SECURITIES LAW360

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FDA, SEC Disclosure: Standard Procedures Can Help

Wednesday, Jun 27, 2007 --- In 2004, the Securities and Exchange Commission and the Food and Drug Administration announced steps to enhance cooperation between them to further protect the public from false and misleading statements by public life sciences companies. The agencies developed a centralized process where the FDA could refer potential disclosure matters to the SEC's Division of Enforcement, and identify FDA point persons and procedures for the SEC to use when gathering information about public life-sciences companies.

Life science companies are frequent defendants in private securities class actions, and recent SEC cases demonstrate the continued need for a cooperative relationship between the two regulatory bodies. Given the relationship between the SEC and the FDA, the consistent flow of information between life sciences companies and the FDA and the frequency with which many such companies utilize the public markets to raise funds, companies in this area are well-advised to own a robust set of disclosure policies and procedures to ensure that material information is being disclosed promptly and accurately.

Although there is no general affirmative duty for a public company to disclose nonpublic information, SEC rules and regulations, such as the revised disclosure obligations under Form 8-K, may require disclosure under certain circumstances. Even when disclosure is not required, however, a life sciences company that receives news from the FDA or through one of its clinical trials may want to disclose that information to the public. Whether information is disclosed to the public because of a regulation or voluntarily, the disclosure must be complete and accurate to avoid misleading the investing public.

Additionally, after a company discloses information regarding a matter, it may have a "duty to update" or a "duty to correct" the information in that disclosure, in a timely fashion, if new information becomes available. Because of the importance of getting accurate information to the investing public even small public life-sciences companies need to focus not just on their clinical trials and FDA communications but also on making sure that information regarding those areas flows within the company and then to the public through its SEC filings and public statements.

One approach for these companies is to develop and utilize standard operating procedures that encourage timely and accurate exchanges of information with regulatory bodies, for dealing with clinical trial developments and for drafting SEC filings, including Forms 10-K, 10-Q and 8-K. A formal written SOP for dealing with communications from the FDA can help a

company identify and disclose pertinent information and may include the following guidelines:

• Written communication to or from the FDA should be circulated within 24 hours to members of the regulatory affairs and clinical trials divisions, and to someone in the general counsel's office and in corporate communications.

• Oral communications should be documented in a written summary and circulated to the same group of people. Two or more people should participate in all oral communications with the FDA.

• Specific personnel should be responsible for drafting and distributing these communications, and there should be a procedure for calling meetings on short notice to allow for discussion about the new information throughout the company.

Clinical trial developments, which may arise in post approval marketing studies such as long term safety studies as well as in pivotal clinical trials, are another area likely to generate material information that a company may need to disclose, particularly if the company has previously disclosed information regarding a clinical trial or the safety of the product. Significant changes or results from trials previously discussed with the public will likely warrant prompt and accurate disclosure.

To communicate new and significant developments in an effective and timely manner, a company should create a distribution list for each ongoing clinical trial that includes at least one member from the regulatory affairs department, the general counsel's office and the corporate communications or investor relations department. The distribution list will ensure that people outside the clinical trials group are informed of the new information and can make an assessment whether disclosure is necessary.

Creating SOPs for the drafting, review and filing of SEC filings is an important component for disclosure policies and procedures. For each periodic filing on Form 10-K or 10-Q, implement an SOP that sets forth the timeline for drafting the filing and also includes the necessary sign-offs for each section.Of particular importance for a company's periodic filings is management's discussion and analysis of financial conditions and results of operations.This section would require management to discuss information that may cause the current financial condition to not be indicative of future financial condition. This may include indications from the FDA regarding status of a pending application or events from a clinical trial.Consequently, an SOP regarding the drafting and review of periodic filings needs to allow for review by members of the regulatory affairs and clinical trials division to ensure that information pertinent to those divisions is included and accurately described.

For instance, news that a life sciences company is under investigation by government authorities for issues relating to off-label marketing, may require prompt disclosure and thus a streamlined SOP is recommended for press

releases, Forms 8-K and registration statements. Ideally, drafts should be reviewed by all relevant company divisions. In August 2004, revisions for the filing of Forms 8-K became effective, requiring that companies file disclosures regarding specified information within four business days. And, although registration statements can integrate prior filings, a company must still ensure that it describes "any and all material changes in the registrant's affairs" that were not previously reported on a Form 10-Q or 8-K.

Finally, because many life science companies are regularly communicating with the investing public, particularly institutional investors, developing an SOP that covers Regulation Fair Disclosure may be useful. Under Reg FD, companies are prohibited from selectively disclosing material nonpublic information to certain parties, such as securities market professionals, institutional investors and investment companies.

If material nonpublic information is disclosed to a select party, Reg FD requires that the information be simultaneously disclosed to the public or if the disclosure is inadvertent, the information must be disclosed to the public as soon as practicable after discovering the disclosure. SOPs regarding communications with the investment community can be a valuable way to prevent running afoul of Reg FD. For example, an SOP to assist with Reg FD compliance might require that:

• All staff that interacts with the investment community complete regular training about Reg FD.

• All communication with investors be logged into a central system, which includes the date of the communication and a description of the information provided to the investor.

• All road show materials be reviewed and approved by specified personnel.

SEC disclosure requirements may not always be given the necessary attention at new or developing public life science companies. However, the increased level of cooperation between the FDA and the SEC, and the increased risk of civil suits, suggest that life science companies need to take special care when disclosing information to the investing public because the potential damage from making inaccurate disclosures can be significant or long-lasting. Using SOPs, a familiar format of control at life science companies, is one way to make disclosure policies and procedures easier and more effective for these dynamic companies.

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