(North Bethesda, Md.; Oct. 22, 2015) – The 505(b)(2) approval process, key regulatory updates, recent court cases and ideal approaches for 505(b)(2) development will be on the agenda at the second annual 505(b)(2) Forum, held in conjunction with the Generic Pharmaceutical Association (GPhA) Fall Technical Conference in North Bethesda, Md. Representatives from Camargo Pharmaceutical Services, Capsugel Dosage Form Solutions and Hyman, Phelps and McNamara, PC will present at the invitation-only dinner event, scheduled for Monday, Nov. 2.

"There is increasing interest in pursuing the 505(b)(2) pathway for NDA approvals, given the potential to reduce overall development time and costs by eliminating most nonclinical studies and extensive safety and efficacy tests by referencing existing data," said Ken Phelps, president and CEO of Camargo Pharmaceutical Services.

The pathway offers the potential to create new, differentiated products with tremendous commercial value. "The range of product candidates and development approaches is vast and can include changes in dosage form, strength, formulation or route of administration as well as new combination products," said James Coward, global head of market development at Capsugel Dosage Form Solutions.

Despite the increasing percentage of new small molecule drugs being approved under the 505(b)(2) process, the pathway is complex for companies historically focused on 505(b)(1) or ANDA 505(j). Significant changes in small molecule development and in the generics market present a growing need for strategies in 505(b)(2) development.

Presentations at this year's 505(b)(2) Forum include:

- By Phelps: "An Overview of the 505(b)(2) Pathway and Ideal Approaches", including relevant case studies.
- Case Studies: "Product Development Using New Formulations for the 505(b)(2) Pathway," Ed Jule, Ph.D., senior manager of pharmaceutical development, Capsugel Dosage Form Solutions.
- "The Changing Landscape of 505(b)(2) and Recent Court Decisions,"Kurt Karst, J.D., director, Hyman, Phelps and McNamara, PC.
- **Registration is free, but space is limited. Learn more about the event at** 505b2forum.com**.**

About the 505(b)(2) Forum

The 505(b)(2) Forum was organized by product developers and service providers interested in improving best practices across the 505(b)(2) development process. From candidate identification and CMC, to shaping regulatory and commercial strategies, participating companies and attendees will discuss the 505(b)(2) regulatory approval pathway and supportive technologies for successful product development.