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SEC and FDA Unite: New MOU Creates Coordinated Regulatory and Enforcement Framework

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KEY POINTS

- The SEC and FDA executed an MOU on August 31, 2026, establishing a formal framework for sharing nonpublic information between the two agencies related to FDA-regulated products and activities.
- Under the MOU, both agencies may share information proactively or on request, with FDA-to-SEC sharing governed by 21 C.F.R. § 20.85 and SEC-to-FDA sharing governed by 17 C.F.R. § 240.24c-1.
- The MOU formalizes historically ad hoc interagency coordination and creates institutional infrastructure that will make cross-agency information sharing faster, easier, and more systematic.
- FDA communications — including warning letters, Form 483 observations, import alerts, and clinical hold letters — that companies previously viewed as purely regulatory matters could now surface in an SEC investigation or disclosure review.
- The MOU is effective for three years from August 31, 2026, and may be extended, modified, or terminated by mutual written consent or by either party on 30 days' notice.

On August 31, the U.S. Securities and Exchange Commission (SEC) and the U.S. Food and Drug Administration (FDA) executed a Memorandum of Understanding (MOU) establishing a formal framework for sharing nonpublic information between the two agencies. The MOU takes effect immediately upon signature and reflects a significant step toward coordinated regulatory and enforcement activity at the intersection of public health and financial markets.

WHY THIS MOU MATTERS

Public companies engaged in FDA-regulated activities, including pharmaceutical, biotechnology, medical device, food and cosmetics, and tobacco companies, now face a meaningfully increased risk that information in the FDA's possession will find its way to the SEC, and vice versa. The MOU is designed to help each agency detect situations where a company may have made false or misleading statements to investors about matters within the FDA's regulatory purview, such as:

- The status of FDA review or product approvals;
- Clinical trial results;
- Manufacturing compliance; or
- Distribution or marketing activities.

KEY PROVISIONS

Broad Scope of Information Sharing. Each agency commits to sharing "appropriate information" related to FDA-regulated products and activities and the persons and firms that manufacture, distribute, and sell them. Information may be shared proactively or in response to a request from the other agency.

Dedicated Points of Contact. Each agency will designate at least one principal point of contact to facilitate requests. The SEC will maintain contacts in both its Division of Enforcement and its Division of Corporation Finance. The FDA will maintain a contact in its Office of the Chief Counsel (OCC). This dual-track structure signals that the MOU will be used for both disclosure review and active enforcement investigations.

Governing Legal Framework. Information sharing operates within existing legal constraints:

- FDA-to-SEC sharing is governed by 21 C.F.R. § 20.85, which permits disclosure of records otherwise exempt from public disclosure, subject to specific statutory carve-outs for trade secrets and confidential commercial information (21 U.S.C. §§ 331(j), 360j(c), 360ll(d), 360nn(e), and 387f(c)).
- SEC-to-FDA sharing is governed by 17 C.F.R. § 240.24c-1, which requires FDA to provide appropriate confidentiality assurances.

Strict Confidentiality Controls. Nonpublic information shared under the MOU may not be further disclosed without the providing agency's written permission. The MOU includes detailed protocols for responding to FOIA requests, subpoenas, congressional inquiries, and other compulsory process, in each case requiring prompt notification to the providing agency and cooperation in asserting applicable privileges.

Three-Year Term. The MOU is effective for three years from August 31, 2026, and may be extended, modified, or terminated by mutual written consent, or by either party on 30 days' notice.

PRACTICAL IMPLICATIONS FOR PUBLIC COMPANIES

The MOU formalizes what has historically been ad hoc coordination between these two agencies and creates institutional infrastructure that will make cross-agency information sharing faster, easier, and more systematic. Companies should consider the following:

- **Disclosure accuracy is more important than ever.** Statements about FDA approval status, clinical trial progress, manufacturing compliance, or regulatory timelines that reach the investing public (whether through SEC filings, earnings calls, or press releases) may now be scrutinized simultaneously by both agencies.
- **FDA interactions carry SEC implications.** Warning letters, Form 483 observations, import alerts, clinical hold letters, and other FDA communications that a company might previously have viewed as purely regulatory matters could now surface in an SEC investigation or public company disclosure review.
- **Internal investigation and privilege considerations.** Because the MOU expressly addresses compulsory process and congressional inquiries, companies facing either an FDA inquiry or an SEC investigation should be alert to the possibility that the other agency has received or may receive related information. Maintaining clear privilege protections over internal communications and investigation materials is critical.
- **Fintech and financial intermediaries take note.** Any firm that securitizes, finances, or otherwise provides capital to FDA-regulated companies should be aware that the SEC's access to FDA nonpublic information may inform disclosure reviews of those financial transactions as well.

For questions about the SEC-FDA MOU and its implications for your company, please contact Jay A. Dubow or Ghillaine A. Reid, co-leaders of Troutman Pepper Locke's Securities Investigations + Enforcement Practice Group.

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