FDA's Push for "Radical Transparency": Key Takeaways from the Agency's Publication of Complete Response Letters



On July 10, 2025, the U.S. Food and Drug Administration (FDA) **announced** publication of over 200 complete response letters (CRLs) issued in response to applications submitted to FDA for approval of drugs or biologics between 2020 and 2024. The FDA has described this move as a step toward the Agency's "broader initiatives to modernize and increase transparency."

CRLs are formal communications sent to applicants when the FDA has completed its review of an application but determined that it cannot approve the application in its current form. Until now, the Agency has only made CRLs available as part of larger approval package files on the Drugs@FDA online database (i.e., after product approval). While the CRLs released this week continue to be limited to approved products—and have been redacted to remove trade secrets and confidential commercial information—the FDA has, for the first time, provided these documents in a central database on **openFDA**. A few key highlights:

- While many of these CRLs have already been disclosed as part of the "Other Action Letters" section of publicly posted drug approval packages, some have not.
- There are multiple CRLs for supplemental New Drug Applications (sNDAs) that had not yet been disclosed, reflecting the fact that approval packages for sNDAs are not consistently posted in the same manner as original NDA approvals.
- Some of these CRLs were issued for products approved before 2020, suggesting that the CRL database scope may exceed the time frame identified in the FDA's announcement.
- At least one CRL has been posted for a product approved as recently as June 2025. For this product, no other portions of the approval package (beyond the label and approval letter) have yet been posted on Drugs@FDA.

Notably, the FDA's announcement references a 2015 analysis conducted by FDA researchers, which found that sponsor disclosures of CRLs did not consistently provide full detail regarding the Agency's specific concerns. The FDA's highlighting of this finding, coupled with the Agency's statement that it plans to publish additional CRLs from its archives, warrants attention from sponsors, especially public company sponsors.

Sponsor disclosures regarding CRLs are always closely scrutinized, and the FDA's move to (1) centralize and regularly release CRLs, and (2) publish additional CRLs (e.g., those for sNDAs, or very recently approved products) is likely to invite further scrutiny—by investors, analysts,

competitors, and patient communities. Sponsors should prepare disclosures around receipt of a CRL with the expectation that the CRL itself will become public upon approval of an application. Even where a product is ultimately approved, third parties may make comparisons between a sponsor's characterization of a CRL and the later-posted CRL itself.

According to the FDA, publication of CRLs is just one step in the Agency's broader transparency push. Our team will continue to monitor the frequency and scope of additional releases, as well as any opportunities for interested stakeholders to provide comments or feedback to FDA on its plans.

California Law Requiring Female Directors on Public Company Boards Held Unconstitutional



A California court has **held** that California **Senate Bill 826**, which required that "publicly held" corporations that listed a California address for their principal executive offices on the cover page of their Form 10-K reports must have specified numbers of female directors by certain dates, violates the California constitution and has enjoined the use of California taxpayer funds to carry out the 2018 law. This ruling follows the **decision** of another California court in April 2022 holding that California **Assembly Bill 979** violated the California constitution and the issuance of a similar injunction preventing California from using taxpayer funds to implement that law. Assembly Bill 979 was enacted in 2020 to add a requirement that publicly held corporations that were already subject to Senate Bill 826 also have specified numbers of directors from "underrepresented minorities," as defined in the law, by certain dates. If the state does not appeal these decisions and California appellate courts do not overturn these decisions, it appears that both of these legislative initiatives to promote more diverse representation on public company boards will have come to an end.

Read the **client alert**.

European Life Sciences Deal Trends



In Europe, life sciences deals increased over the last few years with a strong acceleration in 2021. As a result, the market wonders whether this is just a pick or rather a steady trend which will impact our market in the future as well. Analyzing the reasons of such growth and comparing it with more mature markets such as the U.S. comfort us in thinking that it is just the beginning for continental Europe.

The U.S. life sciences market has been very strong over the past decades and is seen as very mature. The level of venture investments, which are now very much standardized, licensing, M&A and IPOs is very high, both in volume and in number.

For the last ten years or so, the life sciences UK market attracted U.S. investors and an increasing number of growth funds. After a first step of development through venture investments, such companies are now ready for licensing, M&A and IPOs. This is also the trend that we anticipate for the European market even if each country or region still has its own specificities (in particular UK, Germany, France and the Nordic Countries).

Read the **client alert**.

SEC Chairman's Comments Signal Likely Changes to Rule 10b5-1 Trading Plans



Rule 10b5-1 trading plans have faced increased scrutiny since the onset of the COVID-19 pandemic and the corresponding public focus on stock sales by executives of public **life sciences companies**. On June 7, 2021, SEC Chairman Gary Gensler continued that scrutiny when he delivered prepared **remarks** to the *Wall Street Journal*'s CFO Network Summit concerning Rule 10b5-1 trading plans and his view that "these plans have led to real cracks in our insider trading regime." Mr. Gensler outlined four potential reforms that the SEC staff is considering to address those "cracks".

Read the full insight **here**.

Conducting Internal Investigations – In-House Counsel's Guide



Whether you are a director, or a member of an in-house legal, human resources, or internal audit team, there are sensitive scenarios that occur daily in life sciences companies that trigger the need for an internal investigation.

Goodwin has crafted an "In-House Counsel's Guide" that sets forth a framework of best practices and key considerations for effective internal investigations, including special subject matter and industry-specific considerations; preserving the attorney-client privilege and attorney work product protection; the need for disclosure to and coordination with auditors, regulators, and others; and conducting investigations remotely.

