

What's trending in the 'Previously Unpublished' Complete Response Letters?

FDA recently released 89 “previously unpublished” complete response letters (CRLs) associated with pending or withdrawn applications. According to their announcement: “Each of these CRLs detail specific safety and effectiveness deficiencies identified by the FDA as preventing the application from receiving approval.”

<https://www.fda.gov/news-events/press-announcements/fda-announces-real-time-release-complete-response-letters-posts-previously-unpublished-batch-89>

I've reviewed every letter and analyzed key aspects for trends, which I plan to share in a series of informal posts on LinkedIn.

The letters cover the period from January 12, 2024 to August 18, 2025.

Note that although there are 89 letters, one CRL appears to be a duplicate, so 88 unique letters were provided. i.e., Two versions of the CRL for BLA 761303 were uploaded into the archiving system 2 minutes apart. The later version was referenced for this assessment.

I hope you'll join me on this journey!

Disclaimer

First and foremost, some context! Everything stated here is my opinion only and based only on publicly-available information.