Skadden

The Nucleus: Life Sciences Regulation and Enforcement Updates

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FDA Pivots on Publishing Complete Response Letters, Raising SEC Disclosure and Securities Litigation Implications

Executive Summary

- **What is new:** The FDA announced it will publish Complete Response Letters (CRLs) in a move toward "radical transparency," including the potential for real-time publication of CRLs for unapproved products.
- **Why it matters:** This shift could change the securities disclosure and litigation landscape for publicly traded life sciences companies, increasing risks related to SEC disclosure obligations and exposure to securities litigation.
- **What to do next:** Companies should carefully assess and re-evaluate their existing disclosures, particularly under risk factors and management's discussion, to confirm they adequately address the risk of a potentially adverse outcome and any known trends or uncertainties.

FDA's Announcement

On July 10, 2025, the U.S. Food and Drug Administration (FDA) announced that it was embracing "radical transparency" by publishing more than 200 Complete Response Letters (CRLs) — letters the agency issues to a sponsor when it does not approve a New Drug Application, Abbreviated New Drug Application or Biologics License Application. CRLs often contain confidential and critical information regarding the feasibility of drug development, clinical trials, or manufacturing issues, including details that many companies choose not to publicly disclose. While FDA touted its publication as a major transparency initiative, the 200 published letters did not reveal much to the public because they were for drugs that had already been approved. As a result, the relevant approval packages — including CRLs — were already publicly available and, in the end, only 22 of the letters had not been published previously.

While the released letters themselves may not have been as remarkable as touted, FDA's July announcement notably explained that the agency was moving to publish the CRLs because "[d]rug developers and capital markets alike want predictability." FDA Commissioner Marty Makary has since echoed this statement twice. In a July 11, 2025, op-ed in the Washington Post, he said, "[a]s a part of a broader agenda toward radical transparency, we believe getting rid of the black-box culture of FDA decisions will be good for business and, most important, good for patients," and previewed that the agency is in the process of publishing more CRLs "from its archives." Shortly thereafter, on an episode of the FDA Direct podcast released on July 17, 2025, Commissioner Makary stated that "the vision is that someday you'll release [CRLs]

in real time" and that one of the main reasons FDA is pushing to disclose CRLs is that "capital markets like predictability." Taken together, these statements strongly suggest that FDA may be undertaking a major policy pivot — motivated by input from Wall Street, which is not a traditional FDA stakeholder — and that the first 200 CRLs were only the tip of the iceberg.

Below we discuss how an increase in CRL publications, particularly in "real time," could change the securities disclosure and litigation landscape for companies developing new drugs and biologics.

Potential Authority for Future CRL Publication

Historically, FDA has not published CRLs at the time they are issued and has published them only after a drug is approved. FDA recognized CRLs as containing substantial confidential and proprietary information of the applicant, and FDA's regulations at 21 CFR Part 314.430 (for products approved under a New Drug Application) and 21 CFR Part 601.51 (for products approved under a Biologics License Application) state that FDA cannot acknowledge the existence of an application until it is approved, or unless "the existence of the application … [h]as been previously publicly disclosed or acknowledged." Proactively publishing a CRL would inherently involve acknowledging the existence of an unapproved application, which FDA has declined to do in the past.

FDA has not explained the regulatory basis for a potential change in policy, but it is possible that the agency is relying on the fact that many publicly traded companies routinely disclose the filing of applications with FDA through press releases and/or filings with the U.S. Securities and Exchange Commission (SEC). Although FDA has not said as much, the agency appears to be assuming that this practice would allow the agency to publish a CRL for a disclosing company's application because the application would have been "publicly acknowledged" as required under the regulations. It is far less clear whether FDA would have regulatory authority to publish a CRL if a sponsor has not publicly disclosed the filing of the underlying application.

FDA also has not addressed the more specific portion of its relevant regulations, which state that, if an application's existence has been disclosed, "no data or information contained in the application … is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue." Perhaps FDA is choosing to view a CRL as such a "summary," but it has not explained as much. Instead, it has asserted that "although the company owns the proprietary information … they don't own the thinking of the FDA reviewers … That's the public domain." Of course, applicants may not see it quite the same way. As such, in the event that the agency moves forward with publishing CRLs for applications that have not yet been approved, it would not be surprising to see litigation over whether it has regulatory authority to do so.

