

**FDA-Industry PDUFA VI Reauthorization Meeting  
November 3, 2015, 1:00-2:30pm  
FDA White Oak Campus, Silver Spring, MD  
Building 71, Room 1208/1210**

**Purpose:** To discuss FDA and Industry pre-market review process enhancement proposals.

**Participants**

<u>FDA</u>		<u>Industry</u>	
Alonza Cruse	ORA	Cartier Esham	BIO
Joseph Franklin	OCC	Sascha Haverfield	PhRMA
Patrick Frey	CDER	Kay Holcombe	BIO
John Jenkins	CDER	Laurie Keating	BIO (Alnylam)
Christopher Joneckis	CBER	Robert Metcalf	PhRMA (Eli Lilly)
Theresa Mullin	CDER	Mark Taisey	PhRMA (Amgen)
Mary Parks	CDER		
James Smith	CDER		
Kellie Taylor	CDER		
Kimberly Taylor	CDER		

**Discussion of FDA Breakthrough Therapy Program Proposal**

FDA and Industry continued discussion of FDA's breakthrough therapy program proposal.

FDA discussed the workload of the breakthrough therapy program since its inception. The agency stated it has seen no decline in the number of BT requests received or the rate at which requests are granted. However, FDA noted that as more requests are granted, particularly earlier in drug development as is expected of the breakthrough therapy program, the number of INDs with breakthrough designation will continue to grow. FDA observed that the program has not yet evolved to the point where the number of newly designated breakthrough products in the development or marketing review phase is balanced by the number of breakthrough products that are acted upon or have their breakthrough designation withdrawn or rescinded.

FDA also discussed the current resources spent on the breakthrough therapy program in terms of program management and policy development, review work that occurs during the 60-day designation phase, and the review work that occurs during drug development and following submission of a marketing application for a breakthrough designated product. FDA and Industry agreed to continue discussing this proposal.

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