Time- and Money-Saving Strategy

A biotech company worked with a different regulatory for advice with a new formulation and indication for a common already-approved drug. Because the drug is well-known, the biotech believed it could utilize an ex-Agency consultant to determine the best path forward. When the biotech ran into problems based on the consultant's strategy, it sought advice and was recommended to consult with Camargo to correct the problems in order to move forward.

By engaging known strategy, Camargo engaged with the biotech and recommended a CMC NDA supplement, versus a clinical supplement. This change saved the biotech a clinical PDUFA fee of $1,019,050. In addition, the four-month review clock for this type of submission saved the biotech six to eight months of review time. This savings has positioned the biotech for success while creating value and conserving cash.

In addition, one of the biotech's executives states:

> "We have been extremely impressed with the level of high-quality input, guidance and work products we have received from all of the consultant team at Camargo. Camargo has not only demonstrated a superb first-hand knowledge of the most current FDA guidance documents and regulations, but also a willingness to explore and weigh-out regulatory strategies and options as shaped from their own experience with FDA. I would highly recommend Camargo to anybody in the 505(b)(2) space and look forward to working with Camargo on a wide-range of regulatory projects."