SpencerFane®

Brian Malkin and Mike MacPhail Examine the New FDA-SEC Memorandum of Understanding in AZBio

Spencer Fane attorneys Brian Malkin and Mike MacPhail authored the article FDA-SEC Issues Memorandum of Understanding. How Does this Change their Information Sharing and What Does the Future Hold for Life Science Companies? recently published by *AZBio.*

In the article, originally a firm blog post, the team discusses the Memorandum of Understanding (MOU) entered by the U.S. Food and Drug Administration (FDA) and the U.S. Securities and Exchange Commission (SEC) on August 31, 2026, to enhance cooperation in their regulatory and enforcement responsibilities. They compare the new MOU with the agencies' 2004 information-sharing arrangement, highlight key changes such as a two-way referral process and new safeguards for non-public information, and explain why life science companies should give extra scrutiny to public disclosures about FDA developments, particularly around capital raises, critical trading windows, and insider trading compliance.

"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," the team wrote.

At the firm, Brian streamlines processes for clients navigating the complex intersection of patent law and food and drug law, leveraging unique public and private sector experience, in-depth creative and strategic analysis, and advanced negotiation tactics to meet and exceed stakeholder expectations.

Mike is a securities industry defense attorney who represents investment advisors, broker-dealers, publicly traded corporations, transfer agents, accounting firms, law

firms, and licensed individuals in a wide variety of high-stakes civil and criminal investigations, enforcement actions, and private litigation.

Read the team's full article here.