FDA and SEC Open a New Information-Sharing Channel: Implications for Public Life Sciences Companies

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On August 31, 2026, the U.S. Food and Drug Administration ("FDA") and Securities and Exchange Commission (the "SEC") announced a new three-year Memorandum of Understanding (the "MOU") establishing a formal framework for the agencies to exchange nonpublic information concerning FDA-regulated products, activities and companies.[1] For pharmaceutical, biotechnology and medical-device companies that are publicly traded or otherwise are SEC reporting companies, the agreement could have significant implications for disclosures concerning clinical trials, FDA interactions, product approvals, manufacturing and inspection developments, and other regulatory matters that may be material to investors. The SEC emphasized the market significance of FDA-related public-company disclosures in announcing the MOU.[2]

The MOU gives the SEC a more direct mechanism to compare companies' public disclosures with FDA's nonpublic regulatory record. It expressly permits the SEC to use FDA information in public-company filing reviews and in enforcement investigations, proceedings and civil actions. FDA's Office of the Chief Counsel will lead referrals of potential violations, while the SEC will maintain points of contact in its Divisions of Enforcement and Corporation Finance.

Although the MOU does not change the securities-law disclosure standard, it likely makes it easier for SEC staff to test a company's account of an FDA interaction against FDA's own contemporaneous record.

Enhancement of Long-Standing FDA/SEC Relationship. FDA-SEC coordination is not new. In 2004, the agencies adopted measures to enhance an existing cooperative relationship. Those measures included a centralized FDA procedure for referring possible securities-law violations to the SEC, designated FDA points of contact for SEC requests, technical assistance to the SEC's Division of Corporation Finance and the continued sharing of nonpublic information with the SEC.[3]

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1 SEC & FDA, Memorandum of Understanding (Aug. 31, 2026).

2 SEC, SEC and FDA Announce MOU to Bolster Cooperation and Ensure Market Integrity (Aug. 31, 2026).

3 SEC, SEC and FDA Take Steps to Enhance Inter-Agency Cooperation (Feb. 5, 2004).

As we wrote in 2018, that cooperation has long required public life sciences companies to assume the SEC may compare their public statements about regulatory developments against what FDA actually communicated to the company.[4] Our prior article highlighted enforcement matters involving statements about clinical-trial data and FDA interactions and recommended that significant regulatory disclosures be reviewed by an interdisciplinary team including securities, FDA, scientific and investor-relations personnel.

The new MOU formalizes and operationalizes that relationship. It establishes procedures for requests and secure transfers, assigns responsibility for FDA referrals, requires designated SEC contacts and contemplates standard operating procedures and model requests. The SEC requests must describe the information sought and its intended use and include restrictions on further disclosure.

The arrangement is also reciprocal: the SEC may provide nonpublic information to FDA upon a showing of need and appropriate confidentiality assurances.

What Can FDA Share—and What Remains Protected? The MOU does not create new statutory information-gathering authority. Rather, FDA's disclosure of information to the SEC is governed by an existing FDA regulation—21 C.F.R. § 20.85—that permits FDA to share certain records exempt from public disclosure with another federal agency subject to trade-secret and confidentiality protections.

Under this provision, information protected from public disclosure is not necessarily barred from interagency sharing. Section 20.85, however, preserves statutory restrictions on disclosure of certain trade secrets and confidential commercial or financial information, and the MOU likewise provides that FDA will not share information where disclosure is prohibited by applicable law. Thus, the key question is not simply whether information is confidential or exempt from public disclosure but whether federal law prohibits FDA from sharing it with another agency.

The MOU also limits further disclosure. FDA-shared information is restricted to authorized personnel with an official need to know, and the SEC generally may not disclose it outside the agency without FDA's written permission. However, the MOU contemplates that FDA generally will grant such requests if disclosure is required by law and that the agencies will work together if the information will be used in a manner that would require further disclosure (such as in an enforcement proceeding). Accordingly,

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[4] Debevoise & Plimpton LLP, The SEC/FDA Nexus: Best Practices for Publicly Traded Life Sciences Companies, Bloomberg Law (Nov. 19, 2018). Among other recommendations, the article addresses scrutiny of statements concerning clinical-trial results and FDA review, significant inspection findings, disclosure controls and multidisciplinary review involving FDA and securities counsel.

companies should assume the SEC most likely will be free to use the FDA information as it would any other information obtained in its investigations. The MOU also addresses FOIA requests, subpoenas and other third-party demands and provides that interagency sharing does not constitute public disclosure or waive confidentiality or applicable privileges.