Read the **In-House Counsel's Guide — Conducting Internal Investigations**

The Rise of SPACs in Biotech



The use of special purpose acquisition companies, or SPACs, as an alternative to the traditional IPO process has gained significant traction over the past few years and in 2020 in particular. While these transactions have historically focused more on the tech space, with top-tier biotech investors such as Perceptive Advisors, RA Capital, RTW Investments, Foresite Capital and 5AM Ventures serving as SPAC sponsors, SPACs have gained more popularity in the biotech industry.

A SPAC is a blank check company that goes through the standard IPO process to raise capital with the purpose of using the proceeds to acquire one or more business targets or their assets. The IPO proceeds are placed in a trust account to be used at a later date to fund the De-SPAC transaction (the process through which a private target combines with the SPAC and begins trading as a public company).

The use of De-SPAC transactions to bring a private company public is gaining in popularity due to the benefits that such transactions offer. These benefits can include:

- **More Streamlined**: a De-SPAC transaction typically involves both a merger with the SPAC and a concurrent private investment in public equity, or PIPE, which raises additional capital from outside investors and potentially existing investors of the target company and SPAC. Both the SPAC merger and the PIPE are signed and announced simultaneously, which allows for a more streamlined process than the typical two-step crossover financing followed by an IPO.
- **Mitigate Risk**: because valuation is agreed towards the beginning of the De-SPAC process, a De-SPAC transaction helps to mitigate the potential market volatility risk that is inherent with traditional IPOs.

Given the success of recent De-SPAC transactions in the biotech space, with eight (8) De-SPAC transactions with biotech companies closed in 2020, coupled with the peaked interest of biotech investors, the use of De-SPAC transactions by private biotech companies to go public will likely continue to grow in 2021.

Life Science Companies Participate in Convertible Bond Surge



Life science companies have been among the biggest users of convertible debt financing in the first half of 2020. As highlighted in our recent **Client Insight article**, life science, technology and other traditional high-yield debt issuers were the biggest participants in the record issuance of convertible bonds. Through June 30, 2020, U.S. companies raised over $64 billion in 114 convertible bond

offerings with most of the surge occurring in the second quarter. May 2020 saw a record $20.7 billion of convertible debt issued. The previous record monthly high for convertible issuance was $19.2 billion in May 2001.

The strength of the convertible bond market was due in part to high share price volatility in equity markets and wide credit spreads above comparable U.S. Treasuries in debt markets. These market conditions make convertible debt an attractive source of capital versus equity follow-ons and high-yield debt offerings. One notable life science transaction in the first half of 2020 was BridgeBio Pharma Inc.'s (BBIO) pricing of an upsized $550 million (from $375 million) convertible debt offering that featured a 2.50% coupon. Additionally, BBIO entered into capped call transactions to raise the effective conversion prices of the notes and hedge risk of equity dilution upon conversion. The strength of the convertible debt market enabled BBIO and other life science companies to raise capital at attractive levels. In the first half of 2020, the average coupon rate for all convertible debt offerings was 1.25% with an average conversion premium of 37%.

Given that share price volatility and credit spreads are still at historically high levels, convertible bond offerings are expected to remain a popular source of financing for life science issuers in the second half of 2020.

Think Your Drug is Safe and Effective? Not So, Says the SEC



For life sciences companies who are or are looking to become publicly traded in the U.S., one of the most frequent comments that we see from the SEC as part of their review process is the following:

You make several assertions regarding the safety and efficacy of certain of your product candidates. Safety and efficacy determinations are solely within the authority of the FDA (or applicable foreign regulators). Please revise these statements to remove statements/inferences that your product candidates are safe and/or effective. We will not object to a discussion of whether your product candidates were well-tolerated or discussion of whether trial endpoints were met.

Given the frequency with which verbiage such as "safety data" or "efficacy data" is used among drug developers, investors and even the FDA itself, this position by the SEC often catches companies by surprise. However, the SEC has consistently taken the view that such references are not appropriate in companies' SEC disclosures. Importantly, even oblique references to "safety" or "efficacy" (for instance, forward-looking statements regarding the expected safety profile of a product candidate) will often draw an SEC comment.

Fortunately, there are typically relatively straightforward ways to resolve this comment. For instance, rather than referring to a drug's efficacy, companies can instead refer to whether it met trial endpoints or demonstrated activity. Similarly, in lieu of referring to a drug's safety, companies can refer to its tolerability or its adverse event profile observed to date.

While this topic is typically a point of emphasis in the IPO process, we often find that companies become less vigilant about avoiding "safety" and "efficacy" references in their subsequent Exchange Act periodic reports (not to mention their press releases and investor presentations). However, we frequently see this comment come up in SEC reviews of public company periodic reports, and proactively steering away from references to "safety" and "efficacy" can be a useful way to remove some low-hanging fruit that might otherwise draw an SEC comment.

UK Government Announces 'Future Fund' Financing Package for Start-Up Technology and Life Sciences Companies



The UK Government has announced a new fund that provides financing to UK start-ups and scale-ups in the form of a convertible loan which is invested directly by the Government. For further detail on the fund please see: https://www.gov.uk/guidance/future-fund.

Read the Alert >>

Update: U.S. Health and Human Services Clarifies Broad Eligibility of Providers for Payments Under $30 Billion CARES Act Healthcare Provider Relief Fund

As discussed in Goodwin's prior Client Alert, on April 10, 2020, the U.S. Department of Health and Human Services (HHS) began disbursing $30 billion to Medicare providers and suppliers under the Public Health and Social Services Emergency Fund (PHSS Emergency Fund). HHS is requiring providers to agree to certain terms and conditions or return the payments. A number of the terms and conditions created some confusion as to whether providers who have not provided services directly related to COVID-19 may keep the payments. HHS has now clarified that providers may keep payments distributed under the PHSS Emergency Fund regardless of whether they have or will provide services directly related to COVID-19.

Read the Alert >>