

FDA-Industry Stakeholder Meeting for a 351(k) User Fee Program
July 18, 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

<u>FDA</u>	<u>Center</u>	<u>Industry</u>	<u>Company/Affiliation</u>
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	John Finkbohner	MedImmune
Chris Joneckis	CBER	Jeff Francer	PhRMA
Brian Kehoe	OL	Steven Giuli	Apotex
Andrew Kish	CDER	Sascha Haverfield	PhRMA
Theresa Mullin	CDER	Debbie Jaskot	Teva
Donal Parks	CDER	Laura McKinley	Pfizer
Rokhsana Safaai-Jazi	CDER	Nikhil Mehta	Merck
Manju Thomas	CDER	John Pakulski	GPhA (Novartis/Sandoz)
Kathleen Uhl	CDER	Nic Scalfarotto	Momenta
Ann Wion	OCC	Vince Suneja	Mylan
Bob Yetter	CBER	Howard Yuwen	Shire HGT
<u>HHS</u>			
Roger McClung	ASL		

Views on Separate User Fee Program for Biosimilar Biologics

FDA presented the current level of resourcing involved with 351(k) review activities. Momenta and GPhA members proposed that the biosimilar review program remain a part of PDUFA for fiscal years 2013 through 2017. BIO and PhRMA disagreed with this proposal and stated that although PDUFA resources are currently being directed from the review of innovator medicines to support current biosimilars review, this diversion of resources should only continue through the transitional period until a separate 351(k) user fee program is authorized on October 1, 2012. PhRMA and BIO stated that the text of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and its legislative history show that Congress intended to establish a distinct user fee program for biosimilars, effective October 1, 2012, and that the application of PDUFA fees to biosimilar applications was intended to be a transitional measure, so that FDA could assess user fees on biosimilar applications submitted before October 2012. After the transitional period ends, PhRMA and BIO stated that they will be unable to support the use of PDUFA dollars to fund review of the biosimilars review program.

FDA stated that current resourcing for “originator drug” review activities under PDUFA is also limited. 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 biosimilar review program. In addition, FDA stated that if the biosimilars review program is added to the PDUFA program, special reviews and Biosimilar Product Development (BPD) meetings and milestones could not be included.

GPhA stated that they cannot continue to engage in detailed negotiations regarding volumes and metrics without agreement to parity with the PDUFA user fee program. FDA stated that parity with PDUFA would mean that FDA would not be providing the sort of detailed early review of data and advice to biosimilar sponsors that potential biosimilar application sponsors have requested and that was envisioned for a separate program with its own tailored goals and milestones, to minimize uncertainty during the development phase. Instead, FDA would offer the Type B and C meetings in PDUFA, where sponsors provide their summaries for high-level FDA review, not data for detailed review. The advice FDA would provide would be similarly high-level and caveated, resulting in less certainty for biosimilar sponsors.

Examination of Different User Fee Structures and Funding Scenarios

In follow-up to questions raised by industry in the previous meeting, FDA also presented an analysis of the funding impact of alternative fee structures related to establishment and product fees. The analysis indicated that maintaining a fee structure that included both an establishment fee and product fee would provide consistent funding levels.

To further consider how a development-phase fee (as discussed in previous meetings) might be implemented as part of a biosimilar user fee program, FDA and industry stakeholders reviewed FDA-developed draft concepts for legislation establishing a separate 351(k) user fee program. In addition, PhRMA presented draft statutory language to require a workload study during the first 351(k) user fee program to determine the human and capital costs associated with biosimilar development stage and application review activities in order to support user fee negotiations after the initial five years.

In response to a previous industry request for more specific performance metrics, FDA presented different levels of performance commitments that could be made under different resourcing scenarios (e.g. – user fees added to the FY2011 level of budget authority (BA) for biosimilars and user fees added to the level of BA for Biosimilars requested in the President’s Budget for FY2012). Industry stakeholders discussed the merits of including a statutory condition for BA spending on biosimilars similar to other FDA user fee programs to help ensure a continuing base level of resources for the new biosimilars program. Because there appeared to be a difference of opinion among industry stakeholders, FDA asked that industry stakeholders indicate their perspective on the inclusion of a statutory condition for BA spending on biosimilars. GPhA stated that it did not think that such a condition was aligned with what they believed to be the Congressional intent -- to keep biosimilar review within the PDUFA program. PhRMA and BIO stated that they supported a separate trigger for the biosimilar review program that would allow FDA to build resources for the review of biosimilar products and not divert resources from the review of innovator medicines. PhRMA also stated that creation of such an independent biosimilar user fee program was the reason Congress mandated that FDA negotiate a new biosimilar user fee program in the BPCIA. PhRMA requested that FDA develop a resource projection model that included all of the components of a biosimilar fee structure that had been discussed to date. FDA agreed to provide this sort of projection at the next meeting, based on the assumption that there would be a separate biosimilar user fee program.

GPhA stated that they would hold follow-up discussions with their Executive Committee regarding the items discussed at the meeting, particularly regarding a separate biosimilar user fee program versus inclusion in PDUFA.