FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program
August 2, 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
Sunanda Bahl	CDER	Philip Ball	Watson
Daniel Brounstein	CDER	Colin Chiles	Apotex
Leah Christl	CDER	Andrew Emmett	BIO
Amanda Edmonds	OCC	John Engel	GPhA
John Jenkins	CDER	Eric Floyd	Hospira
Christopher Joneckis	CBER	Jeffrey Francer	PhRMA
Brian Kehoe	OL	Sascha Haverfield-Gross	PhRMA
Andrew Kish	CDER	Debbie Jaskot	Teva
Theresa Mullin	CDER	Gordon Johnston	GPhA
Rokhsana Safaai-Jazi	CDER	Jeffrey Kushan	BIO
Jay Sitlani	CDER	Bruce Leicher	Momenta
Manju Thomas	CDER	Laura McKinley	Pfizer
Ann Wion	OCC	Stephen Mason	Amgen
Robert Yetter	CBER	Nikhil Mehta	Merck
		Mary Sibley	GPhA (Novartis/Sandoz)
HHS		Vince Suneja	Mylan
Roger McClung	ASL	Howard Yuwen	Shire HGT

Views on Separate User Fee Program for Biosimilar Biologics

The meeting began with a continuation of earlier discussions of the merits of establishing a separate user fee program for biosimilar biological products. The Generic Pharmaceutical Association (GPhA) stated support for maintaining the status quo by keeping the biosimilars review program within the PDUFA program for fiscal years 2013 through 2017. GPhA stated that this would provide greater certainty of funding for biosimilar biologic review.

FDA reiterated that maintaining the biosimilars review program in the PDUFA program, among many competing new drug review priorities, and statutory requirements for pediatric review, post-market safety activities, and other review activities that need resourcing, would not provide certainty for resourcing biosimilars review activities. Through a separate 351(k) user fee program, FDA could dedicate resources to the biosimilar biologics review process. This would enable FDA to provide special biosimilars development meetings and associated

milestones and metrics, and provide more in-depth review of sponsors' data and feedback during biosimilar development. These specially-tailored biosimilar review activities and related performance goals would not be offered if the biosimilar program remained in PDUFA. Under PDUFA, only the existing PDUFA performance metrics would be applied. BIO (Biotechnology Industry Organization) and PhRMA (Pharmaceutical Research and Manufacturers of America) stated that they do not support maintaining the biosimilars review program in the PDUFA program. PhRMA and BIO stated that a separate biosimilar user fee program would be consistent with congressional intent and would also provide for a dedicated base of biosimilar review funding while not jeopardizing the review goals for innovative medicines established under PDUFA. GPhA agreed to further discuss this issue with their Executive Committee, but noted the need for certainty of funding.

Statutory Conditions for Assessment and Use of Fees in Other Medical User Fee Programs
At the request of industry, FDA described the statutory conditions that must be met in order for the agency to assess and use user fees under PDUFA. GPhA requested additional clarity about how similar statutory conditions could provide greater certainty of future funding for biosimilars review activities. In an earlier meeting, PhRMA presented a proposal for incorporation of a statutory condition that would require FDA to spend a specified amount of non-user fee funds for biosimilar review in order to collect and spend biosimilars user fees (separate biosimilars user fee "trigger"). This proposed provision was modeled on a similar statutory condition in PDUFA. Referring to that proposal, FDA explained that including a condition that requires FDA to spend a specified (achievable) amount of non-user fee funds on biosimilar review, in order to have the authority to collect and spend biosimilar user fees, would effectively ensure that FDA allocates that specified amount of non-user fee funding to biosimilars review activities.

Biosimilar Product Development-Phase Meetings
Pfizer submitted a revised proposal for the focus and timing of proposed biosimilar product development (BPD) phase meetings, to allow for a meeting that involved a specific issue and would require less extensive review by FDA, and would also feature a shorter timeframe for FDA response. The proposal was supported by representatives from PhRMA, BIO, and GPhA member companies. FDA discussed Pfizer's revised proposal of the biosimilar product development (BPD) phase meetings. FDA agreed to incorporate industry's feedback, and further refine the BPD meeting structure to accommodate variations in sponsor development programs.