action
- Improving the Efficiency of Human Drug Review Through Required Electronic Submissions and Standardization of Electronic Drug Application Data

FDA and Industry also conducted a final review of the proposed statutory changes to reflect agreements related to the fee revenue amount for PDUFA V, inflation and workload adjusters, the electronic submission requirement, and the modification to clarify the assessment of product fees when a product is

approved as both a new drug application and an abbreviated new drug application; and the justifications for the proposed statutory changes.

There were no substantive proposals, significant controversies, or differences of opinion discussed at this meeting.