EBG advisors

James A. Boiani

Strategic Advisor
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James Boiani is a Strategic Advisor with EBG Advisors, Inc. Mr. Boiani has extensive experience in FDA and CLIA legal and regulatory matters, having worked with large and small medical device companies (including many *in vitro* diagnostic companies), pharmaceutical companies, clinical laboratories, and trade associations in the life sciences industry on a variety of FDA- and CLIA-related issues. He focuses on advising on FDA compliance matters, with an emphasis on current good manufacturing practices ("cGMPs") and quality systems; post-market surveillance and safety reporting; recalls; and advertising and promotion. Mr. Boiani represents clients in the FDA product approval and clearance process (e.g., NDAs, BLAs, PMAs, 510(k)s, and CLIA waivers). He directs clients in identifying and capturing regulatory opportunities in product development and lifecycle management, and ensuring clinical laboratory regulatory compliance (e.g., CLIA compliance).

Mr. Boiani previously worked as an environmental regulatory consultant.

Representative Experience

- Representing and counseling clients in FDA drug, medical device, and biological approval- and clearance-associated matters, such as application submissions (i.e., NDAs, BLAs, ANDAs, PMAs, and 510(k)s), responses to FDA complete response/deficiency letters, administrative appeals of adverse FDA decisions, clinical and nonclinical trial design issues, and complex 505(b)(2) and combination drug policy issues
- Counseling clients on issues regarding combination products (e.g., preparing requests for designation and advising on cGMPs, registration, and listing) and the development of companion diagnostics, and supporting policy initiatives of trade associations in the area of companion diagnostics
- Assisting companies in pre-enforcement situations by helping them manage FDA inspections; working on responses to FDA-483 observations, untitled letters, and warning letters; developing and implementing remediation strategies to correct compliance issues; evaluating and helping address CLIA audit findings; and advising clients on handling difficult FDA- or CLIA-related compliance issues more generally
- Advising clients on adverse event (AE) and medical device report (MDR) reporting, recalls, and associated issues; of recent note, Mr. Boiani has served as the primary outside legal advisor to a major medical device company for more than over two years, providing extensive support on all facets MDR reportability, recall decisions, recall communications to customers, recall reports to regulatory agencies and associated

agency communications, and recall-related issues (such as root cause investigations and CAPAs), from both a case-specific and global corporate policy standpoint

Education

- George Mason University (J.D.)
  - Antonin Scalia School of Law
- Cornell University (M.S.)
  - Chemistry
- Massachusetts Institute of Technology (B.S.)
  - Chemistry