



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

December 9, 2020 | 9:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA

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| Josh Barton | CDER |
| Yanming Chae | CBER |
| Angela Granum | CBER |
| Bharat Khanna | CDER |
| Ted Liazos | OC |
| Alison Lyndaker | CDER |
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| Patrick Zhou | CDER |

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

Resource Capacity Planning

FDA and Industry discussed the proposal to continue enhancing the FDA’s resource capacity planning capability. FDA and Industry subgroup members are aligned on draft commitment letter and statutory language. There is alignment that the commitment should focus primarily on providing an implementation plan for maturing the Resource Capacity Planning capability over the course of PDUFA VII. Industry asked questions regarding the FDA’s resource request related to the proposal. The subgroup agreed to further discuss this topic in a subsequent meeting.

3rd Party Study

FDA provided draft commitment letter language responsive to the prior meeting’s discussion on this topic. The language focuses a third-party assessment on financial aspects of the program that will continue to mature over PDUFA VII, namely resource capacity planning. Industry asked clarifying questions regarding the proposed language. The subgroup agreed to follow-up on the topic in the next meeting.

Inflation Adjustment

FDA answered Industry questions regarding the FDA’s inflation adjustment proposal. FDA described its analysis of the impact of the inflation adjustment on the total annual revenue amounts. This proposal will be discussed at a subsequent meeting.

Performance and Financial Reporting

FDA and Industry continued conversation on the FDA proposals to streamline aspects of the annual PDUFA performance and financial reporting.

Health of the Workforce

FDA and Industry continued discussing the metrics that could be provided within an annual report describing the Health of the Workforce. This proposal will be discussed in additional detail at a subsequent meeting.

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