Simpson Thacher

Memorandum

SEC and FDA Announce New MOU on Cooperation

September 8, 2026

Public companies regulated by the U.S. Food and Drug Administration ("FDA") may encounter additional scrutiny of their statements to investors as a result of the FDA's new three-year memorandum of understanding ("MOU") with the U.S. Securities and Exchange Commission ("SEC").[1] While this is not the first time that the two regulators have issued formal statements of their commitment to protect investors from misrepresentations about the status of FDA product reviews, the MOU signals SEC interest in public companies' statements about their non-public communications with the FDA. We discuss the MOU and implications for life sciences companies below.

The MOU

On August 31, 2026, the SEC and the FDA formalized a process for sharing non-public information in the interest of pursuing their respective missions. Effective immediately, the regulators commit to facilitate the exchange of information related to FDA-regulated products and activities.

In 2004, the SEC and the FDA had previously memorialized a process for FDA assistance to the SEC with respect to FDA referrals to the SEC for possible securities laws violations and sharing non-public information.[2] The new MOU aims to build on this collaboration, providing a framework for sharing information related to persons and firms who manufacture, distribute and sell FDA-regulated products. The regulators will establish a secure mechanism for sharing non-public information, subject to existing confidentiality laws and regulations and disclosure limitations for trade secret and confidential commercial information. "Non-public information" is defined in the MOU as information not generally available to the public and that is provided, received, or otherwise shared between the SEC and the FDA. The MOU relies on existing information-sharing regulations, which enable the SEC to use non-public information to review public company filings for potential issues under securities laws and for SEC enforcement investigations, proceedings and actions.

Implications for Life Sciences Companies

The MOU underscores the need for collaboration among outside counsel, investor relations and regulatory personnel to ensure that statements about FDA-regulated products and activities are not false or misleading. The SEC may now be able to more quickly verify statements made in public filings and issue comments on confidential

[1] SEC Press Release, SEC and FDA Announce MOU to Bolster Cooperation and Ensure Market Integrity (Aug. 31, 2026), SEC and FDA Announce MOU to Bolster Cooperation and Ensure Market Integrity.

[2] SEC, Press Release, SEC and FDA Take Steps to Enhance Inter-Agency Cooperation (Feb. 5, 2004), SEC and FDA Take Steps to Enhance Inter-Agency Cooperation.

submissions from companies seeking to go public. Such statements may cover topics such as FDA feedback on product approvals and clearances, clinical trial design, the adequacy of the clinical trial data provided to the FDA, the risk-benefit profile of a product, FDA concerns about particular investigational, pre-commercial products and other FDA matters that could affect investment decisions.

Compared to the 2004 initiative between the SEC and the FDA, this MOU contains a stronger commitment to provide timely responses. The MOU emphasizes that the parties will respond to requests for information in a timely manner and permits follow-up requests to be handled by phone. The FDA also commits to promptly respond to SEC requests for permission to disclose non-public information if such disclosures are required by law or judicial order. The MOU's formal mechanism for non-public information requests and designation of principal points of contact will also facilitate requests for non-public information.

Conclusion

This MOU signals the SEC's interest in using existing authorities to more quickly validate FDA-related statements that public companies are making to investors. FDA-regulated public companies should ensure such statements are accurate, complete and consistent with confidential FDA discussions and have been reviewed by appropriate personnel and counsel familiar with those discussions.

For further information regarding this memorandum, please contact one of the following authors:

WASHINGTON, D.C.

Vanessa K. Burrows
+1-202-636-5891
vanessa.burrows@stblaw.com

William R. Golden
+1-202-636-5526
wgolden@stblaw.com

NEW YORK CITY

John C. Ericson
+1-212-455-3520
jericson@stblaw.com

Richard A. Fenyes
+1-212-455-2812
rfenyes@stblaw.com

Hui Lin
+1-212-455-7862
hui.lin@stblaw.com

Karen Hsu Kelley
+1-212-455-2408
kkelley@stblaw.com

Lesley Peng
+1-212-455-2202
lpeng@stblaw.com

Jacob Madden
+1-212-455-3283
jacob.madden@stblaw.com

SAN FRANCISCO

William B. Brentani
+1-415-426-7220
wbrentani@stblaw.com

LOS ANGELES

Rebecca Rose
+1-310-407-6982
rebecca.rose@stblaw.com