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The New SEC–FDA Information-Sharing Pact: What Tobacco and Nicotine Companies Should Know

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On August 31, 2026, SEC Chairman Paul S. Atkins and FDA Commissioner Kyle Diamantas signed a Memorandum of Understanding (MOU) creating a formal framework for the two agencies to exchange information about FDA-regulated products and the firms that manufacture, distribute, and sell them. Much early commentary will focus on drug and device issuers, but the MOU expressly references FDA's authority over the manufacturing, marketing, and distribution of tobacco products. Public and

large private companies selling cigars, cigarettes, e-vapor, and modern oral nicotine products should take note.

What the MOU Does

- Each agency will share appropriate information about FDA-regulated products and the companies behind them, using dedicated request mailboxes and secure file transfer for non-public information.
- The SEC's designated contacts come from both the Division of Enforcement and the Division of Corporation Finance, signaling use in investigations and in routine filing reviews.
- Under 21 C.F.R. 20.85, the SEC may use non-public FDA information to inform any public company filing review and any enforcement investigation, proceeding, or civil action.
- FDA's Office of the Chief Counsel is FDA's lead for referrals to the SEC of potential violations, meaning FDA may flag issues proactively.
- The MOU took effect on signature and runs for three years.

How SEC Scrutiny May Evolve

The MOU specifically targets companies that may have made false or misleading statements to investors about the status of FDA review, product approvals, or other matters within FDA's authority. For this industry, the analogues are statements about premarket tobacco product applications (PMTAs), marketing orders, modified risk claims, product standards, and FDA enforcement exposure. Projections about authorization timing, characterizations of an "authorized" portfolio, and assessments of how illicit products affect market share can now be tested against FDA's own record, including deficiency letters, inspection findings, and review status.

Expect sharper Corporation Finance comment letters on risk factors and management's discussion and analysis of financial condition and results of operations (MD&A), and Enforcement inquiries that begin with an FDA referral rather than a whistleblower tip or stock drop. Large private companies are not insulated: the antifraud provisions reach private placements and debt offerings, and any IPO or significant transaction will bring SEC review.

The MOU has limits. FDA will not share trade secret or confidential commercial information protected by 21 U.S.C. 387f(c), the tobacco-specific confidentiality provision, except as that statute allows. The MOU does not cover testimony or subpoenas, and it creates no binding obligations. The SEC also cannot pass FDA's non-public information to outside parties without FDA's written permission, which may shape what surfaces in parallel private securities litigation.

Key Pointers for Directors and Officers

1. **Assume the SEC can see what the FDA sees.** Reconcile risk factors, earnings call scripts, and investor presentations against actual FDA correspondence before each filing.
2. **Calibrate regulatory forecasts.** Avoid unqualified statements about PMTA outcomes or timing, and update disclosures promptly when the regulatory picture changes.
3. **Put regulatory counsel on the disclosure committee.** FDA compliance staff should review and sub-certify regulatory disclosures.
4. **Treat FDA actions as potential disclosure events.** Warning letters, inspection observations, and marketing denial orders call for a prompt, documented materiality assessment.
5. **Document board oversight.** FDA compliance is a mission-critical risk for these companies; regular board reporting supports both disclosure controls and a defense to oversight claims.

6. **Prepare for coordinated inquiries.** Build a protocol for document preservation, privilege, and consistent messaging, because an FDA matter may now lead to an SEC inquiry.
7. **Private companies: early diligence.** Before an offering or sale process, confirm that offering materials match the FDA record.

The MOU does not change the substantive law, but it removes friction between two regulators with overlapping interests in this industry. Companies that align their regulatory and investor messaging now will be better positioned when the first referral arrives.