SEC Disclosure Considerations

A move by FDA to immediately publish CRLs for unapproved products could force public companies to consider the risk that SEC disclosure obligations around the submission of an application to FDA may lead to the earlier publication of a CRL, if one is issued, compared to historical practice. SEC disclosures are typically made in companies' annual reports on Form 10-K and quarterly reports on Form 10-Q, although certain specified types of events require real-time disclosure through current reports on Form 8-K.[1] While the SEC does not have a specific, line-item disclosure requirement relating to CRLs, or regulations that pertain specifically to FDA-regulated companies, SEC regulations generally require that publicly traded companies disclose "material" developments. In this context, information is generally deemed material if a reasonable investor would consider it important in making an investment decision. Similarly, under federal securities laws, materiality is assessed based on whether there is a substantial likelihood that the disclosure of the omitted information would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.

Under these standards, for annual or quarterly reports, companies are required to consider the materiality of any changes to their operational, financial, legal and other risks or any known trends or uncertainties that are likely to significantly impact the company's financial condition or results of operations. Current reports have a specific list of items that are presumptively deemed material (such as the appointment of a new director), but a current report also can be used to voluntarily disclose any significant event that the company considers to be important. Notably, because SEC regulations also require that disclosures in SEC filings not be materially false or misleading, a company that voluntarily discloses the filing of an application with FDA may have an obligation to continue to update such information for any material developments so that, in light of the circumstances, the previous disclosure is not materially false or incomplete. In this regard, companies should consider the level of detail provided in initial disclosures relating to an FDA application because, once such information is publicly available, companies may set an expectation that a similar level of detail will be provided on any significant developments going forward.

[1] For foreign private issuers, the key SEC requirement is annual reports on Form 20-F, and interim updates may be required under their home country rules.

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Materiality determinations involve both qualitative and quantitative assessments, and while many companies historically have chosen to disclose the filing of an application with FDA, the materiality of an individual application is likely to vary significantly with the size of a company. For instance, for a small company that does not have any marketed products or has only a small number of products on the market, the submission of an application to FDA may be more likely to be deemed material and the company may decide to issue a press release or file a current report on Form 8-K close in time with the submission. Even if no such disclosure is made, the small company should consider whether it needs to disclose the submission of an application to FDA in its annual and quarterly reports as a material development. On the other hand, a large, established pharmaceutical company that has dozens or hundreds of marketed products may not always disclose the submission of an application to FDA on Form 8-K or even in its annual or quarterly reports.

As noted above, if FDA is looking to publish CRLs more freely going forward, it is possible that the agency will view a company's press release or SEC filing, whether voluntarily made or not, which discloses the submission of an application as proof that the existence of application has been "previously publicly disclosed or acknowledged." In turn, the potential to trigger publication of a CRL by FDA if one is issued may impact disclosure strategy more generally. While companies vary in their approaches to disclosing regulatory interactions — such as meetings with the relevant review division — prior to the filing of an application and while an application is under review, the majority do not disclose the details of those interactions. If FDA in fact adopts "radical transparency" by beginning to disclose CRLs for unapproved products in anything close to real time, applicants will need to take this into consideration in their disclosure strategy during the pre-submission period. This is especially true if interactions with FDA leading up to the submission of the application have been mixed or if the clinical approach is novel. In certain instances, FDA's disclosure of CRLs for unapproved products may result in investors questioning whether the company should have provided disclosures in earlier SEC filings regarding what the company knew or reasonably expected at the time about the ongoing application process, especially following an adverse or surprising outcome.

As a general matter, drug developers have multiple opportunities to discuss development programs, study outcomes, manufacturing issues and application contents with FDA before formal application review begins. In certain instances, sponsors may choose to submit applications against FDA advice, or that contain aspects FDA has said will be a "review issue" with regard to approval. In these circumstances, sponsors may appreciate that this approach may lead to a CRL. Due to confidentiality concerns, however, sponsors historically may not have disclosed substantial detail about pre-application interactions. As a result, investors often have been unable to gauge the likelihood of a CRL in advance. Although sponsors likely would disclose the receipt of a CRL in such circumstances, they often do not disclose the full details of the CRL to investors. The looming risk that investors may have full access to the range of deficiencies listed in a CRL going forward could change disclosure strategy leading up to application submission.

In addition, the views of new FDA leadership have led to midstream changes in approval standards for some innovative drugs, leading to CRLs for applications that FDA had previously indicated were on track for approval. One CEO of a company that recently received a CRL for a gene therapy said, "we are surprised by this FDA decision … The issues highlighted in the CRL were not raised by the agency during the mid- and late-cycle reviews. Additionally, we had also aligned on the design of the confirmatory study." This statement highlights the disclosure challenges smaller companies may face navigating the new FDA. At each quarterly or annual filing, companies should carefully assess and re-evaluate their existing disclosures, particularly under risk factors, the business section, and management's discussion and analysis of financial condition and results of operations (MD&A), to confirm the disclosures adequately address the risk of a potentially adverse outcome and any known trends or uncertainties at the time of the filing relating to a pending application.

