

DuVAL CLIENT ALERT

Passing on Tribal Knowledge of FDA Law

Volume 26

Issue 01

**FIRM
UPDATE**

Dear Clients and Friends of the Firm,

2025 was a very good year for our firm and 2026 is proving to be even busier with lots of growth. Despite the political machinations and distractions going on (e.g., a new President being sworn in, DOGE audits, confirmation hearings for the Secretary of HHS, political departures and additions, the loss of rank and file and senior leadership, etc.), all of which affected FDA's performance, we navigated through all of it well with our clients. And we continue to in 2026, despite the Iran conflict, the ups and downs of the economy, etc. The firm itself has grown, adding a senior regulatory strategist, cybersecurity expert, and a lawyer. We have never tried to be big, just good at what we do. But with success comes growth. We are laser-focused on our clients' success.

The firm continues to have success with FDA on a wide variety of matters. We are probably best known for our informal and formal appeals on submissions, usually with an outright win, or with a negotiated path forward. Fortunately, clients are now coming to us earlier to understand how to construct a better submission rather than getting "stuck" at FDA and bringing us late into an intractable appeal. We have also seen an uptick in FDA enforcement matters which requires lots of push back and negotiations with FDA. We pursued competitive FDA complaints against our client's competitors and defended FDA's and competitor's complaints against our clients as well. We helped management teams and boards assess their state of compliance and do compliance training. We help our clients understand the nuances of FDA's advertising and promotional regulations (especially First Amendment protections for off-label promotion), the Anti-kickback Statute, False Claims Act, HIPAA, and the Physician Payments Sunshine Act. Our website says it best: Our goal is to help our clients be appropriately aggressive, yet compliant.

Most of all we had fun doing what we love to do — assisting companies through a labyrinth of laws, regulations, guidance documents, and administrative behaviors, to get to their destination. We try to simplify things, be creative, bold where necessary, yet pragmatic, and assertively defend and advance our client's position through it all.

When you are in the service industry, you had better enjoy serving, putting your clients' needs ahead of your own and ensuring the focus is not on your firm's success, but on the clients. For some firms that is a challenge, but not for us. We do not exist without our clients. We are in the battle, their battle, together. And we do it with an unparalleled and genuine passion. Our clients know that.

And part of our service is public service. We first give back by doing these DuVal Client Alerts to help you understand what is going out there in real time. We have a series of Client Alerts coming out on a wide variety of topics, so hang on. We'll be releasing them individually

as they're ready, with a few coming out in quick succession before settling into a steadier rhythm.

We also try to give back by serving our trade associations, industry groups. **We are active speaking for the Regulatory Affairs Professional Society (RAPS)** on webinars, in conducting workshops, and participating in the annual national RAPS Convergence meeting (workshops and speaking), and at other regional, local (Twin Cities Chapter and other chapters throughout the country) as well at international locations. Three of our firm members have achieved the "FRAPS" distinction as a Fellow of the Regulatory Affairs Professional Society.

We also serve the Medical Device Manufacturers Association (MDMA) by participating in groups and speaking at their annual meetings. **We annually sponsor the MedTech MVP Investing Conference** and speak and hold break-out groups. This year Bryan Feldhaus, President, Chris Lyle, Vice President Evidence Development, and I spoke in a breakout session on "Escalation Options for FDA Submissions: Getting (and Keeping) the Review Process on Track."

We also annually sponsor and co-host, with Fox Rothschild and Medtech MVP, the MedTech Monitor Conference in Minneapolis. We were able to bring to speak, Bill Maisel, former Chief Medical Officer, Scientist and Director of the Office of Product Evaluation and Quality (OPEC) at CDRH (he is now at Intuitive), as well as some well-known CEOs, Alyssa Huffman from Allumin8, Arnon Chait from Cleveland Diagnostics, John Schorgl from Peytant Solutions and including Mike Blue, from the high-flying medical device company HistoSonics.

We also support the St. Cloud State University (SCSU) master's degree programs in regulatory, quality, and clinical, by serving on the board of advisors and teaching. You could find our people speaking all over the country at the University of Minnesota Entrepreneurship Program and the Biomedical Engineering Program, MichBio, SDRAN, OCRA and elsewhere.

To further support industry, we file comments to proposed regulations, make docket submissions and Citizen's Petitions, **commenting and challenging FDA's administrative positions and actions,** and we even filed an amicus brief with the United Supreme Court, advocating for industry positions on issues.

So, thanks to our clients for entrusting your FDA work with us. We promise to deliver the high quality, creative, assertive, practical and passionate representation we have provided for over 24 years.

Mark DuVal, JD, FRAPS, CEO

DuVal & Associates

Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufactures medical devices, pharmaceuticals, biologics, nutritional supplements, and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients with appropriately aggressive, yet compliant, guidance on any FDA-related matter. We pride ourselves not only on our collective legal and business acumen but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS

For more information, visit our website at duvalfdalaw.com or call Mark DuVal today for a consult at 612.338.7170 x102.

DISCLAIMER: Material provided in Client Alerts belongs to DuVal & Associates and is intended for informational purposes only and does not constitute legal advice.
