

Why It Matters

Do you remember where you were when you heard that the FDA released the Complete Response Letters (CRLs) for unapproved products? I do! This was huge!!!

Until these letters were released last week, there was a long-held belief (legal constraint?) that CRLs are not in the public domain until a product is approved. Companies share their summary of CRL comments in a press release. But it was generally not the purview of the FDA to put this information out there.

But with one keystroke, suddenly, that's not how it works anymore! The public now has access to a batch of FDA complete response letters for pending and withdrawn applications. We can study them to understand how the FDA is acting on submissions – and not just from the products that make it through successfully. As more letters are released, there will be more data to put regulatory actions in context.

I sincerely appreciate the folks who made this release of information possible. I think it's a very positive step that anyone can now pursue a hobby of following new drug regulation.

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unpublished-batch-89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