

**FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program**  
**June 15, 2011, 10:00am – 3:00pm**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 32, Room 2162**

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**Purpose**

To begin 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	Lisa Barclay	Momenta
Leah Christl	CDER	Sandi Dennis	BIO
Amanda Edmonds	OCC	Andrew Emmett	BIO
Denise Esposito	CDER	Owen Fields	Pfizer
John Jenkins	CDER	John Finkbhoner	MedImmune
Brian Kehoe	OL	Jeff Francer	PhRMA
Andrew Kish	CDER	Eric Floyd	Hospira
Theresa Mullin	CDER	Sascha Haverfield	PhRMA
Donal Parks	CDER	Debbie Jaskot	Teva
Rokhsana Safaai-Jazi	CDER	Yatika Kohli	Apotex
Manju Thomas	CDER	Marcie McClintic-Coates	Mylan
Kathleen Uhl	CDER	Nikhil Mehta	Merck
Ann Wion	OCC	John Pakulski	GPhA (Novartis/Sandoz)
Bob Yetter	CBER	James Weston	Shire HGT
<u>HHS</u>			
Roger McClung	ASL		

FDA proposed a set of ground rules for the conduct of FDA-industry stakeholder meetings, including the following:

- Regular attendance at the FDA-industry stakeholder meetings to provide continuity throughout the stakeholder process.
- Efficient and professional conduct and participation in meetings.
- Positions taken are based on facts, to the extent possible.
- Meeting discussions will be captured in meeting minutes that will summarize key topics of discussion.
- The goal of these discussions is to develop a set of proposed recommendations for a fair and adequate biosimilar user fee program.

FDA presented an overview of the information published in the *Federal Register* in May 9, 2011, <http://www.gpo.gov/fdsys/pkg/FR-2011-05-10/pdf/2011-11348.pdf>, including identified principles for development of a 351(k) user fee program, the proposed structure for a 351(k) user fee program that would adhere to these principles, and proposed performance goals for this program.

Following the FDA presentation, different industry stakeholders provided an overview of their respective comments submitted to the May 9, 2011 public docket. Some industry stakeholders highlighted the importance of ensuring user fee resources are not diverted from innovator review activities to biosimilar review activities. Some stated that the Biosimilar Product Development (BPD) fee should be collected in earlier stages of 351(k) product development, i.e., during the pre-IND stage. Industry stakeholders requested further clarification of the activities that occur during the BPD phase. Some industry stakeholders presented an alternative set of principles focusing on safety, access, and transparency.

Some of the industry stakeholders agreed with FDA's proposal that that user fees for a 351(k) program should be comparable to user fees for the 351(a) program in order to support the level of effort required, and stated that the BPD fee should sunset after the initial five years of authorization and the establishment of a sustainable revenue stream. Other industry stakeholders proposed an alternative fee structure, similar to the European Union (EU) structure, and proposed that the 351(k) application fee should be equivalent to 50 to 65 percent of the current user fee for a 351(a) application. This proposed alternative structure would also replace the FDA-proposed product and establishment fees with an annual establishment registration fee. FDA stated that, unlike the fee-for-service model used in the EU, each component fee of the proposed 351(k) user fee program would pay for a package of services rather than an individual service.

Most of the industry stakeholders stated that the FDA-proposed 351(k) application review performance goals were not sufficiently aggressive and proposed that the application review goals align with 351(a) performance goals. FDA stated that it currently lacks resources necessary to implement performance goals comparable to the current goals for 351(a) review. FDA explained that the FY 2011 appropriation included a total of \$1.8 million with only 4 Full Time Equivalent staff for biosimilar biological product review. Therefore, FDA proposed a phased approach to implement performance goals for 351(k) products, commensurate with the availability of additional funds to increase staffing and program review capacity.