MACKRELL INTERNATIONAL'S REGULATORY SUBGROUP PRESENTS

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REGULATORY MATTERS!

FDA Due Diligence – An Ounce of Prevention. . .

A crucial part of any business transaction is the due diligence conducted by the prospective purchaser to evaluate the deal and identify the potential liabilities it might be assuming. Virtually no buyer would skip an assessment of the corporate structure, tax status, intellectual property portfolio, or ongoing litigation.

For companies regulated by the U.S. Food and Drug Administration (FDA) (such as manufacturers of food, drugs, cosmetics, dietary supplements, and medical devices), one would expect that ensuring compliance with FDA requirements would be a high priority. Surprisingly, however, FDA due diligence is often something that is overlooked or that purchasers decide to do "after the deal." For a variety of reasons, this is a strategy that can be costly and have significant legal consequences. To read more, please **click here**.

This issue of "Regulatory Matters" was written by **Frederick Stearns**, a Partner at Keller and Heckman LLP who specializes in a wide range of issues affecting manufacturing of prescription and over-the-counter drugs, medical devices, dietary supplements, and cosmetics. To read more about Mr. Stearns, please **click here**.

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FDA DUE DILIGENCE

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As a starting point, it is important for a purchaser to understand what FDA issues may exist with the target company. Potential landmines could be present in product formulations, product claims, manufacturing conditions (i.e., deviations from "current good manufacturing practice" (cGMP) requirements), or post-market reporting obligations. The fact that FDA does not appear to have taken regulatory action in the past does not mean that such action may not be coming in the future. In fact, in the last year-plus, FDA has been very clear (and very public) about the fact that it is ramping up its enforcement activities. If the Agency believes that a marketed product violates the Federal Food, Drug, and Cosmetic Act (FDCA) in some way, it will not be sympathetic to an argument that the new owner just recently purchased the product line. FDA will expect the product to comply, and the new owner will be the party responsible for bringing about that compliance.

On a related point, the outcome of the FDA due diligence could have an impact on the valuation of the deal. If the purchaser may need to upgrade the manufacturing facilities or processes to comply with cGMPs, or if there are regulatory issues with product formulations or claims, correcting these problems can potentially lead to substantial costs that the purchaser had not foreseen. By identifying likely problems during the due diligence phase, the deal could be structured to better represent the value that is being conveyed by the seller. Of course, if there is too much regulatory uncertainty (or the problems are too costly to justify fixing), the purchaser could choose to abandon the deal entirely. From the purchaser's standpoint, it is certainly better to have a complete picture of the FDA regulatory issues before closing, rather than after.

Poor FDA due diligence can result in disruptions to the business if significant changes need to be made. If a product needs to be reformulated, or if labeling claims need to be changed, the time lag in implementing the corrective action could result in supply chain disruptions, possibly resulting in breaches of supply agreements with customers (and corresponding claims for damages). The delay also may provide an opportunity for competitors to gain traction with your customers. Under such a scenario, the loss of market share may be difficult to win back. Any supply interruptions also could damage the reputation of the brand.

Finally, FDA regulatory issues can have consequences for both companies and executives. FDA enforcement action is often publically announced and picked up by the industry trade press.

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FDA's Warning Letters are posted to the Agency's web site each week. Product seizures and court injunctions are commonly announced by FDA in its own press releases. Any of these actions can mean negative publicity for the company. From a corporate official's standpoint, it is important to understand that the FDCA is a strict liability criminal statute. In a series of cases decades ago, FDA established the principle that it can hold senior corporate executives criminally responsible for violations that they had the power (via their positions) to prevent or correct. In a landmark case, the U.S. Supreme Court ruled it is not a defense against criminal liability to assert the executives did not have actual knowledge of the violations or that they had delegated the responsibility for addressing them to someone else. After a lull in such prosecutions during the past 10 years or so, FDA has stated very clearly that it intends to resume bringing criminal actions against corporate executives as a means of "encouraging" compliance.

In summary, it may be tempting for a purchaser to overlook FDA due diligence to focus on other, more conventional, due diligence issues. However, there are substantial potential risks to both the business and corporate executives if FDA compliance matters are not addressed properly. For a prospective purchaser in the FDA arena, it is clearly advantageous to identify potential issues before, rather than after, the deal closes.

ABOUT THE AUTHOR

Frederick Stearns joined Keller and Heckman in 1993.

He helps product manufacturers evaluate the need for marketing approval from FDA, to pursue appropriate clearance when necessary, and address regulatory compliance issues with marketed products (including OTC drug monographs, product labeling and promotion, and current good manufacturing practices). He also works with clients to respond to FDA enforcement activities, navigate the interrelationship of the patent laws and the FDA drug approval process, communicate with Agency officials, and develop innovative strategies to deal with evolving FDA regulatory requirements. In addition, Mr. Stearns has worked with numerous companies to conduct FDA due diligence reviews, both for internal control purposes and as part of product line or corporate acquisitions. For more information about FDA due diligence and Keller and Heckman's capabilities, please contact Rick at stearns@khlaw.com.

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