The practical question, then, is how much useful regulatory information remains shareable after legally protected information is withheld or redacted.

What FDA Information May Reach the SEC? FDA correspondence may be particularly significant because it can combine commercially sensitive sponsor information with FDA's own scientific, regulatory or manufacturing conclusions. Even if protected trade-secret information is withheld, a redacted communication may still reveal that FDA identified concerns more serious than the company's public statements suggested, requested another clinical trial, questioned an approval timeline or identified significant manufacturing or compliance issues.

The potential universe of information that may be shared by FDA also extends beyond formal letters: the MOU defines "non-public information" broadly to include information shared orally, electronically, in writing or in any other form.

Inspection-related information may also be shared. One of FDA's two initial points of contact is the Associate Commissioner for Inspections and Investigations, a designation that may signal sharing of facility-inspection information, although the MOU does not expressly state that such information will be shared. Inspection findings and manufacturing deficiencies can, in certain circumstances, become material before a Warning Letter or other public enforcement action.

The MOU Builds on FDA's Broader Transparency Initiatives. The MOU also should be viewed alongside FDA's broader transparency push. As we wrote earlier this year, FDA's near-real-time publication of redacted complete response letters ("CRLs") enables investors, plaintiffs and regulators to compare company descriptions of FDA feedback with FDA's contemporaneous written communication.[5] Although FDA redacts trade secrets, confidential commercial information and personal information, published CRLs can retain substantial clinical, statistical and regulatory information.

The MOU extends that dynamic beyond documents FDA makes public. Subject to applicable confidentiality limits, SEC staff may request nonpublic FDA information directly. Companies therefore should consider not only that a CRL may become public

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[5] Debevoise & Plimpton LLP, FDA's Real-Time Release of Complete Response Letters ("CRLs"): Disclosure Considerations for Life Sciences Companies (Apr. 29, 2026).

but also that other FDA interactions may be available to the SEC even if never publicly disclosed by FDA.

Practical Implications for Public Life Sciences Companies. While the substantive securities-law principles remain unchanged, the MOU may make inconsistencies easier to identify. Companies should continue to subject clinical and regulatory disclosures to coordinated review by securities counsel, FDA regulatory counsel, relevant scientific and clinical personnel, investor relations and management. Disclosures related to clinical trial results should distinguish final from preliminary or "top-line" analyses, address material limitations or contrary data where necessary and avoid selectively presenting favorable information in a misleading manner.

Statements about FDA interactions warrant particular care. Companies should assess whether descriptions of "constructive" or "positive" feedback fairly convey material concerns, whether approval-timing statements remain reasonable in light of current FDA communications and whether risk factors mischaracterize as hypothetical certain existing material regulatory developments.

The review should extend across the disclosure record, including SEC filings, press releases, earnings calls, investor presentations, website disclosures, social media postings and other public statements. Companies should assume that SEC staff may be able to test a characterization of what "FDA said" against FDA's own record.

The same applies to manufacturing, inspection and post-approval compliance developments. As we noted in 2018, routine inspections are ordinarily not material, but serious findings may require disclosure depending on factors such as FDA's characterization, the likelihood and severity of potential sanctions, the company's history with FDA and the potential impact on the company.

How the MOU Will Work in Practice. Much will depend on implementation. Key questions include:

- **How frequently will information be requested?** Will FDA requests become routine in SEC Corporation Finance reviews or remain concentrated in matters presenting particular red flags?

- **What categories of FDA information will be shared?** The MOU reaches beyond CRLs and other written correspondence; whether inspection records, meeting communications or internal FDA assessments will be regularly exchanged remains to be seen.

- **How will FDA draw the confidentiality line?** Many FDA records contain both protected and shareable information, making segregation and redaction practices important to how useful shared documents will be.

- **Will companies know that information has been shared?** The MOU does not appear to require FDA to notify an affected company when it provides information to SEC.

The MOU does not rewrite the law governing life sciences disclosures, but it formalizes a more direct channel between FDA and the SEC. Publicly traded FDA-regulated companies should therefore take this development into account when drafting disclosures that address FDA regulatory developments.

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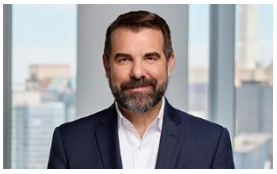

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