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## HP&M Welcomes Senior FDA Official, Ana Loloiei, to the Firm

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Hyman, Phelps & McNamara, P.C. (“HP&M”) is pleased to announce that Ana Loloiei has joined the firm as Counsel. Ms. Loloiei is a 14-year veteran of the FDA, where most recently she served as a Senior Regulatory Counsel in the Office of Policy at CDRH. While at FDA, Ms. Loloiei also served as a Senior Policy Advisor in CDRH and as a Special Advisor in the Office of the Commissioner.

During her FDA tenure, Ms. Loloiei tackled legal matters related to various aspects of the regulation of medical devices, in vitro diagnostics, and combination products including regulatory and compliance issues, dispute resolutions between the FDA and sponsors, and FDA enforcement actions. She also worked closely with Congress, the Department of Health and Human Services, the National Institutes of Health (NIH), and the Centers for Medicare & Medicaid Services (CMS) on the development of numerous guidances, rulemakings, and policy and legislative initiatives.

Ms. Loloiei will focus on guiding clients through complex premarket and postmarket regulatory requirements and assisting with the management of total product life-cycle matters. Ms. Loloiei’s deep knowledge includes the requirements for advertising and promotion of FDA-regulated products, and she advises clients on matters regarding product marketing, labeling, promotion, and advertising.

Prior to entering the legal field, she served as a biomedical/electrical engineer at an engineering firm involved in the design and development of radio frequency (RF) distribution systems from initial market and data preparation through testing and troubleshooting of these products.

“I am thrilled to be joining HPM to collaborate with an experienced and dedicated team. It was a true honor and privilege to collaborate with so many fantastic coworkers and partners for nearly 14 incredible years at FDA. The journey has been filled with great memories,” said Loloiei. “Now, I’m eager to contribute my experience to our shared mission of working towards protecting the public health with this talented team.”

“I am very excited to have Ana join HP&M. Her extensive knowledge of, and insights into, some of the most important device regulatory and legal issues, such as digital health technologies, in vitro diagnostic products and labeling/advertising will be of immense value to device manufacturers. We look forward to working with Ana as she further enhances HP&M’s capacity to assist companies with regulatory strategy, marketing applications, product promotion, and post-market issues,” notes Jeffrey N. Gibbs, HP&M Director.

Ms. Loloie graduated *magna cum laude*, with a degree in Biomedical Engineering with a concentration in Electrical Engineering from The George Washington University. She then went on to receive her J.D. from the University of Maryland School of Law.