Evaluating disclosure strategy may be further complicated by the fact that not all CRLs are created equal. Some are minor and easy to remedy, and it is clear from the CRL that an approval is likely upon resubmission. Others can require redoing a clinical program, changing manufacturers or going after a different indication, all of which can involve a lengthy, expensive process. Knowing that all of this may ultimately become public, companies may have a hard time preparing investors for what they learn when a CRL is ultimately published.

Securities Litigation Considerations

Particularly for CRLs that raise more substantial issues, their publication by FDA is likely to lead to more scrutiny from investors and greater exposure to private securities litigation.

Publicly traded life sciences companies are frequent targets of opportunistic strike suits by the plaintiffs' bar, usually because of potentially large stock price drops following negative public disclosures regarding products or drug candidates under development. Shareholder securities class action suits are often filed alleging, for example, that a company's positive statements about a drug candidate's efficacy and safety were rendered false and

misleading when the company failed to disclose the full extent of adverse event data. In another common scenario, shareholders allege that a company's positive statements about a drug candidate's prospects for approval by FDA were rendered false and misleading when the company failed to disclose negative interim communications with FDA in connection with seeking drug approval.

These investor complaints usually allege that the purported "truth emerged" following a negative public announcement, such as the publication of negative clinical trial data, or an FDA decision not to approve the drug, such as a CRL. If FDA's "radical transparency" initiative takes hold and FDA begins publishing CRLs while applications are pending, companies may find themselves at a greater risk of being sued for securities fraud based on allegedly insufficient disclosure of concerns articulated by FDA in the CRL. These lawsuits, which are frequently filed after an approval is denied, may be more likely to be filed earlier in time, as CRLs will allow investors to look for perceived inconsistencies between a company's prior public disclosures about the efficacy and safety of the drug and likelihood of FDA approval, on the one hand, and the deficiencies identified in the CRL, on the other. Companies may also find themselves at greater risk for serial suits: If a stock price drop and securities suit follow the disclosure of a CRL while an application is still pending or there are ongoing discussions with FDA, it is possible that a second stock price drop and securities suit will follow if the CRL is published later, while the review process is still ongoing.

While they are unlikely to eliminate the risk altogether, disclosures of the type described above can mitigate the risk of securities suits or, at a minimum, mitigate the risk that such suits survive a motion to dismiss. Courts routinely dismiss securities suits against public life sciences companies where, for example, the company adequately warns investors about the various potentially adverse outcomes from FDA review, including denial of an application or approval of a drug with a narrower label than sought by the company. Companies should therefore carefully analyze their disclosures concerning the assumptions underlying their expectations regarding FDA review as such disclosures may be helpful in defending allegations that the companies intended to deceive investors about approval. Companies should also pay particular attention to whether their disclosures regarding the range of potential FDA review outcomes or the likelihood of approval have adequately included meaningful cautionary language indicating that certain statements were forward-looking, as the Securities Exchange Act provides a safe harbor for such statements.

Conclusion

If FDA in fact moves toward broader and more contemporaneous disclosure of CRLs, it is likely that, over time, the market and drug companies will adjust. In the meantime, however, some companies may find themselves in a precarious situation. For example, companies generally disclose the receipt of a CRL for an application that they have previously disclosed, but often do not give full details of the deficiencies identified in the CRL based on the confidential nature of that information and a belief that the deficiencies are likely to be remedied. It is also not unusual for securities litigation to be filed if a stock drop follows a company's disclosure that FDA has issued a CRL. Those types of cases could become far more complicated in the future if FDA chooses to publish a CRL containing the full details of the deficiencies while litigation is pending. Companies in this situation likely have not amended their disclosure practices to account for CRL publication, and may already be embroiled in a lawsuit. If the true nature of the CRL is highly detrimental for a development program, but investors are not aware of the details of the CRL, FDA's disclosure of such a critical CRL could lead to further stock drops, additional lawsuits and other potential exposure based on an alleged failure to disclose material information.

FDA's potential move to more broadly disclose CRLs appears to be driven by the agency's view that at least some companies have not been fully forthcoming to investors about the nature of the CRLs they have received. Whether or not FDA is correct in this regard, a move to embrace "radical transparency" by broadly publishing CRLs in close to real time would likely create substantial risks for publicly traded life sciences companies when it comes to SEC disclosure requirements and related securities litigation.

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