Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

January 28, 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 documentation required for financial qualification of orphan drug exemption
Industry agreed to FDA's proposed change to the statutory language regarding the timing and nature of the financial information needed to document financial qualification for the orphan drug exemption. This includes changing the timeframe to the prior calendar year for submitting a certification supported by tax returns or, when necessary, other appropriate financial information.

Same product exemption
Industry agreed to FDA's updated proposal regarding the same product exemption to recommend a technical change to the statutory language to codify the FDA's current practice of granting the same product exemption to products that are pharmaceutically equivalent.

Clarifications to section 736(i)
Industry agreed to FDA's proposed technical change to the statutory language to clarify the application of this provision.

Clarifying Transfers to the Discontinued Section
FDA and industry discussed a technical change to clarify the timing by which products are considered listed in the discontinued section of the Orange Book and the CBER and CDER biologics lists.

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