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SEC and FDA Formalize Information-Sharing Framework

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On August 31, 2026, the US Securities and Exchange Commission (SEC) and US Food and Drug Administration (FDA) entered into a memorandum of understanding (MOU) establishing a framework for sharing nonpublic information concerning "FDA-regulated products and activities" in support of the agencies' respective regulatory and enforcement responsibilities.

The MOU is particularly relevant for life sciences companies because it expressly mentions sharing information that bears on securities disclosures. While information sharing between the two agencies is not new, the MOU serves as a reminder that the SEC will use information shared by the FDA to evaluate whether companies may have made false or misleading statements "about the status of FDA review, product approvals, clinical trial results, or other matters within the FDA's regulatory authority that could affect investors' decisions," and that such information could ultimately form the basis for an enforcement action. The MOU also signals increased enforcement scrutiny on FDA-related disclosures. SEC Enforcement Director David Woodcock recently noted, "From the Division's perspective, FDA-related disclosures have a significant impact on our markets, and fostering a closer partnership with the FDA goes hand-in-hand with our responsibility to enforce applicable disclosure requirements under the securities laws."

A formal framework based on existing legal authority

The MOU does not create new authority for information sharing between the agencies. That authority already exists under 21 CFR § 20.85 (which permits the FDA to disclose records exempted from public disclosure to other federal agencies), as well as 17 CFR § 240.24c-1 (which permits the SEC to provide nonpublic information to certain third parties upon a showing that the information is needed and subject to confidentiality assurances).

Instead, the MOU creates a formal operational framework for the agencies to share information under those regulations. The MOU states that the agencies will establish mechanisms for receiving information requests and securely providing nonpublic information. The agencies also will maintain designated points of contact, including at least one SEC point of contact in both the Division of Corporation Finance and the Division of Enforcement. The FDA's Office of the Chief Counsel will serve as the FDA lead for referrals of potential violations to the SEC.

The MOU seeks to make the information-sharing process more routine and efficient. The agencies commit to responding to information requests in a timely manner and contemplate developing standard operating procedures and templates to facilitate such requests.

The MOU preserves limitations under § 20.85 regarding disclosure of trade secret and confidential commercial or financial information. In addition, the MOU contains substantial confidentiality protections, including procedures for FOIA requests and other compulsory processes, restrictions on personnel access, and an express provision that the SEC cannot further disclose information shared by the FDA without the FDA's written permission.

The MOU is effective for three years and may be extended, modified or terminated.

MOU signals increased – but not new – cooperation between the agencies

As noted, the MOU does not create new authority, and the SEC has historically relied on information from the FDA in connection with investigations concerning biopharmaceutical companies. Two enforcement actions serve as examples of instances in which the SEC obtained information from the FDA, and inconsistencies between that information and the companies' FDA related disclosures led to liability.

On February 5, 2026, the SEC charged CBA Pharma, a private biopharmaceutical company, and its executives for allegedly conducting a fraudulent securities offering in which they misrepresented to investors that CBA Pharma's drug, CBT-1, "was effective in treating cancer by preventing multidrug resistance to cancer treatments," and "was in the final stages of obtaining approval from the ." The SEC alleged that CBT-1 was never close to FDA approval, the FDA had informed the company that its drug application for CBT-1 lacked evidence of efficacy, and, by April 2023, the FDA told the company that it had withdrawn CBA Pharma's drug application for CBT-1.

In another example, on May 15, 2023, the SEC charged public biopharmaceutical company Quanta, and its CEO, for misrepresenting the FDA staff's response to the company's proposed clinical trial of a scorpion venom product called Escozine as a COVID-19 treatment. The SEC alleged that the company's press releases misrepresented "that the FDA staff's response validated the clinical study," and that the FDA had "recognized the potential therapeutical benefits of Escozine."

In the SEC's press releases announcing each of these actions, it noted its appreciation of the FDA's assistance. This language indicates that the FDA provided information to the SEC in connection with the investigation. The MOU signals increased cooperation between the agencies, and with the designation of points of contact, a more streamlined process for information sharing.

Implications for FDA's informal intended use safe harbor

The MOU may have implications for the already uncertain boundary between securities disclosures and FDA-regulated promotional communications. The FDA has generally refrained from treating routine investor-directed communications as promotional labeling. In the preamble to its 2020 proposed intended use rule, the FDA stated that SEC filings containing "required disclosures of development activities or potential or actual sales for an unapproved use" would not by themselves provide evidence of an off-label intended use. But this informal safe harbor has never been formally codified, and the FDA's 2021 final intended use rule states that the agency may consider "any relevant source of evidence" – not just traditional promotional materials – in determining a product's intended use, which could encompass statements in SEC filings, earnings calls, investor presentations and press releases.

With the SEC and FDA now committing to routine information sharing and closer coordination under the MOU, the practical scope of any existing informal safe harbor may narrow further. Information shared between the agencies could prompt the FDA to more regularly examine investor-facing statements for promotional content, or the SEC to scrutinize whether such statements are consistent with a company's FDA submissions. Companies should therefore consider the potential dual-audience nature of their public communications and ensure that investor disclosures are drafted with an awareness of both the securities law and FDA regulatory frameworks.

Key takeaways

Although framed as a bilateral information-sharing agreement, the MOU appears principally designed to facilitate the SEC's access to nonpublic FDA information. While publicly traded life sciences companies would have been wise even before the MOU to assume that any nonpublic information in the FDA's possession would be readily accessible by the SEC (indeed, the SEC has historically received information from the FDA in connection with investigations regarding company disclosures), the MOU emphasizes the SEC's focus on this disclosure area and increases the likelihood that discrepancies between a company's securities disclosures and FDA-facing information will be more readily identified and investigated by the SEC. Woodcock's recent statements further signal that the Enforcement Division will focus on FDA-related disclosures given their "significant impact on our markets." It would therefore be prudent for companies to revisit their disclosure control processes to ensure that information communicated to and received from the FDA is appropriately considered when preparing FDA-related securities disclosures.

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