



# Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

November 18<sup>th</sup>, 2020 | 9:00am-12:00pm

Virtual Format (Zoom)

## PARTICIPANTS

### FDA

Josh Barton	CDER
Yanming Chae	CBER
Angela Granum	CBER
Bharat Khanna	CDER
Ted Liazos	OC
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

## MEETING SUMMARY

### Limited Allowable Expenditures Under FDARA Section 905(b)

FDA and Industry discussed the limitation of allowable expenses that under current law will take effect on October 1st, 2023. After the FDA highlighted the anticipated adverse impacts of this section on the program, FDA and Industry discussed if this can be addressed through the PDUFA reauthorization process.

### Inflation Adjustment

FDA and Industry continued discussion on FDA’s inflation adjustment proposal, which is to update the Personnel Costs and Benefits (PC&B) component of the inflation adjustment to represent actual changes in PDUFA-program specific PC&B rather than actual changes in total FDA PC&B. FDA presented on the current mechanisms of the inflation adjustment and provided analysis on the projected impact on fee amounts. FDA noted that this change would support its ability to fund PC&B for existing PDUFA program staffing and is necessary to ensure that FDA can fund pay flexibilities and strategies for staff retention over the long-term. This proposal will be discussed further at a subsequent meeting.

### Resource Capacity Planning Follow-Up

FDA and Industry continued the discussion of the FDA proposal on continuous enhancement of the Resource Capacity Planning capabilities in the PDUFA program. FDA addressed Industry clarifying questions on the use of Resource Capacity Planning. This proposal will be discussed further at a subsequent meeting.

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