



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

September 30th, 2020 | 9:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To provide FDA and Industry perspectives on enhancements for PDUFA VII.

PARTICIPANTS

FDA

Josh Barton	CDER
Yanming Chae	CBER
Angela Granum	CBER
Bharat Khanna	CDER
Ted Liazos	OCC
Alison Lyndaker	CDER
Robert Marcarelli	OO

Industry

E. Cartier Esham	BIO
Carl Garner	PhRMA (Eli Lilly)
Brad Glasscock	BIO (BioMarin)
Kelly Goldberg	PhRMA
Ann Kurowski	BIO (Alkermes)
Kristy Lupejkis	PhRMA
Mark Taisey	PhRMA (Amgen)
Lucy Vereshchagina	PhRMA

FDA Perspective on Financial Aspects of PDUFA VII

FDA presented on the progress made to-date in PDUFA VI in the financial area, as well as the impacts of these changes made in PDUFA VI on the program. FDA also highlighted its goals for the financial aspects of PDUFA VII: to enhance the operational capabilities, efficacy, and agility of the PDUFA program. FDA proposed continuing to advance resource capacity planning, updating the inflation adjustment to accurately account for program costs, enhancing flexibility in the operating reserve, eliminating a problematic limitation on allowable expenditures, streamlining annual reporting requirements, and implementing technical fixes.

Industry Perspective on Financial Aspects of PDUFA VII

Industry stated its goals for the financial aspects of PDUFA VII are to build on financial enhancements included in PDUFA VI, while ensuring transparency, accountability, and the long-term sustainability of the program. Industry proposed to augment the agreements made in PDUFA VI to support continued enhancement of user fee resource management, improve hiring and retention of review staff, and enhance performance reporting.

Industry and FDA agreed that the hiring proposals would be addressed by the Steering Committee.

Industry and FDA agreed to discuss the proposed financial enhancements in greater detail in future meetings.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.