FDA Regulatory

From beginning to end, every life sciences enterprise has one enormously important, albeit silent, partner: The Food and Drug Administration (FDA). Rothwell Figg's FDA Regulatory practice assists clients in both navigating and managing this critical, ongoing relationship. Whether the client is an emerging growth company with an innovative new therapy or a global behemoth with an extensive array of products, we assist and guide them in navigating a critical, high-stakes segment of their strategy.

Our practice includes advising clients on filing Abbreviated New Drug Applications (ANDA) for generic drugs, as well as counselling clients in submissions for branded products. Because we are Hatch-Waxman litigators as well, we bring a unique, hands-on perspective to this work, and are able to examine strategic questions from a tactical perspective.

In doing this, we walk clients, and ourselves, through a series of questions derived from their competitive strategy. These range from “How do I maintain 180-day exclusivity as a first-to-file ANDA applicant?” to “How do I avoid Hatch-Waxman litigation by filing Section viii ('skinny label') carve-outs?” to “How do I get the FDA to agree that a first-to-file ANDA applicant has waived their 180-day exclusivity?” These are complex, far-reaching questions, the answers to which have enormous financial implications. The Rothwell Figg team is skilled in devising answers to these questions that will both serve each client’s larger goals, and ensure the smoothest, straightest path forward.

What makes us the firm of choice for so many of our pharmaceutical clients? Our team is focused, effective, and strategic. We communicate efficiently and quickly, and can gain traction quickly when a matter arises. We are also almost all trained scientists, many with either industry experience, advanced degrees, or both. We understand our clients’ products, and the science behind them. This makes analyzing, explaining, and communicating about them efficient and lucid.

As practitioners, we are also exceptionally versatile, and bring a wide spectrum of experience to what we do. Our lawyers, although focused on pharmaceuticals, see and work on each situation from every angle. This makes us innovative and hands-on, because we are personally aware of the potential consequences of our work. It is one thing to propose an approach because it seems great in theory. It is quite another to propose something because you’ve personally handled Hatch-Waxman litigation. We fit into the latter category, and as a result, are known for providing guidance to our clients that is both highly effective and legally sound.

Finally, we are detail-oriented, and have a business-based approach to what we do. All our advice and guidance is based on helping our clients reach their business objectives with as little risk and as much opportunity as possible. We think like seasoned attorneys because we are, but we operate like businesspeople, because that’s what our clients are. Our approach to clients’ ANDA filing strategy is to identify and pursue the most efficient, profitable path to approval.

In addition to counseling clients concerning FDA filings, we also advise them on FDA regulations regarding pharmaceutical advertising. Marketing is a fundamental part of the industry – our clients need to communicate the benefits of their innovations in advertising and communications with healthcare professionals. However, they have to do this while staying within the bounds of strict FDA regulations and guidance. If not, the result is a warning letter and accordingly, a major bump in the road to revenue. This is the problem we work to help clients avoid.

We work closely with clients' advertising review teams. We help them connect the contents of their advertising with supporting scientific evidence, and provide guidance to avoid regulatory pitfalls in a cost-effective, experienced manner, often covering multiple products. Whether it's revising the language of a print ad, reviewing the script of a planned television campaign, or evaluating communications to healthcare professionals, we help ensure that our client's desired messaging reaches its target market as effectively as possible without running afoul of regulatory requirements.