FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program
July 11, 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	Sandi Dennis	BIO
Leah Christl	CDER	Andrew Emmett	BIO
Amanda Edmonds	OCC	Jim Fenton	GPhA
John Jenkins	CDER	Owen Fields	Pfizer
Chris Joneckis	CBER	John Finkbohner	MedImmune
Andrew Kish	CDER	Eric Floyd	Hospira
Theresa Mullin	CDER	Jeff Francer	PhRMA
Donal Parks	CDER	Sascha Haverfield	PhRMA
Rokhsana Safaai-Jazi	CDER	Debbie Jaskot	Teva
Manju Thomas	CDER	Yatika Kohli	Apotex
Bob Yetter	CBER	Bruce Leicher	Momenta
		Nikhil Mehta	Merck
		John Pakulski	GPhA (Novartis/Sandoz)
		Vince Suneja	Mylan
HHS			
Roger McClung	ASL		

FDA presented an analysis of alternative biosimilar product development (BPD) phase fees, incorporating projected resource levels and potential performance goals, including metrics that could be achieved for 351(k) marketing application review. Industry stakeholders inquired whether the proposed BPD phase meetings were mandatory. FDA explained that the BPD phase meetings were not mandatory. The agency proposed different types of meetings to anticipate variations in sponsor development programs. Industry stakeholders conveyed concerns regarding performance goals for BPD meetings and stated their preference for more aggressive performance goals. FDA stated that the proposed time frames would be necessary in order for FDA to provide comprehensive review of data of this volume and complexity, and provide comprehensive feedback to sponsors, given the level of staffing achievable under the projected resource scenarios Following the FDA presentation, industry stakeholders agreed to further review the BPD scenarios presented by FDA and provide alternative proposed frameworks for the BPD meeting structure through their respective trade associations.

FDA and industry stakeholders discussed the administration of BPD-phase fee payments, including what would happen if a company failed to pay the proposed annual BPD-phase fee. The proposed approach calls for placing the sponsor's Investigational New Drug (IND) application on hold if the sponsor fails to pay the annual fee. However, some industry stakeholders stated that, if a company didn't have the resources to develop multiple drugs in parallel, the company might prefer to temporarily discontinue participation in the BPD program and have their IND on hold, while focusing their resources on another

IND program, with the intention of resuming participation in the BPD program at some point in the future. FDA and Industry discussed the application of a reactivation fee to address those cases.

The FDA-proposed fee structure includes biosimilar biological product development fees, application fees, establishment, and product fees. FDA and industry stakeholders discussed alternatives to including both a product and an establishment fees. FDA proposed two possible options: charging an establishment fee and a product fee, or charging double the amount for the product fee and eliminating the establishment fee. GPhA stated that regardless of the establishment fee model, there should be parity among domestic and foreign establishments. PhRMA proposed a separate establishment and product fee. FDA agreed to conduct further analysis of these alternative fee scenarios.

Industry stakeholders and FDA supported an annual flat BPD-phase fee at approximately 10% of the PDUFA marketing application fee for that fiscal year. FDA agreed to conduct further analysis to better define the BPD-phase fee structure. FDA also agreed to consider proposed statutory language for discontinuing participation in the BPD-phase program, and a reactivation fee that would apply upon re-entry into the BPD-phase program. Industry stakeholders agreed to develop proposed commitment letter language defining a workload study during the first authorization of the 351(k) user fee program with the intent to determine adequate resourcing levels for future user fee discussions. This would be presented at the next industry stakeholder meeting scheduled for July 18, 2011.