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## The 505(b)(2) Forum in Israel Will Review Case Studies and Strategies for 505(b)(2) Approval Pathway

(Cincinnati, Ohio; April 14, 2015) – The 505(b)(2) Forum, organized by thought leaders and service providers dedicated to improving best practices across the 505(b)(2) development process, will hold an event in Tel Aviv, Israel, on Monday, April 27.

The event's theme, "Step-by-Step Success: A Review of Case Studies Spanning the 505(b)(2) Development Pathway and Product Packaging," reflects the range of subject material to be covered. Representatives from Camargo Pharmaceutical Services, TheraCoat, Capsugel Dosage Form Solutions and Bioforum will present case studies on identifying and developing viable products as well as creating strategies for successful manufacturing and packaging.

Presentations include:

- "Strategic Decision Making to Utilize the 505(b)(2) Pathway or the 510(k)" presented by TheraCoat and Camargo Pharmaceutical Services
- "Effective Use of BA Enhancement and Controlled Release Strategies" presented by Capsugel Dosage Form Solutions
- "Quality in Clinical Supply A Road Map to Marketing Approval" presented by inPACK Clinical Supply Management, Bioforum

"It's no coincidence that The 505(b)(2) Forum is holding an event outside of the U.S. at this time," said Ken Phelps, Camargo president and CEO. "The 505(b)(2) pathway gives companies outside of the U.S. a cost- and time-effective route to bring products to the U.S. market. The first step is making those companies aware of the opportunity."

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The 505(b)(2) Forum's first event, which took place stateside in late 2014 at the Generic Pharmaceutical Association (GPhA) Fall Technical Conference, saw an excellent turnout. "It underscores the industry's growing interest in 505(b)(2) development and the need to have a group discussing its use and potential," said James Coward, Capsugel global head of marketing and market development.

Learn more about the event and register to attend 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 discuss the 505(b)(2) regulatory approval pathway and strategies for successful product development. Read more about The 505(b)(2) Forum at 505b2forum.com.

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