DOJ-HHS Announces False Claims Act Working Group, Emphasizes Healthcare Fraud Enforcement Priorities

The Trump administration recently announced the renewal of a new cross-agency collaboration between the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) in the form of the **DOJ-HHS False Claims Act Working Group**. The Working Group will be jointly led by Deputy Assistant Attorney General (DAAG) of the Commercial Litigation Branch Brenna Jenny, HHS Acting General Counsel Sean Keveney, and HHS Office of Inspector General Acting Chief Counsel Susan Edwards, and will include the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity and U.S. Attorneys' Offices.

Read the full alert **here.**

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:

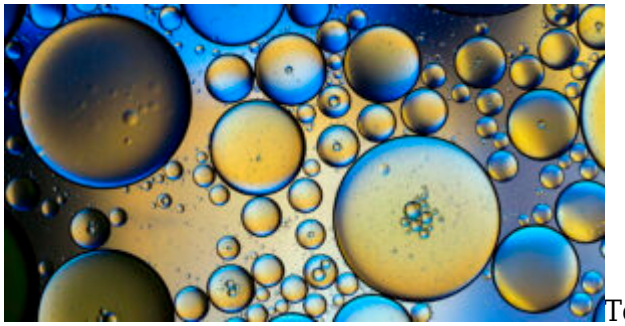
- While many of these CRLs have already been disclosed as part of the "Other Action Letters" section of publicly posted drug approval packages, some have not.
- There are multiple CRLs for supplemental New Drug Applications (sNDAs) that had not yet been disclosed, reflecting the fact that approval packages 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.

A Look Ahead in Life Sciences: What We Are Tracking in the Third Quarter of 2025 and Beyond

 To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q3 2025 updates **here**.

One Big Beautiful Bill Act – Tax Implications for Life Sciences Industry

On July 3, 2025 Congress passed, and on July 4, 2025 President Trump signed into law, the One Big Beautiful Bill Act (**OBBB**), which extends various expiring tax provisions from the Tax Cuts and Jobs Act and introduces a variety of other substantial tax law changes. The developments highlighted below are expected to have particular impact on life sciences transactions and business operations.

Read the full alert **here.**