

### FDA Lawyer Seth Mailhot Joins Sheppard Mullin Washington, D.C.

05.20.2011

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Seth A. Mailhot has joined the Washington, D.C. office of Sheppard, Mullin, Richter & Hampton LLP as special counsel in the firm's Food and Drug Law group and Life Sciences group. Mailhot most recently practiced with Nixon Peabody in Washington, D.C., where he was lead attorney for the firm's FDA Regulatory practice.

"Seth brings a valuable, substantive background that will be a great asset to our clients," states Peter S. Reichertz, leader of the firm's Food and Drug Law Group and co-leader of the firm's Life Sciences group. "Seth's experience is unique in the FDA bar, as it combines a lengthy career as a chemical engineer with the U.S. Food and Drug Administration with a practice that covers a broad range of matters involving the FDA. This provides clients with a unique perspective that draws on his experience as an investigator, a regulatory researcher, and a compliance officer."

Mr. Mailhot's FDA regulatory experience covers the pharmaceutical, biologic, medical device, tobacco, food, cosmetic, and dietary supplement industries, and includes enforcement and recall matters, preparation and prosecution of FDA premarket submissions, product promotion and labeling issues, pharmaceutical exclusivity matters, and compliance with quality, regulatory, and manufacturing requirements. Mr. Reichertz adds, "while many in the FDA bar look to subspecialize, Seth's broad experience within the FDA and in private practice allows him to advise clients strategically. This is critical when clients look to develop long-term product marketing strategies. As companies look to expand in new areas or develop combination products, they need counsel that can advise them on a broad range of issues."

Mr. Mailhot also has significant experience with corporate matters that touch on FDA regulation. His work includes counseling FDA-regulated clients through the initial public offering process, assisting underwriters with various financing, and offering transactions involving FDA-regulated targets, and preparing and reviewing agreements related to clinical trials, mergers between FDA-regulated companies, and licensing of FDA-regulated products.

Mr. Mailhot's understanding of manufacturing regulations and current good manufacturing practices spans all industries, with a focus on regulatory issues involving foreign manufacturing. Seth has worked with foreign clients in both Asia and Europe on navigating the U.S. regulatory landscape, as well as U.S. clients with significant foreign operations. While at the FDA, he was a Level II certified medical device investigator and conducted foreign and domestic inspections.

“Among the other assets Seth brings to Sheppard Mullin,” concludes Mr. Reichertz, “is his experience leading an FDA practice and helping to shape a firm’s Life Sciences efforts. This will provide a unique voice at Sheppard Mullin as we continue to expand and grow our Life Sciences group.”

Mr. Mailhot received a J.D., Valedictorian, *summa cum laude*, from New England School of Law in 2004, and a B.S. in Chemical Engineering from University of Massachusetts at Amherst in 1994.

### ***About Sheppard, Mullin, Richter & Hampton LLP***

Sheppard Mullin is a full service AmLaw 100 firm with more than 560 attorneys in 11 offices located in the United States and Asia. Since 1927, companies have turned to Sheppard Mullin to handle corporate and technology matters, high stakes litigation and complex financial transactions. In the U.S., the firm’s clients include more than half of the Fortune 100.

## **Industries**

Life Sciences and FDA