inThought Research
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FDA Uncertainty

2025 PDUFA Misses and Ad Board Trends

Drugs with PDUFA delays in 2025:

- **ET-400** (Eton Pharmaceuticals)
- **NVX-CoV2373** (Novavax)
- **troriluzole** (Biohaven)
- **elamipretide** (Stealth Bio)
- **Nucala** (GSK)
- **sebetralstat** (KalVista)

Advisory Board Meetings scheduled in 2025:

- **VRBPAC** (May 22)
- **ODAC** (May 20-21)
- **DSaRM & AADPAC** (Feb 5 rescheduled to May 5)
- **GPSDP** (Feb 20 postponed with no new date)
- **AADPAC** (Jan 10)

inThought is currently tracking 100+ announced PDUFA dates in 2025 as well as advisory meetings, orphan and breakthrough designations, and accelerated approvals. We will continue to report on trends

As with much of the U.S. government, the Food and Drug Administration (FDA) has experienced an increase in uncertainty since the beginning of the year, and it is likely that this uncertainty will persist. At the FDA, leadership changes and the loss of 3,500 staff have sparked concern about delayed drug approvals and disrupted advisory committee meetings. In this paper, we examine the data on the PDUFA date misses and the use of advisory committee meetings, comparing the results to historical precedent. We conclude that, so far in 2025, the PDUFA misses are not significantly more than historical norms.

The number of advisory board meetings so far in 2025 is lower than in 2023 and 2024, but not significantly different from multi-year averages.

Still, the changes and transitions at the FDA could introduce pressure points that shape review dynamics moving forward. This is a dynamic topic with almost daily updates that inThought is monitoring closely. Other topics, like changes to accelerated approval guidelines and incentives programs, are also being tracked.

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Company	Drug	Type	Indication	Original Date	Outcome	Reasoning
Eton Pharmaceuticals	ET-400 (oral hydrocortisone)	Small molecule	Adrenocortical insufficiency	February 28, 2025	Approved on new PDUFA date after review extended by 3 months (May 28)	Requires additional time to conduct a full review of supplemental information provided in December[1]
Novovax	NVX-CoV2373	Protein vaccine	COVID-19 vaccine (full approval)	April 1, 2025	Approved on May 19 after ~7-week delay	Requested more data[2]
Biohaven	Troriluzole	Small molecule	Spinocerebellar ataxia (SCA)	April 30, 2025	Review extended by 3 months (est. July)	Requires additional time to review recent information requests[3]
Stealth Bio	Elamipretide	Small molecule	Barth syndrome	April 30, 2025	Rejected after ~4-week delay	Required additional time for review, note this is not first application for approval for this drug[4]
GSK	Nucala (mepolizumab)	Monoclonal antibody	COPD	May 7, 2025	Approved on May 22 after ~2-week delay	None provided
KalVista Pharmaceuticals	Sebetralstat	Small molecule	Hereditary angioedema (HAE)	June 17, 2025	New decision expected in ~4 weeks	Due to heavy workload and limited resources

1. Eton Pharmaceuticals press releases (Feb 2025, May 2025)
2. WSJ report (April 2025)
3. Biohaven press release (May 2025)
4. Stealth Bio press releases (April 2025, May 2025)
5. KalVista Pharmaceuticals press release (June 2025)

A Clustering of Missed PDUFAs

So far in 2025, the number of PDUFA misses is not significantly more than historical norms

In the first half of 2025, the FDA missed or extended decision dates for at least six therapies. Each delay is attributed officially to standard review rigor. Most delays have now been resolved, resulting in decisions that were delayed 2 weeks to 3 months. Historically, the FDA has missed 3-11% of PDUFA dates for novel drug approvals (by the FDA's definition of "novel"; a drug with an active ingredient never before approved or marketed in the U.S.). In 2025 to date, 14 novel drugs have been approved meeting their PDUFA dates. One novel drug, KalVista Pharmaceuticals' sebetralstat, was delayed with a new decision expected ~1 month after the original PDUFA date.

Advisory Committee Use in Transition

The FDA's advisory committee infrastructure, critical for evaluating novel approvals, has also been impacted by the uncertainty with formerly robust planning processes becoming strained. Some meetings, like the flu vaccine strain review, were canceled entirely then eventually rescheduled. A Novartis advisory committee meeting for Fabhalta was deemed no longer necessary and a meeting to discuss opioids was delayed. The number of advisory board meetings to date this year is low, but not historically low, noting that the last two years had an exceptionally high number of ad boards. Overall, only 5 advisory committee meetings have been scheduled so far this year, lagging far behind the number scheduled per year in 2023 and 2024 (an average of 41 ad boards per year). However, if we look longer term, the 5 scheduled so far this year are not that far off the average of 17 per year in 2016-2022. The number of meetings will likely continue to remain lower in the coming years, closer to historical norms.

While the data suggests the system is still functioning as intended at the moment, the confluence of leadership turnover, staffing

constraints, and shifting priorities at the FDA will continue to heighten concerns about PDUFA misses and lack of advisory board input. It will be important to monitor for:

- Slower review timelines and slower responses from FDA staff
- Fewer advisory committee meetings, with decisions on important drugs made without as much expert input
- Uncertainty in incentive programs such as orphan drug designation, breakthrough therapy designation, and the possibility of accelerated approvals, especially in the gene therapy space
- Use of AI tools to facilitate and expedite decision making at the FDA

Advisory Committee Meeting Tracker