

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Agenda

December 17, 2020 | 11:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA

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Industry

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Within the Finance subgroup, FDA proposed a set of technical fixes to clarify fee administration aspects of the statute for the PDUFA program. This meeting was held to discuss aspects of four of these proposals, which Industry indicated it had issues with and further questions.

Clarifying the small-business application fee waiver

FDA proposed a technical fix to clarify the way small business affiliates would be considered under the small business waiver provision. Industry raised concerns about changing the definition of the term “small business” and the companies that could be considered “affiliates” under this proposal and elsewhere under section 736. The group agreed to revisit these issues in a subsequent meeting.

Clarifying financial documentation for the orphan drug exemption from program fees

FDA proposed fixes regarding the timing and nature of the financial information to be submitted to FDA as evidence that an applicant meets the statutory criteria for the orphan drug exemption from prescription drug program fees. Industry asked clarifying questions and said it would consider the questions internally.

Clarifying same product definition for the same product exemption from program fees

FDA proposed clarifying the definition of “same product” for the same product exemption from prescription drug program fees. Industry indicated that the proposal as drafted would predominantly impact section 505(b)(2) applications and that it did not believe it represented the stakeholders that would be most impacted by the proposal as drafted. FDA indicated that it is important to clarify the application of this provision. FDA agreed to consider this further before the next meeting.

Clarifications to section 736(i)

FDA proposed fixes to clarify this section. FDA addressed clarifying questions regarding this proposal.

FDA and Industry agreed to reconvene and further discuss these proposals in a subsequent meeting.

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