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FDA-SEC Issues Memorandum of Understanding. How Does this Change their Information Sharing and What Does the Future Hold for Life Science Companies?

On August 31, 2026, the U.S. Food and Drug Administration (FDA) and the U.S. Securities and Exchange Commission (SEC) entered a Memorandum of Understanding (MOU) to enhance cooperation in their regulatory and enforcement responsibilities to improve market oversight and compliance.

SEC's press release included the following supporting statements from the SEC and FDA:

> SEC Chairman Paul S. Adkins said: "FDA-related disclosures by public companies have a significant impact on our markets. … The FDA is a valuable partner in our efforts to administer and enforce applicable disclosure requirements under the federal securities laws, and I look forward to further strengthening our partnership through the MOU."
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> Acting FDA Commissioner Kyle Diamantas said: "We are proud to partner with the SEC to enhance transparency across the life sciences sector. … Streamlining our information-sharing helps protect both the patients who rely on FDA-regulated products and the public trust that drives healthcare innovation."

The new MOU builds upon a prior sharing of letters between the FDA and the SEC in February 2004, which lasted until the new MOU, to enhance Inter-Agency Cooperation. First, in the letter from the FDA to the SEC, the FDA proposed:

1. A centralized process for referrals from the FDA to the SEC, when FDA staff believes an FDA-regulated firm has disseminated false or misleading statements to the investment community about the status of review or other matters within

the FDA's regulatory authority,
2. Designating the Associate Commissioner for Regulatory Affairs as the FDA liaison along with identifying SEC contacts in each of FDA's main organizational units.
3. Formal training by FDA to help the SEC understand how the FDA responds to requests for non-public information or testimony and vice versa.
4. Using electronic communication for such requests when practicable.
5. Continuing to share non-public information consistent with current practice but adding a "blanket" authorization to the FDA employees identified by the SEC contacts to enable information sharing.

In response, the SEC sent a letter from the SEC to the FDA, agreeing with FDA's suggestions and further designating the Deputy Director of the SEC Division of Enforcement to handle referrals on behalf of the SEC as initiated by the FDA.

What's New and Enhanced?

At a high level, some of the new and enhanced features of the new MOU:

- Whereas the prior process appeared to be initiated by FDA, this the revised MOU is more of a two-way process, where either agency may initiate the process.
- The new MOU designates FDA's Office of Chief Counsel as FDA's lead for legal issues relating to the MOU, referrals related to potential violations, and when an SEC matter is in a civil or judicial adjudication.
- In addition to the previously identified FDA points of contact, FDA will have one contact from its Office of Chief Counsel and the SEC will have one from its Division of Enforcement and one from its Division of Corporation Finance.
- The FDA's and SEC's legal provisions for information sharing are included, indicating provisions related to when non-public information may be shared and when it may not be shared without FDA's permission, and related confidentiality assurances provided by each agency in addition to establishing appropriate safeguards to prevent unauthorized disclosures of confidential information. Some FDA information, e.g., trade secret or confidential commercial information will still not be shared with the SEC, except as provided by related statutory provisions.
- Provisions added regarding the secure transmittal of information between the FDA and the SEC, as well as an agreement that the information from FDA cannot

be disclosed without FDA's written permission.

- Provisions added for the FDA and the SEC to coordinate Freedom of Information Act-related requests, subpoenas, discovery requests, litigation complaints or motions, or other court or administrative body orders requiring the production of non-public information, including requests by duly authorized Committees of the U.S. Congress.
- Provisions added for how the agencies will cooperate to either protect or seek a means for further disclosure of non-public information, consistent with applicable laws and their respective regulatory and enforcement responsibilities.
- Finally, the MOU indicates that the sharing of non-public information consistent with the MOU does not constitute public disclosure nor a waiver of confidentiality or any applicable privilege to such information.

Fraud by Life Science Companies is a SEC Priority

False and misleading statements by life science companies are an SEC priority under the current Administration. For example, on March 12, 2025, the SEC announced charges against Massachusetts-based biopharmaceutical company Allarity Therapeutics, Inc. According to the SEC, Allarity learned in February 2020 that the FDA had concluded that the company's data concerning its cancer drug was insufficient to support approval and recommended that Allarity conduct another Phase III clinical trial. The SEC alleged that Allarity did not disclose this information to investors and instead made false and misleading statements, while continuing to raise monies from investors concerning: the drug's efficacy, the likelihood that of FDA approval, and the company's prospects.

Impact of the New MOU and What's Missing

While the prior letter exchange appeared to indicate that FDA wanted to proactively address situations where life science companies provided inaccurate or misleading information, the new MOU recognizes that this is a two-way street where either agency may identify companies and their executives responsible for such disclosures for closer scrutiny regarding FDA's communications and regulatory developments. The MOU seeks to provide the SEC with greater transparency regarding FDA's activities related to life science companies but appears to leave a

higher amount of discretion to the FDA, which must provide written consent for any disclosure of non-public information. The MOU, however, does not change the security laws or disclosure obligations for either agency.

For regulated life science companies, the MOU suggests that the SEC and FDA intend to pay greater attention to public disclosures to ensure that such disclosures provide an accurate overall summary of regulatory actions, especially when provided during critical trading windows. Any disclosures related to significant FDA developments warrant extra internal scrutiny to align with internal documentation of such developments and care must be taken to provide balanced information including critical feedback or setbacks such as clinical holds. The SEC, for instance, has pursued alleged failures to disclose before critical events like capital raises. Insider trading compliance should also be evaluated with the new MOU backdrop, where nonpublic clinical results may be cited and can now be more easily confirmed by a more transparent disclosure process between the agencies. The MOU also indicates that the SEC may use non-public information to bring actions even though FDA's written permission to disclose is required and cannot be withheld if compelled by law or judicial order.

The MOU applies only to requests after the effective date of the MOU and will not modify any pending requests, The MOU will continue for three years and may be extended, modified, or terminated by mutual consent upon a 30-day advance notice by one party to the other.

We will continue to monitor the impact of the new MOU in future SEC-related actions but reiterate the MOU did not substantively change existing statutory protections or disclosures for FDA-related regulatory information, though it may have made the process to share information easier between the two agencies for future actions.

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