FDA's Real-Time Release of Complete Response Letters ("CRLs"): Disclosure Considerations for Life Sciences Companies

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FDA's new practice of releasing Complete Response Letters ("CRLs") in near real time, including for pending or unapproved applications, represents a material shift for the agency. A CRL is issued at the conclusion of FDA's review of a new drug application ("NDA") or biologics license application ("BLA") when the agency determines that it cannot approve the application in its current form. CRLs typically identify the deficiencies precluding approval, including issues relating to safety or efficacy, statistical analysis, product quality, and good manufacturing practices compliance, and may include recommendations for addressing those deficiencies.

Historically, CRLs for unapproved products were treated as confidential, affording companies significant discretion in how to characterize FDA's feedback in public disclosures. Under the new approach, FDA may publish a redacted version of a CRL shortly after issuance, enabling investors and other stakeholders to assess a company's public statements against FDA's contemporaneous written communications. In fact, FDA has acknowledged that one goal of the new practice is "ensuring sponsors provide complete and contextualized information in communications to investors and shareholders."[1]

This development has significant implications for life sciences companies. In particular, it is likely to increase scrutiny of press releases, earnings-call remarks, investor presentations and SEC filings relating to pending or unapproved applications with CRLs. Company statements about the significance of a CRL, the likelihood or timing of approval, or the nature of the underlying deficiencies may now be tested against FDA's own statements on a much shorter timeline. It may heighten exposure to securities litigation and enforcement risk, where company statements are alleged to be incomplete or misleading when compared with the released CRLs.

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[1] FDA News Release, FDA Announces Real-Time Release of Complete Response Letters, Posts Previously Unpublished Batch of 89 (Sept. 4, 2025).

FDA's New CRL Disclosure Policy

In July 2025, FDA announced an initiative to "embrace radical transparency" by publishing CRLs in a centralized, publicly accessible format.[2] FDA said it intended to provide the public with "significantly greater insight into the FDA's decision-making and the most common deficiencies cited that sponsors must address before their application is approved." In connection with the announcement, FDA released more than 200 CRLs issued between 2020 and 2024 associated with drugs and biologics that were ultimately approved. Although many of those letters had been available in some form in approval packages or other FDA materials, FDA's July initiative placed them in a centralized and much more accessible location.

The more consequential step came in September 2025. FDA announced that it would release newly issued CRLs promptly after sending them to NDA and BLA applicants, published 89 previously unreleased CRLs associated with pending or withdrawn applications and stated that, upon approval of an application, it would release all CRLs associated with that application.[3] FDA also indicated that it intends to continue publishing historical CRLs associated with withdrawn or abandoned applications.

This policy represents a departure from FDA's long-standing practice. Historically, CRLs for unapproved products were treated as confidential portions of unapproved applications. As a practical matter, the substance of the letters became public only in relatively narrow circumstances—for example, through a Freedom of Information Act request subject to extensive redactions, through voluntary disclosure by the company or, in some cases, through the approval package if the product was eventually approved. Especially for unapproved or still-pending products, companies generally retained more control over how the market understood the basis for FDA's action.

FDA's centralized CRL database now states that it contains CRLs associated with both approved and unapproved NDAs and BLAs and that the agency will continue adding CRLs as they are issued.[4] Although the CRLs are redacted to remove confidential commercial information, trade secrets and personal information, the letters nevertheless provide meaningful insight into FDA's rationale for not approving a product. In particular, while information relating to manufacturing processes and product quality is often extensively redacted, descriptions of clinical, clinical/statistical

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2 FDA News Release, FDA Embraces Radical Transparency by Publishing Complete Response Letters (July 10, 2025).

3 FDA News Release, FDA Announces Real-Time Release of Complete Response Letters, Posts Previously Unpublished Batch of 89 (Sept. 4, 2025).

4 openFDA, Complete Response Letters (last accessed Apr. 14, 2026).

and regulatory deficiencies are generally less heavily redacted. The company and product name also remain unredacted.

Deficiencies cited by FDA in the CRLs released to date frequently fall into several categories, including facility inspection findings, product quality issues (such as analytical validation deficiencies, stability data gaps and container closure concerns) and clinical or statistical deficiencies. These categories are not mutually exclusive, and many CRLs identify multiple bases for non-approval.

A recent citizen petition underscores emerging industry concern with FDA's new approach to CRL disclosure. On April 20, 2026, an unnamed pharmaceutical company filed a petition requesting that FDA significantly modify its practice of publishing CRLs for unapproved applications. The petition argues that FDA should, at a minimum, provide sponsors with advance notice of any intended disclosure and a meaningful opportunity to review and propose redactions before a CRL is made public.

The petition further contends that FDA's current process creates a risk that commercially sensitive information will be disclosed and that publication of improperly redacted CRLs may lead to misinterpretation of FDA's conclusions regarding unapproved products. At the same time, FDA is seeking to reinforce its transparency initiative: in its fiscal year 2027 appropriations justification, the agency requested explicit authority from Congress to disclose certain information regarding safety and efficacy data deficiencies identified in CRLs.[5] Taken together, the citizen petition and FDA's legislative proposal highlight a growing tension between the agency's push for increased transparency and industry concerns regarding confidentiality, context, and potential market impact.

Implications for Disclosures

FDA's real-time publication of CRLs materially alters the context in which life sciences companies communicate with investors regarding regulatory developments. Companies should assume that any CRL they receive will be made public shortly after issuance and that their public statements may be evaluated against the contents of the CRL.

Investors and other members of the public may now form, in much closer to real time, their own views about whether a CRL reflects a potentially remediable manufacturing or process issue or a more fundamental concern that may not be easily remedied. The publication of CRLs associated with pending applications also gives competitors and

[5] FDA Congressional Justification for the FY 2027 Budget.

investors more timely insight into a company's development program and commercial strategy.

