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Current Issues Affecting FDA-Regulated Companies

FDA Law Update

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The FDA Transparency Initiative: Another One Way Street?

On May 19, 2010, FDA published on its website a series of proposals designed to promote "openness" and "transparency" in government. The document, entitled "FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the United States Food and Drug Administration" can be found here. The document contains 21 specific proposals about changing the Agency's policies of disclosure of information submitted to it and about interim decisions made by it.

The disclosure changes that FDA proposes to make raise a number of concerns for FDA-regulated life sciences companies, particularly drug and medical device companies (especially those not publicly traded), as information until now considered trade secret and/or confidential/proprietary may be subject to disclosure by FDA in the future if the Agency's proposals are adopted. Furthermore, while purportedly promoting "openness", the draft proposals rejected the public comments about making the Agency's own deliberation more "open" and "transparent".

Of most concern to FDA-regulated life sciences companies are 9 of the proposals that would allow FDA to disclose the existence, status and contents of investigational products and products pending for approval. See items 8-17, p. 6-7. This is information FDA currently does not disclose, except in limited circumstances. For example, FDA proposes to disclose the existence of IND's and IDE's, providing information about not only the name of the sponsor and date received, but the proposed indication(s) and intended use(s). It proposes to disclose information about IND's or IDE's put on clinical hold, and the reasons therefor. It proposes to do the same for NDA's, ANDA's, NADA's, BLA's, PMA's, and 510(k)'s. It proposes to make public refusals to file and complete response letters for NDA's and other drug applications, and "not approvable" letters for PMA's and "additional information" letters for 510(k) notifications.

Disclosures of such information may not be of much concern to publicly traded companies who have financial disclosure obligations, but it should be of concern to small and emerging privately-held companies, as disclosure of such information may have a devastating effect on the ability of a company to develop a product. Interim FDA decisions are often given to different interpretations, do not mean a product will not be approved, and are often accorded more significance than they deserve.

Of further concern, to both publicly and privately traded companies, is how such information will be used by competitors – given that it is preliminary in nature only. Fortunately, FDA is not proposing to disclose letters relating to CMC and labeling supplements. See pages 47-48.

Some of the other proposals are less problematic. For example, FDA proposes to post "untitled letters" and responses thereto on its website – these are letters FDA sends to firms notifying them of alleged violations of the FFDCA, providing the opportunity to respond as to how they will address the alleged violations voluntarily. Many untitled letters – such as those issued by the Division of Drug Marketing, Advertising and Communications – are already public. FDA currently does so with regard to Warning Letters, and, as such, there is no logical reason that untitled letters should also not be posted on the FDA website. The same is true with regards to documents relating to inspections, which are available through the Freedom of Information Act, and sometimes placed on the FDA website when of widespread public interest. Similarly making adverse event information currently available on-line more user-friendly and searchable should not be controversial. Lastly, FDA has said it "will explain the Agency's reasons for not following the recommendation of an advisory committee in reviewing documents, and their reasons will be disclosed when those documents are disclosed." See p. 58.

The FDA declined, however, to propose disclosure of how it makes certain decisions. For example, the Agency said it would not propose to disclose the documents it reviews to respond to a Citizen Petition. See p. 58. It is a mystery how denying this proposal makes FDA decisions more transparent and open, and does not portend well for Phase III of its Transparency Initiative, which is to address the Agency's transparency to the regulated industry. It is certainly the hope of the industry that transparency and openness will not be a one-way street, but there are indications FDA's initiative may be.

FDA is requesting comments on the proposal, which can be submitted to www.fda.gov/transparency. Comments are due by July 20, 2010.

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