FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program
August 08, 2011, 1:00 pm – 5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 2162

Purpose

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

Participants

FDA	Center	Industry	Company/Affiliation
Daniel Brounstein	CDER	Philip Ball	Watson
Leah Christl	CDER	Sandi Dennis	BIO
John Jenkins	CDER	David Drake	GPhA (Novartis/Sandoz)
Christopher Joneckis	CBER	Andrew Emmett	BIO
Brian Kehoe	OL	John Engel	GPhA
Andrew Kish	CDER	Eric Floyd	Hospira
Theresa Mullin	CDER	Jeffrey Francer	PhRMA
Rokhsana Safaai-Jazi	CDER	Sascha Haverfield-Gross	PhRMA
Jay Sitlani	CDER	Gordon Johnston	GPhA
Manju Thomas	CDER	Yatika Kohli	Apotex
Kathleen Uhl	CDER	Bruce Leicher	Momenta
Ann Wion	OCC	Laura McKinley	Pfizer
Robert Yetter	CDER	Stephen Mason	Amgen
		Nikhil Mehta	Merck
		Vince Suneja	Mylan
		Howard Yuwen	Shire HGT

Biosimilar Product Development-Phase Meetings
In follow up to the discussion at previous meetings, FDA presented a revised set of defined biosimilar product development (BPD) phase meetings. FDA reiterated that BPD phase meetings are not mandatory, and sponsors can choose the combination of BPD phase meetings matching their specific development needs. Industry agreed that the proposed meeting structure provides greater flexibility, and accommodates the variability in sponsor development programs.

Draft Statutory Language for a Biosimilar User Fee Program
FDA and industry reviewed and discussed proposed draft statutory language that would authorize a separate user fee program for biosimilar biological products. The draft statutory language included the FDA-proposed fee structure of BPD-phase, application, establishment, and product fees. As part of the proposed fee provisions, FDA would subtract the sum of all of the sponsor's previously-paid BPD-phase fees for a given product from the application fee that would be paid on submission of the marketing application for that product. Based on the discussion, FDA agreed to revise the draft statutory language, and distribute the revised draft.

Discussion of Performance Goals
FDA and industry discussed proposed performance goals for biosimilar biological product review, assuming a separate biosimilar user fee program. GPhA stated interest in having shorter

review time frames for the BPD-phase meeting performance goals. FDA stated that the proposed time frames were needed in order for FDA to provide comprehensive data review and feedback. FDA also stated that it was important to have realistic performance goals in managing application reviews. FDA agreed to develop a draft performance goal commitment letter and to distribute the draft.