Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

January 14, 2021 | 2:00pm-3:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Krista Carver	Covington & Burling (PhRMA)
Ted Liazos	OC	Cartier Esham	BIO
Jeen Min	CDER	Kelly Goldberg	PhRMA
Carla Vincent	CBER	John Murphy	BIO
		Lucy Vereshchagina	PhRMA

Clarifying the small-business waiver/reduction rule
FDA indicated that it would not pursue this proposed change further.

Clarifying documentation required for financial qualification of orphan drug exemption
FDA and industry continued to discuss options for clarifying the timing and nature of the financial information to be submitted as evidence that an applicant meets financial qualification for the orphan drug exemption from prescription drug program fees.

Same product exemption
FDA and industry continued to discuss options to clarify the application of this statutory provision.

Clarifications to section 736(i)
FDA and industry continued to discuss options to clarify the application of this statutory provision.

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