FDA to Cooperate with SEC to Protect Public from False or Misleading Market Disclosures

The Food and Drug Administration (FDA) announced last week new measures to improve the manner in which the FDA assists the Securities and Exchange Commission (SEC) in protecting the investing public and maintaining the integrity of the securities market. The hallmark of this initiative is the establishment of a centralized procedure for FDA personnel to use in referring to the SEC statements by FDA regulated firms that may be false or misleading.

The FDA routinely works with the SEC in reviewing registration statements and other securities filings. "Unfortunately," according to the Commissioner Mark B. McClellan, M.D., Ph.D., "companies sometimes violate the public trust by issuing false or misleading statements about FDA related issues." He noted that the FDA has observed false and misleading statements both with respect to the status of premarket review and in the interpretation of the scientific results submitted to the agency to support product applications.

Under the new referral procedure, any FDA employee who believes a publicly held, FDA-regulated firm has made a false or misleading statement to the investment public concerning a matter within the FDA's authority can initiate a process for referring the matter to the SEC Division of Enforcement. Under this procedure, the Food and Drug Division of the Office of the General Counsel of the Department of Health and Human Services would serve as the conduit for such referrals.

In addition to establishing this new referral procedure, the FDA is implementing administrative measures to improve the assistance it provides to the SEC. These administrative measures include: (1) identifying contacts for the SEC within the FDA's principal operational components; (2) training on issues of mutual interest; and (3) the use of electronic communication to facilitate the transfer of information.

"Blanket" authorization to share non-public information

The most significant of the administrative measures is that the FDA will provide specified FDA employees a "blanket" authorization to enable them to share non-public information with the SEC or its staff, rather than executing such authorizations on a case-by-case basis. This measure will likely increase the flow of information substantially.

In his briefing to the media, the Commissioner's message to companies was clear: "We will protect confidential information; but, that does not mean you can feel free to mislead the investment community. If you provide information that mischaracterizes your confidential communications with the FDA, the law will catch up with you."

This initiative highlights the importance of accurate market disclosures for companies regulated by the FDA. Sound legal advice on these matters requires intimate familiarity with the FDA process, the underlying clinical and basic science, and SEC enforcement. The Life Sciences Practice at Ropes & Gray provides coordinated cross-disciplinary expertise to provide sound advice and evaluation regarding market disclosures of FDA developments.

If you have any questions or would like to learn more about this issue, please contact the Ropes & Gray lawyer who normally represents you.