FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program
August 17, 2011, 12:30 pm – 3:00 pm
Teleconference

Purpose

To review draft proposed statutory language and draft commitment letter language for a 351(k) user fee program.

Participants

FDA	Center	Industry	Company/Affiliation
Sunanda Bahl	CDER	Philip Ball	Watson
Daniel Brounstein	CDER	Sandi Dennis	BIO
Leah Christl	CDER	Andrew Emmett	BIO
Amanda Edmonds	OCC	Owen Fields	Pfizer
John Jenkins	CDER	Eric Floyd	Hospira
Christopher Joneckis	CBER	Jeffrey Francer	PhRMA
Brian Kehoe	OL	Debbie Jaskot	Teva
Andrew Kish	CDER	Gordon Johnston	GPhA
Theresa Mullin	CDER	Yatika Kohli	Apotex
Rokhsana Safaai-Jazi	CDER	Bruce Leicher	Momenta
Jay Sitlani	CDER	Stephen Mason	Amgen
Manju Thomas	CDER	Nikhil Mehta	Merck
Kathleen Uhl	CDER	John Pakulski	Sandoz/Novartis
Ann Wion	OCC	Mary Sibley	Sandoz/Novartis
Robert Yetter	CBER	Vince Suneja	Mylan
		David Wheadon	PhRMA

Draft Statutory Language for a Biosimilar Biological Product User Fee Program
FDA and industry discussed industry comments on the proposed draft statutory language authorizing a separate biosimilar biological product user fee program. The draft statutory language included the FDA-proposed fee structure, including a biosimilar biological product development (BPD) fee, application fee, establishment fee, and product fee. For a given fiscal year, FDA proposed to set the application fee, establishment fee, and product fee equal to PDUFA fee levels for that fiscal year. FDA proposed to set the annual BPD fee in a given fiscal year to 10% of the PDUFA application fee for that fiscal year. The draft statutory language included the conditions for initiating the annual BPD fee, the options for discontinuing participation in the BPD phase program, and the consequences of failing to pay the BPD fee. FDA also proposed a reactivation fee, equal to twice the BPD fee, for re-entry into the BPD phase program. At marketing application submission, FDA would subtract the sum of previously-paid BPD-phase fees, including reactivation fees, from the application fee. The draft statutory language also included a provision for FDA to conduct a workload study to determine adequate resourcing levels for future user fee discussions. FDA agreed to incorporate proposed revisions, and to convene another meeting.

Discussion of Performance Goals
FDA and industry stakeholders discussed industry comments on the proposed review, major dispute resolution, clinical hold, and meeting management performance goals for biosimilar biological product applications. Industry stakeholders proposed to include a goal for special

protocol assessments, and to add a BPD meeting type to address stalled biosimilar biological product development programs. FDA agreed to incorporate these revisions.