

**FDA-Industry PDUFA V Reauthorization Meeting**  
**Premarket Sub-Group**  
**February 24, 2011, 9:30-11:30am**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 31, Room 2442**

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**Purpose**

To continue discussion of proposals related to the pilot program for enhanced review communication, regulatory science, and enhanced communication for emerging sponsors

**Participants**

<u>FDA</u>		<u>Industry</u>	
Ed Cox	CDER	Kay Holcombe	Genzyme
Patrick Frey	CDER	Sara Radcliffe	BIO
John Jenkins	CDER	Jay Siegel	Johnson & Johnson
Chris Joneckis	CBER	David Wheadon	PhRMA
Bob Yetter	CBER		
Matt Sullivan	CDER		
Dave Roeder	CDER		
Theresa Mullin	CDER		
Gary Gensinger	CDER		
Carla Cartwright	OCC		
Wade Ackerman	OCC		

**Regulatory Science Proposals**

FDA discussed its commitment language for the proposals related to regulatory science. FDA and Industry discussed minor clarifying edits and agreed to recommend the following proposals to the Steering Group:

- Advancing biomarkers and pharmacogenomics
- Ensure quality of patient-reported outcomes and other endpoint assessment tools
- Ensuring quality in meta-analysis
- Advancing development of drugs for rare diseases

**Enhanced Communication for Emerging Sponsors**

To address Industry's request for a communication and response pathway for emerging sponsors, FDA proposed to create an emerging innovator liaison function. This point of contact would assist emerging sponsors in navigating the regulatory process. The liaison would triage requests from emerging sponsors, with one of several potential outcomes: (a) the request would be processed promptly; (b) the request would be processed within a designated timeframe after internal deliberation; or (c) the request could not be adequately addressed through this pathway and would require a formal meeting request to address the issue. Industry indicated an interest in this modification. There was not uniform Industry support for this smaller scale proposal. FDA stated that this proposed solution was the best option in a resource-limited situation.

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