Disclosures that omit, minimize or selectively characterize FDA's stated concerns may be subject to scrutiny by regulators and private litigants. In particular, discrepancies between FDA's articulated rationale for non-approval and a company's public disclosures may be cited in securities complaints or enforcement actions.

These risks are reinforced by prior research indicating that companies have historically omitted a substantial portion of FDA's concerns in public communications regarding non-approval. In the July press release, FDA cited a 2015 FDA-authored journal article finding that companies' public announcements omitted most of FDA's stated safety and efficacy concerns.[6] FDA noted that according to the study, companies avoided mentioning 85% of the agency's safety and efficacy concerns and that, when FDA called for a new clinical trial to address safety or efficacy concerns, that information was omitted in approximately 40% of company announcements.

Securities Litigation and Enforcement Considerations

The increased transparency resulting from FDA's publication of CRLs is likely to affect both private securities litigation and regulatory enforcement. Plaintiffs may seek to rely on CRLs to support claims under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5, alleging that prior disclosures were materially false or misleading in light of information contained in subsequently released CRLs. Similar claims could also be made under the Securities Act of 1933 in connection with disclosure by life sciences companies in registered offerings of securities. More broadly, plaintiffs will have access to more detailed information allowing them to make more targeted and credible requests for books and records. The information in the CRLs may also help plaintiffs develop more detailed and substantiated allegations in derivative and other shareholder suits.

Regulators, including the Securities and Exchange Commission and the Department of Justice, may similarly compare a company's public disclosures with FDA communications in assessing potential disclosure violations. Where material discrepancies are identified, such differences may be cited as evidence of scienter or inadequate disclosure controls.

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[6] FDA News Release, FDA Embraces Radical Transparency by Publishing Complete Response Letters (July 10, 2025); Peter Lurie et al., Comparison of Content of FDA Letters Not Approving Applications for New Drugs and Associated Public Announcements from Sponsors: Cross-Sectional Study, BMJ 2015;350:h2758.

In addition, the publication of previously confidential CRLs—particularly those relating to unsuccessful or abandoned programs—may give rise to retrospective claims as investors (including shareholder activists) reassess prior disclosures in light of newly available information.

Key Takeaways for Life Sciences Companies

In light of FDA's revised approach, life sciences companies should consider the following actions:

Actions to Consider Today

- **Assess existing disclosures against FDA feedback to date.** Companies often receive unfavorable FDA feedback before a CRL is issued. Where that feedback suggests approval may be delayed, unlikely, or subject to substantial additional work, companies should carefully assess whether continued public statements about timing, approvability, or the status of review remain accurate and complete. Companies should also ensure that those statements are appropriately and explicitly framed as statements of opinion and/or forward-looking statements accompanied by meaningful cautionary language identifying important factors that could cause actual results to differ materially from the company's predictions. Additionally, companies should ensure that any relevant risk factors do not frame as hypotheticals any events that have already materialized.

- **Maintain a careful written record with FDA.** Companies should expect that their interactions with FDA may later be scrutinized against the public record. Companies therefore should preserve a clear internal record of what FDA said, how the company understood it, and whether the company raised any objections, clarifications or corrections. That record may become important if the company later needs to defend its public statements or explain differences between its description of events and the published letter.

- **Assess exposure from historical, previously unpublished CRLs.** Companies with older CRLs that have not yet been made public should consider in advance how those letters might be used if FDA later releases them. A newly public CRL may prompt investors and other stakeholders to revisit earlier statements about a product candidate, potentially creating securities-fraud or other litigation theories based on alleged inconsistencies.

Actions to Consider After Receiving a New CRL

- **Assume the CRL will become public.** Companies should approach CRL-related disclosures with the expectation that a redacted version of FDA's actual letter may be posted shortly after issuance. SEC disclosures (especially risk factor disclosures and forward-looking statement cautionary language), press releases, talking points, internet and social media communications and investor materials should be drafted with that prospect in mind.

- **Use precise and balanced language in public communications.** Companies should avoid phrasing that is vague, promotional or capable of being read as minimizing FDA's concerns. Particularly now that the market may be able to compare the company's language to the published CRL itself, ambiguous statements about the significance of the deficiencies or the expected path to approval carry greater risk.

- **Consider whether additional context is warranted.** Some companies may conclude that a simple statement announcing receipt of a CRL is no longer enough. Depending on the circumstances, a company may wish to explain the categories of deficiencies identified, describe prior interactions with FDA, outline its planned next steps or, in some cases, address areas in which it disagrees with FDA's assessment.

- **Review the full disclosure record.** The relevant universe of public statements extends well beyond the press release announcing a CRL. Risk factors in annual and quarterly reports, earnings-call remarks, company websites, investor presentations and offering materials should all be considered in light of new material regulatory information.

- **Coordinate FDA and securities-law review.** Because CRL disclosures now sit squarely at the intersection of FDA regulation and securities law, public and nonpublic statements alike should be reviewed jointly by regulatory and securities counsel. A multidisciplinary review process is increasingly important to ensure that the company's characterization of FDA's action is both accurate and disclosure-law compliant. Recall that statements in response to publication of a CRL may potentially constitute material nonpublic information and should therefore be reviewed for compliance with Regulation FD, insider trading law and policies and general antifraud principles.

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FDA's decision to release CRLs in near real time increases transparency in the drug approval process but also introduces additional complexity for life sciences companies. Companies must now account for the likelihood that FDA's written assessments will be made public and may be compared directly with their own disclosures. A disciplined approach to regulatory communications and securities disclosure will be critical.

Please do not hesitate to contact us with any questions.

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