FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program
August 26, 2011, 11:00 am – 1:00pm
Teleconference

Purpose

To continue review of proposed draft statutory language and 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	John Finkbohner	MedImmune
John Jenkins	CDER	Jeffrey Francer	PhRMA
Christopher Joneckis	CBER	Sascha Haverfield-Gross	PhRMA
Andrew Kish	CDER	Debbie Jaskot	Teva
Rokhsana Safaai-Jazi	CDER	Gordon Johnston	GPhA
Manju Thomas	CDER	Yatika Kohli	Apotex
Ann Wion	OCC	Bruce Leicher	Momenta
Robert Yetter	CBER	Stephen Mason	Amgen
		Laura Mckinley	Pfizer
		Nikhil Mehta	Merck
		John Pakulski	Sandoz/Novartis
		Mary Sibley	Sandoz/Novartis
		Vince Suneja	Mylan

Draft Statutory Language for a Biosimilar Biological Product User Fee Program

FDA and industry stakeholders discussed industry comments on the proposed draft statutory language authorizing a separate biosimilar biological product user fee program for fiscal years 2013 to 2017. The proposed draft statutory language included a spending trigger condition, previously proposed by industry, that must be satisfied in order for FDA to have the authority to collect and spend biosimilar biological product user fees. This condition specifies that FDA may collect and spend user fees in a fiscal year only if FDA also spends at least $20 million in non-user fee funds (adjusted for inflation), on biosimilar biological product review. FDA and industry stakeholders reached tentative agreement, pending ratifier approval, on the draft statutory language. FDA agreed to draft the "justification" document that would accompany the proposed draft statutory language.

Discussion of Performance Goals

FDA and industry stakeholders discussed industry comments on the proposed performance goals. FDA revised the goals to include special protocol assessments and another BPD meeting type addressing stalled biosimilar biological product development programs. FDA and industry stakeholders reached tentative agreement, pending ratifier approval, on the proposed performance goals for a 351(k) user fee program.