# Prescription Drug User Fee Act (PDUFA) Reauthorization

### FDA and Industry Steering Committee

March 5, 2026 | 3:30pm – 5:00pm

FDA's White Oak Campus, Silver Spring, MD and Virtual Format

## MEETING PURPOSE

To discuss the America First fee incentives and non-orphan indication fee proposal and share subgroup progress updates.

## PARTICIPANTS

| FDA | |
|---|---|
| Andrew Kish | CDER |
| Emily Ewing | CDER |
| Mary Thanh Hai | CDER |
| Amy Ramanadham | CDER |
| Larry Lee | CDER |
| Josh Barton | CDER |
| Sonday Kelly | CBER |
| Christine Hunt | OCC |
| Kate Greenwood | OCC |
| Grace Graham*‡ | OC |

| INDUSTRY | |
|---|---|
| Annetta Beauregard | BIO |
| Rob Berlin* | BIO (Vertex) |
| Steve Berman | BIO |
| Adora Ndu* | BIO (Bridge Bio) |
| Drew Sansone | BIO (Alkermes) |
| Derek Scholes | BIO |
| Mark Taisey | BIO (Amgen) |
| Donna Boyce | PhRMA (Pfizer) |
| Carl Garner | PhRMA (Eli Lilly) |
| Kelly Goldberg | PhRMA |
| Kristy Lupejkis | PhRMA |
| Alison Maloney | PhRMA (Bayer) |
| Katrin Rupalla | PhRMA (J&J) |
| Lucy Vereshchagina | PhRMA |
| Carolyn Herrmann*† | CHPA |
| Marcia Howard† | CHPA |
| David Spangler*† | CHPA |
| Erin Oliver*† | CHPA (Haleon) |

**These participants attended virtually.*
*†These participants left after the discussion of America First fee incentives.*
*‡This participant joined for the discussion of orphan drug fee exemptions/exceptions.*

## MEETING SUMMARY

FDA responded to Industry's counterproposal for the America First fee structure. The FDA and Industry subgroup leads provided summaries of their subgroup's accomplishments from this week. FDA also provided perspectives on FDA's non-orphan indication fee proposal.

## America First Fee Incentives

At the Steering Committee meeting on February 26th, and in response to FDA's proposal to introduce a fee incentive for applications that anchor their phase 1 clinical trials in the United States, Industry counter proposed that the fee for such applications would be half of the application fee. At that meeting, Industry also proposed that FDA and Industry discuss process improvements to streamline the review of investigational new drug applications (INDs).

FDA reiterated the importance of the Agency's America First proposals to the administration and stated that FDA views the proposal to streamline IND review as a separate proposal that FDA cannot engage on within PDUFA negotiations. However, FDA agreed to an incentive-only approach to the fee structure, in which qualifying applications would pay a half application fee and non-qualifying applications would pay the normal application fee. FDA noted that with this approach, the overall fee structure could remain unchanged. FDA also agreed that only applications beginning their clinical development in or after fiscal year 2028 would be eligible for the incentive.

FDA and Industry agreed that additional discussions would be needed to define the eligibility criteria for anchoring phase 1 clinical trials in the United States and qualifying for the fee incentive.

Industry restated that companies go outside the United States for early drug development due to time and cost. Industry also restated their perspective that the timeline for IND review is important to incentivizing early drug development in the United States but acknowledged that FDA would not engage on the proposal to streamline IND review as part of PDUFA negotiations. FDA and Industry briefly discussed challenges with IND review. Industry agreed to consider FDA's proposed agreement for fee incentives and indicate their position at a future meeting.

## Subgroup Progress Updates

The FDA and Industry subgroup leads from the Pre-Market; Chemistry, Manufacturing, and Controls (CMC); and Finance subgroups, as well as the Steering Committee, summarized their accomplishments and plans for next steps. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

## Non-Orphan Indication Fee Proposal

FDA restated the purpose of the Agency's proposal to assess a fee for the first supplement seeking to add a non-orphan indication to a product approved for an orphan indication, and FDA described how the proposal would function. Industry stated it shared the concerns raised by some stakeholders at FDA's public meeting including concerns about potential effects of the proposal on incentives for orphan and limited-population drug research and development. FDA shared that it is the Agency's view that this proposal does not change the incentives to develop orphan

drugs and questioned the notion that an application fee would deter a sponsor from pursuing an additional indication. FDA also noted that other waivers (e.g., public health waiver, barrier to innovation waiver) would still be available.

### Plan for Next Meeting

FDA and Industry agreed to continue discussing FDA's America First proposals and the non-orphan indication fee proposal at upcoming meetings.