

**Biographical Sketch:**

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James Boiani is a Senior Counsel in the Health Care and Life Sciences practice of Epstein Becker Green. His practice focuses on FDA legal matters related to *in vitro* diagnostics and other devices, pharmaceutical and biotech products, and combination products. Some particular areas of focus include:

- FDA compliance matters, such as investigational device and drug requirements; current good manufacturing practices and quality systems; post-market surveillance and safety reporting; and recalls
- Advertising and promotion of regulated products
- FDA product approval/clearance processes
- FDA regulatory issues and opportunities in product development
- Pharmacy compounding

Prior to entering the legal profession, Mr. Boiani worked as an environmental chemist and studied chemistry at the Massachusetts Institute of Technology and Cornell University.

**Headshot Photo:**

