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SECURITIES

(A joint advisory by the Securities and Life Sciences Industry Practice Groups)

SEC and FDA Announce New Referral Program

The Food and Drug Administration and the Securities and Exchange Commission have announced new streamlined measures to gather and share information to assist the SEC in its investigations of pharmaceutical companies that provide misleading information to investors. In the past, the FDA would generally provide information to the SEC about pharmaceutical companies only when specifically requested by the SEC in conjunction with one of its investigations. The FDA's new process sets up a pipeline for this information to be transferred regularly to the SEC's enforcement division. The FDA described the new process as "a centralized procedure for FDA personnel to use in referring to the SEC statements by FDA regulated firms that may be false or misleading." Specifically, the process will include the following elements:

- A referral procedure will be instituted whereby any FDA employee who believes a publicly-held company has made a false or misleading statement in any matter relating to the FDA's activities or authority can provide such information to the Food and Drug Division of HHS's General Counsel's office which, in turn, will provide the information directly to the SEC's Division of Enforcement.

- The information referred to the SEC can include otherwise confidential information relating to applications for pre-marketing approval of drugs or any other filing with the FDA. There does not appear to be any mechanism in place where the pharmaceutical company would be notified that information it believed to be confidential was referred to the SEC's Division of Enforcement.

- In order to assist the transfer of such confidential information in a timely fashion, the FDA will appoint an employee in each of its Centers as well as in the Office of Regulatory Affairs, to be SEC liaisons. These liaisons will further be provided with "blanket authorization" to refer otherwise confidential information to the SEC Enforcement Division without going through a case-by-case review of the information prior to referral as was done in the past.

- The SEC and the FDA will work together to identify areas where the SEC Enforcement Division and the FDA could jointly train its employees. This appears to signify a greater emphasis on the FDA's enforcement role than its historical role as a regulatory body.

- The FDA will increase its use of electronic communication with the SEC. No procedures have been offered relating to the retention of such communications.

The Sarbanes-Oxley Act of 2002 has provided the SEC's Enforcement Division with broader authority than it has ever had, as well as significantly stiffer penalties to enforce that authority. Moreover, there are now civil and criminal sanctions for CEOs and CFOs regarding required certifications of SEC reports. Finally, the Sarbanes-Oxley Act and underlying SEC rules impose new obligations on counsel to report "up the ladder" within the organization evidence of material violations of the law.

Pharmaceutical company counsel involved in reviewing or preparing disclosures for SEC filings, press releases and other statements to investors, relating to matters within the FDA's jurisdiction, must redouble their efforts in this area. In particular, in addition to considering the accuracy of existing FDA-related disclosure, counsel should review all correspondence and memoranda of telephone contacts and conferences between company employees and the FDA, alert to the possibility that such materials may reflect indications of possible referrals to the SEC under the newly announced program.

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