

**FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program**  
**June 30, 2011, 1:00 pm – 5:00pm**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 32, Room 2162**

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**Purpose**

To continue FDA-industry stakeholder discussions regarding development of a 351(k) user fee program.

**Participants**

<u>FDA</u>	<u>Center</u>	<u>Industry</u>	<u>Company/Affiliation</u>
Sunanda Bahl	CDER	Philip Ball	Watson
Leah Christl	CDER	Sandi Dennis	BIO
Chris Joneckis	CDER	Andrew Emmett	BIO
Andrew Kish	CDER	Jim Fenton	GPhA
Steven Kozlowski	CDER	Owen Fields	Pfizer
Theresa Mullin	CDER	John Finkbohner	MedImmune
Donal Parks	CDER	Eric Floyd	Hospira
Rokhsana Safaai-Jazi	CDER	Sascha Haverfield	PhRMA
Manju Thomas	CDER	Mary Clare Kimber	PPTA
Ann Wion	OCC	Yatika Kohli	Apotex
		David Korn	PhRMA
		Bruce Leicher	Momenta
		Nikhil Mehta	Merck
		John Pakulski	GPhA
			(Novartis/Sandoz)
		Terri Stewart	Teva
		Vince Suneja	Mylan

FDA presented an overview of the anticipated review activities that would occur during the biosimilar product development (BPD) phase; FDA explained that it would need adequate funding during the BPD phase in order for those review activities to occur. Based on the need for resourcing to support BPD-phase review and meetings with sponsors, the industry stakeholders representing BIO, PhRMA, and GPhA, as well as the other industry participants, expressed support for the inclusion of a BPD-phase fee for at least the first authorization of the program. Participants also discussed mechanisms for administering the BPD fee. Some industry stakeholders suggested the BPD fee should be linked to the submission of an IND or in the earlier stages of 351(k) product development, i.e. after the pre-IND meeting. Industry stakeholders and FDA agreed that it would be helpful to develop draft proposal(s) for a mechanism for initiation and application of BPD-phase fees, for further discussion at the next industry stakeholder meeting.

In terms of the total marketing application fee from which the BPD phase would be subtracted, there were different opinions among the industry participants. While some of the individual company participants who are interested in pursuing biosimilar biologics development, and representatives from BIO and PhRMA, expressed support for having 351(k) user fees be set equal to 351(a) user fees for at least the initial five years of the biosimilar user fee program, representatives from GPhA indicated that they were not fully supportive of this. Industry stated that they appreciated the thought that FDA put into its presentation on BPD-phase review and consultation, but were not certain that they were willing to pay

100 percent of the fee amount charged for 351(a) marketing applications, to support reviews under the biosimilar biologics program. In response, FDA questioned whether industry was interested in increasing business certainty and enabling shorter timeframes for the completion of FDA reviews. If so, then the program would require adequate resourcing to support that; FDA would need fees comparable to those charged under PDUFA.

FDA agreed to conduct further analysis of alternative BPD fee structures, including use of a lump sum BPD-phase fee, charging a higher initial fee with a subsequent lower annual fee, and charging the same fee initially and each subsequent year, as originally proposed in the FR notice. In addition, FDA agreed to examine the impact of different plausible resourcing scenarios on performance goals, including metrics that could be achieved for 351(k) marketing application review. FDA stated that it would base its analyses on the assumption that 351(k) marketing applications would be paying the same level of fee as 351(a) marketing applications. These analyses would be presented at the next industry stakeholder meeting scheduled for July 11, 2011.