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Camargo Celebrates Two 10-Year Anniversaries at DIA

(Cincinnati, OH; June 4, 2013) – The U.S. regulatory landscape has changed dramatically in 10 years. In 2003, the FDA finally resolved legal hurdles to the 505(b)(2) approval pathway, making it a practical alternative route for drug development. The same year, Ken Phelps and Ruth Stevens founded Camargo Pharmaceutical Services to help companies gain approval under 505(b)(2).

The Camargo team will be celebrating both events in booth #410 at the Drug Information Association (DIA) Annual Meeting in Boston, June 23-27.

"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 often still receive patent protection," Phelps said. "2012 was another record year, with 47 505(b)(2) drug approvals in all, 50 percent more than the number approved under 505(b)(1)."

Typically, a new drug application approved under the standard 505(b)(1) regulatory path will take as much as 15 years and a nine-figure investment to work its way through the system. However, drugs approved under 505(b)(2), which can rely in part on data from existing reference drugs, can be developed and achieve FDA approval in as little as 30 months with fewer required clinical trials and at a much lower cost.

"Since the 505(b)(2) pathway became viable, it has rendered significant changes on the drug development landscape," Stevens said. "Today, companies around the world are using 505(b)(2) to gain entry into the U.S. market, and a similar development pathway is being implemented in the E.U. and elsewhere. This is an important and increasingly complex area of drug development, and we're here to help clients sort it out."

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Camargo is currently setting 505(b)(2) consultation appointments with Ken Phelps at DIA. To arrange an appointment, call 1.513.561.3329 or email rbell@camargopharma.com.

About Camargo Pharmaceutical Services

Camargo Pharmaceutical Services is your full-service drug development partner specializing in the 505(b)(2) process. We manage your plan throughout your development continuum, from feasibility assessments, formulation and testing, to conducting preclinical and clinical studies, to final submission. Connect with Camargo on LinkedIn, the President's blog or visit www.camargopharma.com.

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