

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

November 4th, 2020 | 12:30pm-3:00pm

Virtual Format (Zoom)

PURPOSE

To continue discussion about FDA and Industry pre-market review process enhancement proposals.

PARTICIPANTS

FDA

Chris Joneckis	CBER
Ted Liazos	CDER
Alex May	CDER
Lubna Merchant	CDER
Mike Pacanowski	CDER
J. Paul Phillips	CDER
Carolina Reese	CDER
Khushboo Sharma	CDER
Jim Smith	CDER
Peter Stein	CDER
Mary Thanh Hai	CDER

Industry

E. Cartier Esham	BIO
Brad Glasscock	BIO (BioMarin)
Kelly Goldberg	PhRMA
Mathias Hukkelhoven	PhRMA (BMS)
Heidi Marchand	BIO (Gilead and Kite)
Mark Taisey	PhRMA (Amgen)

At the sixth meeting of the PDUFA VII pre-market subgroup, FDA and Industry continued discussions about FDA and Industry proposals to enhance the review process. After addressing each topic noted below, both sides agreed to further exploration of each proposal and preparation of responses to questions raised.

Use-Related Risk Analysis (URRA) and Human Factor (HF) Protocol Review

FDA and Industry continued discussions about a proposal to enhance the review of HF protocols and URRAs submitted by Sponsors, especially during combination product development programs. FDA provided additional details about proposed modifications to current PDUFA timelines associated with HF protocol review, including the potential impact on resources. In addition, FDA provided further details about resources potentially needed to implement PDUFA goals related to URRA review timelines, which are not currently supported by the user fee program.

Medical Product Information

FDA and Industry continued discussions about a proposal to enhance the accessibility of FDA-approved medical product information for patients and healthcare providers. Industry provided additional details about proposed public stakeholder engagement events intended to advance the electronic accessibility of medical product information. Industry also expressed interest in

potentially achieving harmonization with international standards related to electronic labeling. FDA noted that discussions of international harmonization were better suited for other venues outside of PDUFA negotiations, such as the International Council for Harmonisation.

Bioinformatics Review Expertise

FDA and Industry continued discussions about a proposal to enhance CBER and CDER's expertise in various aspects of bioinformatics to support the Agency's ability to provide detailed and consistently timed feedback to Industry earlier in the development cycle. FDA provided additional details about resource needs associated with bioinformatics review programs in CBER. Industry asked clarifying questions about potential resources required to expand bioinformatics expertise in CBER and CDER, including alignment with other planned or proposed initiatives to advance the information technology infrastructure across the Agency.

FDA/Sponsor Interactions (Meeting Management)

FDA and Industry continued discussions about proposals for enhanced interactions between FDA and Sponsors for certain types of product development programs, focusing on a specific proposal related to establishing communication best practices for stakeholders on both sides. Industry asked clarifying questions about FDA's current and planned internal initiatives to promote the effectiveness and consistency of such interactions across all review divisions within CDER and CBER. Both sides discussed options for updating existing guidances and practices to address the challenges noted.

Innovative Review Approaches

FDA and Industry continued discussions about a proposal to enhance the efficiency of efficacy supplement review in order to expedite patient access to treatments that may demonstrate a substantial improvement over currently available therapies. FDA asked clarifying questions about Industry's proposed framework for expanding the scope and utilization of innovative review approaches to additional product types and review disciplines.

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