

Case Study 4

Case Study 4: Full NDA approval without conducting any clinical studies using the 505(b)(2) pathway

Challenge: A Literature-only NDA. Eliminate the need for clinical studies for a fixed dose combination product.

Background: Client wanted to leverage the significant public knowledge about each of the drugs in a fixed dose combination product to file an NDA without conducting any clinical studies. The Agency is understandably reluctant to approve a combination product without clinical studies to address possible drug-drug interaction and biological variabilities.

Solution: With its proprietary research capabilities Camargo was able to collect the relevant information and leverage its 505(b)(2) expertise, build the narrative to support approval while fully addressing the literature that was not entirely supportive of the application. NDA was filed.