FDA-SEC Initiative May Signal Increased Scrutiny of Investor Communications

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The Food and Drug Administration and the Securities and Exchange Commission recently announced new measures designed to improve the coordination between the two agencies with respect to investor communications by FDA-regulated firms (2 PLIR 172, 2/13/04). The measures, which include the identification of inter-agency liaisons, increased training, more sharing of confidential information, and an emphasis on electronic communications, will facilitate information coordination between FDA and SEC in cases where pharmaceutical, medical device, biotechnology, and other FDA-regulated companies disseminate, in an SEC-regulated investor communication, false or misleading information about a product in clinical development or under FDA premarket review.

As a practical matter, the announcement of these measures may signal an era of increased FDA scrutiny of how firms characterize, in investor communications, the developmental and regulatory status of drugs, medical devices and biologics in clinical development by facilitating input from the very FDA staff involved in their premarket review.

Investor communications include annual reports, prospectuses, letters to shareholders, and all other materials disseminated by FDA-regulated firms that are directed at the investment community. Although investor communications do not constitute advertising in the traditional sense, the FDA has consistently held that such communications are subject to the same regulatory constraints as statements made to consumers and the medical community. In practice, the FDA, recognizing that investor communications are not primarily intended to promote a product to physicians or consumers, has not aggressively exercised enforcement authority against firms for statements made in communications solely directed at investors. Further, while the FDA has long worked with the SEC in reviewing such statements by regulated entities, there has not been, until now, a formalized procedure for exchanging information.

ImClone Systems Scandal. Recently, however, in the wake of the ImClone Systems Inc. insider-trading scandal, the FDA has faced heightened scrutiny regarding the traditional processes by which the agency communicates with pharmaceutical companies regarding the status of their drug candidates under premarket review, and its role in reviewing public statements by such companies for consistency with the agency’s own understanding of the status of the product development and approval process.

In the ImClone case, Sam D. Waksal, the former chief executive officer of ImClone, admitted selling his shares of the company’s stock after he received information that an FDA report on ImClone’s Erbitux drug product, at that time under premarket review by the agency, would be negative. This information, which apparently was mistakenly disclosed by an FDA employee, raised

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concerns because it did not accord with the positive public statements the company had previously made regarding the status of the FDA review.

“This initiative may be a harbinger of increased FDA scrutiny of investor communications . . . [focused on] firms with products in clinical development or under regulatory review.”

The ImClone case typifies an inherent problem faced by emerging pharmaceutical, biotechnology, and medical device firms whose product portfolio is entirely in clinical development, as well as firms that have invested substantial capital in developmental products. For these firms, a product in clinical development may be critical to the financial health of the company and its ability to raise capital. As a result, such a firm has a built-in incentive to characterize the data from clinical trials on the product and the likelihood of ultimately obtaining marketing approval from the FDA in the most positive terms possible when communicating with the investment community.

This unavoidable predilection to characterize favorably the clinical and regulatory status of a developmental product also may be exacerbated by the company’s genuine and understandable enthusiasm for its product’s potential benefits (whether ultimately warranted or not). The incentive to emphasize clinical development activities in positive terms when communicating with potential investors is strikingly illustrated by juxtaposition of the ImClone case, where “negative” feedback from the FDA regarding that company’s likelihood of obtaining marketing approval for Erbitux, once disseminated widely, caused a steep drop in the price of ImClone stock.

For its part, the FDA, as a dispassionate reviewer, may not share a firm’s positive characterization of clinical data, regulatory status, or overall commercial prospects of the firm’s developmental products. As a result, the FDA may consider such statements in investor communications to be false, misleading, or simply premature. Indeed, historical approval rates suggest a dissonance between industry expectations regarding developmental products and the FDA’s view once in receipt of marketing applications, as fewer than 50 percent of new drug applications and premarket approval applications for medical devices are approved by the FDA, and many such approvals are subject to marketing restrictions not foreseen by the applicants.

FDA Referrals to SEC. Against this background, the FDA began to assess whether the agency’s traditional frameworks for reviewing investor communications by FDA-regulated firms and for releasing information on premarket reviews are sufficient to protect the public and potential investors from the dissemination of inaccurate or misleading information. As part of this assessment, the FDA and SEC have attempted to formalize collaborations between the two agencies, resulting in the announcement of this new initiative.

In the FDA’s press release, Commissioner Mark McClellan summarized the need for these collaborative measures: “Unfortunately, companies sometimes violate the public trust by issuing false or misleading statements about FDA-related issues, such as the progress of FDA’s premarket review. When we identify suspected misstatements, we have a new process to bring them to the attention of the SEC staff as quickly and efficiently as possible.”

The FDA-SEC initiative is intended to raise FDA employees’ awareness about the problem of FDA-regulated firms making false or misleading statements in investor communications about products under clinical development or undergoing regulatory review. This initiative reflects the increased public interest in such statements resulting from the ImClone scandal. It does not, however, otherwise change the law. Indeed, the FDA has maintained that the measures are substantially internal and will not impact industry interactions with the FDA.

Specifically, under a new centralized referral procedure, “any FDA employee who believes a publicly held, FDA-regulated firm has made a false or misleading statement to the investment community concerning a matter within FDA’s authority can initiate a process for referring the matter to the SEC Division of Enforcement.” Under this procedure, an FDA employee who believes that a firm has made a false or misleading statement, and who otherwise may not have had the resources to contact SEC directly and to fill out the requisite paperwork, will notify the Food and Drug Division of the Office of the General Counsel of the Department of Health and Human Services of the problem statement. The Office of General Counsel then will review the statement and serve as the conduit for a referral to SEC. The SEC’s director of the Division of Enforcement has been designated as the employee responsible for receiving such referrals on behalf of the SEC.

In addition to this referral procedure, the FDA has identified individuals in each of the agency’s centers and the Office of Regulatory Affairs to serve as internal contacts for the SEC and its staff to use in requesting information from the FDA. These contacts are responsible for ensuring that SEC requests are handled promptly and thoroughly. The FDA also has identified the associate commissioner for regulatory affairs, currently John Taylor, as a “liaison officer” task with implementing this FDA/SEC initiative and notifying SEC of any personnel or organizational changes affecting the identified FDA contacts.

Another key change of the initiative is the shift from case-by-case written authorizations to individual FDA employees to share nonpublic information with the SEC to a system where the identified SEC contacts are given “blanket” authorization to share such confidential information.

Finally, the FDA/SEC initiative will result in an increased emphasis on training FDA and SEC staff in areas of mutual interest, as well as an emphasis on promoting electronic communications between the two agencies. Taken together, these initiatives increase the likelihood that the FDA staff most knowledgeable about the clinical and regulatory status of particular products and product candidates will be involved in the scrutiny of statements regarding those products in investor communications.

It is unclear whether this initiative will result in improved investor communications as firms navigate the era of heightened scrutiny resulting from recent corpo-
rate scandals. What is clear, however, is the FDA’s recognition of the negative impact of these scandals on investor confidence, and the agency’s intent to elevate these issues in the consciousness of its employees.

As a practical matter, the announcement of this initiative may be a harbinger of increased FDA scrutiny of investor communications made by drug, device, and biotechnology companies with particular focus on those firms with products in clinical development or under regulatory review. For such companies, it will be essential to recognize this heightened sensitivity, and to take the steps to ensure that investor communications do not prematurely or inaccurately characterize the regulatory or clinical status of product under development and premarket review.