After receiving notice from the FDA that an application cannot be approved, would you consider pursuing an Accelerated Approval Pathway, instead?

If that sounds surprising to you, consider the Complete Response Letters for NDA 215244 and BLA 761211 via the link below.

After clinical trials failed to meet planned endpoints for these treatments for rare and serious diseases, FDA recommended the applicants consider pursuing the Accelerated Approval pathway. The letters don't detail the entire development program, so it's not clear whether Accelerated Approval could have been an option earlier.

What is clear, however, is that having these letters in the public domain offer a window into drug development.

Note that my comments and analysis are based on the FDA complete response letters that were released publicly on September 4, 2025:
https://www.fda.gov/news-events/press-announcements/fda-announces-real-time-release-complete-response-letters-posts-previously-unpublished-batch-89

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