

FDA Release of Complete Response Letters Raises Confidentiality, Disclosure Questions But Offers Insights for Development

July 11, 2025

On July 10, 2025 — in a move it characterized as “radical transparency” — the U.S. Food and Drug Administration (FDA or Agency) published over 200 Complete Response Letters (CRLs), which are issued when the Agency determines that it will not approve a New Drug Application (NDA) or Biologics License Application (BLA). We analyze the implications of this development for life sciences companies and their investors.

CRLs traditionally have not been routinely publicly disclosed. Historically, some CRLs for applications that were ultimately approved have been included in publicly available approval documents, but that has been on a case-by-case basis due to commercial sensitivity. According to FDA, the now-released batch of letters pertains to applications initially submitted between 2020 and 2024 and approved since; it appears, however, that some may predate 2020. In addition, the Agency has signaled that it may be considering releasing additional CRLs, including for applications that have not been approved, although such disclosures typically face steep obstacles in light of confidential commercial information and trade secret limitations imposed by law.

As a threshold matter, affected companies should first consider whether a released CRL is, in fact, being released for the first time or if it was already publicly available. The Agency’s decision also raises several potential issues:

Do any newly public letters contain confidential commercial or trade secret information?

Although FDA states that “the CRLs were redacted for trade secrets and confidential information,” recent [reports](#) have indicated that FDA’s resources for doing this were significantly affected by reductions in force at the Agency earlier this year.

Accordingly, affected companies should scrutinize newly released CRLs to determine whether they contain unredacted confidential commercial or trade secret information. It may be that redactions occurred historically, before this reduction in force, or that the CRLs were successfully redacted more recently. If, however, sponsors believe that confidential commercial information or trade secrets have been publicly released, they should speak with counsel about potential remedies.

Do the letters contain information that raises questions about previous disclosures made by the applicants to whom the letters were sent?

FDA's announcement also raises questions about previous regulatory and CRL-related disclosures and whether sponsors "misrepresent the rationale behind FDA's decision" in such disclosures.

The current CRL release provides an opportunity for the shareholder plaintiffs' bar to search for inconsistencies (or arguable inconsistencies) in an attempt to identify a securities fraud claim. Additionally, with the Agency's note that it is considering proactively publishing additional CRLs, including for applications under active review, this is a good reminder that companies should always be mindful of statements (and the level of detail in such statements) about communications and developments with FDA, particularly those that characterize FDA communications or interactions or refer to alignment with FDA or confidence in FDA approval, as well as risks related to FDA approval.

Do the released letters contain information that can be used to inform development strategies or future interactions with the Agency?

The FDA Commissioner noted that a benefit of releasing the letters is to enhance transparency into its decision-making, given that the public, "drug developers and capital markets alike want predictability."

FDA's decision to publish these letters does potentially provide drug developers with an opportunity to more clearly understand the Agency's thinking and expectations across a range of precedents. This information can and should be incorporated into new and existing drug development strategies in an effort to reduce the time it takes to bring new drugs to market and to bring additional predictability to outcomes. CRLs can delay drug approvals by months, and in some cases years, and having insight into other companies' challenges should help companies avert those same challenges.

¹ [OpenFDA: Press Release: FDA Embraces Radical Transparency by Publishing Complete Response Letters \(Jul. 10, 2025\).](#)

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