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Camargo Celebrates 10 Years With the 505(b)(2) Pathway

(Cincinnati, Ohio; Oct. 24, 2013) – The U.S. regulatory landscape changed dramatically 10 years ago. In 2003, legal roadblocks to the 505(b)(2) approval pathway were resolved, making it a practical alternative route for drug development. That same year, Ken Phelps and Ruth Stevens founded Camargo Pharmaceutical Services to help companies gain approval — and market exclusivity — under 505(b)(2). Camargo will be celebrating both anniversaries at the 2013 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Nov. 10–14, in San Antonio.

"'When the FDA obtained closure on constitutional challenges surrounding the use of safety and effectiveness data, it opened a floodgate," said Phelps, Camargo's president and CEO. "FDA approvals under 505(b)(2) have risen every year since 2003 because it offers a faster and less costly process that permits developers to minimize risk and still receive marketing exclusivity."

Three Camargo executives will be speaking at AAPS. Lynn Gold, Ph.D., vice president of chemistry, manufacturing and control (CMC) services, will speak on "Can We Have One CMC Submission for a Worldwide Registration?" at the Preconference Short Course, from 2:15–2:45 p.m. Nov. 10. Stevens, Ph.D., MBA, chief scientific officer and executive vice president, will speak on "Practical Applications of the Similarity Factor, F2" in a roundtable discussion, from 2:10–2:20 p.m. Nov. 11. Phelps will present a poster titled "U.S. Marketing Exclusivity for Prodrugs" from 1:30–4:30 p.m. Nov. 12.

"Today more drugs are approved through 505(b)(2) than through traditional development," Phelps said. "We're here to help clients makes the most of this option."

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For more information, visit Camargo at booth #4304 at AAPS or online at camargopharma.com.

About Camargo Pharmaceutical Services

Camargo Pharmaceutical Services is your full-service drug development partner specializing in the 505(b)(2) process. Before development even begins, we verify profit potential by working with your team to develop a comprehensive program and timeline complete with important milestones and cost objectives. We manage every facet of the plan throughout your development continuum, from feasibility assessments, formulation and testing the drug product, to conducting preclinical and clinical studies, to final submission. Connect with Camargo on LinkedIn, the President's blog or visit www.camargopharma.com for more information.

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