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Camargo Uses 505(b)(2) To Fast Track Indian Products

(Cincinnati, OH; July 24, 2012) – Camargo Pharmaceutical Services successfully completed five Food and Drug Administration (FDA) pre-IND meetings for 505(b)(2) products in the month of June, including successful meetings with two of India's top 10 largest pharmaceutical companies.

In all meetings, the FDA concurred with Camargo's recommended strategy, giving clients a clear drug development pathway with costs and timing. Camargo's in-house pre-clinical, clinical and regulatory experts leveraged hard-to-find public data and developed innovative study designs to meet the FDA's exacting standards, while minimizing client investments.

A 505(b)(2) is a new drug application that contains full safety and effectiveness reports, but allows at least some of the pivotal information required for approval to come from studies not conducted by or for the applicant.

Camargo, an end-to-end drug development service provider specializing in the 505(b)(2) process, provides expertise to companies in 26 countries in North America, Europe, India and China with the opportunity to gain U.S. approval for new or reformulated drugs in a fraction of the time and cost required by traditional paths.

According to Ken Phelps, Camargo president and CEO, "With numerous blockbuster drugs coming off patent and the impending generic cliff, faster and cheaper development can relieve the pressure of a congested generics landscape."

In 2006, approximately 20 percent of new drugs were approved through the 505(b)(2) process. Today, the percentage of new, small-molecule drugs approved through this process exceeds 80 percent.

Typically, a new drug application approved under the FDA standard 505(b)(1) regulatory path takes as long as 15 years and a nine-figure investment to work its way through the system.

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Drugs approved under 505(b)(2) rely in part on data from existing drugs; therefore, the drugs can be developed and achieve FDA approval in as little as 30 months with only a fraction of the number of required trials and at a much lower cost.

About Camargo Pharmaceutical Services

Camargo Pharmaceutical Services is an end-to-end drug development service provider specializing in the 505(b)(2) approval pathway. Camargo works with companies to develop comprehensive programs, managing every facet of the plan from formulating and testing the drug product, to conducting pre-clinical and clinical studies and FDA application submissions. Connect with Camargo on LinkedIn, the President's blog or visit www.camargopharma.com for more information.

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