FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program
July 25, 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	John Finkbohner	MedImmune
John Jenkins	CDER	Jeffrey Francer	PhRMA
Christopher Joneckis	CBER	Sascha Haverfield-Gross	PhRMA
Brian Kehoe	OL	Gordon Johnston	GPhA
Andrew Kish	CDER	Bruce Leicher	Momenta
Theresa Mullin	CDER	Laura McKinley	Pfizer
Donal Parks	CDER	Stephen Mason	Amgen
Rokhsana Safaai-Jazi	CDER	Nikhil Mehta	Merck
Jay Sitlani	CDER	Mary Sibley	GPhA (Novartis/Sandoz)
Manju Thomas	CDER	Terri Stewart	Teva
Ann Wion	OCC	Vincent Suneja	Mylan
Robert Yetter	CBER	Howard Yuwen	Shire HGT

Continued Discussion of the Merits of a Separate Biosimilar User Fee Program
FDA presented a recap of the differing industry views from the previous meeting and reiterated that placing biosimilars review in the larger PDUFA program, with many competing priorities and statutory requirements and very large volumes of new drug review work, would diminish the attention to and the success of the new biosimilars review program. FDA also stated that, if the biosimilars review program is added to the PDUFA program, FDA would not provide detailed early review of sponsors' data, or special biosimilars development meetings and associated milestones. Instead, FDA would offer Type B and C meetings in PDUFA, where sponsors provide their summaries for high-level FDA review, not data for detailed review. This would result in less detailed feedback and therefore less certainty for biosimilar sponsors.

The Generic Pharmaceutical Association (GPhA) stated that increasing the amount of non-user fee funding that FDA must spend on PDUFA activities would allow integration of innovator and biosimilars review work under one user fee program, adding certainty for future biosimilars funding. FDA stated that increasing this amount would not result in increased certainty for future biosimilars funding because FDA would not be required to direct the additional amount to biosimilars review activities.

PhRMA and BIO stated that a statutory spending condition that is separate and specific for the Biosimilars review program is necessary and consistent with congressional intent under the user fee provision of the BPCIA.

GPhA stated that their organization was unable to make a commitment to a separate biosimilars user fee program, and agreed to further discuss the issue with their Executive Board and provide the Board's response by the end of the week.

Discussion of Model Projections of Program Resourcing
In follow up to the discussions of the previous meeting, as requested by industry, FDA presented an updated biosimilars resource model including two different resourcing scenarios. Both scenarios assumed a separate biosimilar user fee program, and both assumed a flow of biosimilar development-phase work and applications submissions—and associated estimated fee revenues-- based on projections in the HHS 2009 report. The first scenario also assumed spending of non-user fee funding at the FY 2011 level ($1.8 M) through the years FY 2013-2017. The second scenario assumed spending of non user fee funding in an amount equal to the current level of effort reported in FDA time-reporting for biosimilars work (an estimated $ 5 million) plus the level of funding for biosimilars requested in the President's Budget for FY 2012. For each of these scenarios the funding levels were converted to estimated levels of direct Full Time Equivalent (FTE) staffing for biosimilars review work, and FDA described the level of performance goal commitments that could be made under each of these scenarios.

Biosimilar Product Development-Phase Meetings
Based on industry stakeholder discussions, FDA proposed a revised set of biosimilar product development (BPD) phase meetings. To greater accommodate variations in sponsor development programs, some industry stakeholders suggested adding another meeting type with fewer data review components, and a shorter performance goal timeframe. Industry stakeholders agreed to further review the BPD scenarios, and provide alternative proposed frameworks for the BPD meeting structure.

Draft Statutory Language for a Biosimilar User Fee Program
FDA presented draft FDA statutory language for the biosimilars user fee program. PhRMA proposed inclusion of a requirement for a biosimilar review workload study and inclusion of a requirement for FDA to allocate a specified amount of non-user fee funds to support biosimilar review as a condition that would trigger the authority to collect and spend biosimilar user fees. GPhA stated that they would review the statutory language with GPhA ratifiers and provide their feedback by the end of the week. PhRMA agreed to perform a detailed analysis of the FDA draft statutory language. In addition, BIO stated that they would share their proposals for additional statutory provisions at the next meeting. FDA agreed to further review PhRMA's proposed trigger language.