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Camargo Pharmaceutical Services and FDA to Share 505(b)(2) Expertise at 2015 AAPS Annual Meeting and Exposition

(Cincinnati, Ohio; Oct. 14, 2015) – Camargo Pharmaceutical Services, the most experienced global strategists specializing in the 505(b)(2) approval pathway, will moderate a roundtable discussion with two FDA representatives and present three research posters at the upcoming annual meeting of the American Association of Pharmaceutical Scientists (AAPS).

Ken Phelps, president and CEO, will lead a roundtable discussion, "Conducting Successful PIND Meetings to Reach FDA Concurrence for Sound 505(b)(2) Development," from 2 to 4 p.m. Oct. 28. Phelps will be joined by the pharmacologist lead and the quality assessment lead at the U.S. Food and Drug Administration (FDA). Topics to be discussed include creating a detailed pre-investigational new drug (PIND) meeting request, providing key information for the PIND submission package and best practices and common missteps when submitting to the FDA.

"Early preparation in the 505(b)(2) application process can result in quicker FDA approval at a fraction of the cost of traditional pathways," Phelps said. "PIND meetings can help improve the value of the product in the pipeline and nearly eliminate the chance of clinical holds."

On Oct. 27, Dr. Loan Pham, a Camargo pharmacokinetic scientist, will present three posters:

- "An Application of Pharmacokinetic Simulation in Drug Development via the 505(b)(2) Pathway" – 8:30 a.m.–12 p.m.

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- *"In Vitro* Dissolution Profile Comparison: Bootstrap Methodology Using the SAS System for Analysis of the Similarity Factor, f2" – 1:30–5 p.m.
- "Clinical Trial Simulation to Evaluate the Pharmacokinetics of an Abuse-Deterrent Opioid in Pediatric Subjects" – 1:30–5 p.m.

Members of Camargo's leadership team attending AAPS include Dr. Ruth Stevens, Dr. Gary Barnette and Dr. Lynn Gold, who is co-chair of the AAPS CMC focus group and will be available to discuss formulation challenges in 505(b)(2) development.

Visit camargopharma.com to schedule a meeting or visit Booth 459.

About Camargo Pharmaceutical Services
Camargo Pharmaceutical Services is the most experienced global strategist providing comprehensive drug development services specialized for the 505(b)(2) approval pathway and global equivalent processes. By assessing the scientific, medical, regulatory and commercial viability of product development opportunities, Camargo systematically builds and executes robust development plans that align with business strategies and ensure FDA buy-in every step of the way. Routinely holding three to six pre-IND meetings a month, Camargo works with product developers across more than 25 countries. Connect with Camargo on LinkedIn, read the company blog and visit camargopharma.com for more information.

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