

15TH ASIA-PACIFIC PHARMA CONGRESS

July 18-20, 2018 Melbourne, Australia

Drug approval pathways in the US: A focus on the 505(b)(2) pathway and the role of BA/BE studies

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Background: There are 3 major pathways through which drugs can be approved in the US, depending on their similarity to existing drugs, and the source of data that will support the application (see image). The 505(b)(2) regulatory pathway relies to some extent on existing data that comes from sources other than Sponsor studies, and results in smaller development programs than that of previously unknown drugs. A 505(b)(2) approval usually relies heavily on well-designed bioavailability/bioequivalence studies to bridge to the existing data.

Methodology & Theoretical Orientation: This talk will cover the basics of the US regulatory pathways, with special emphasis on products intended for approval via the 505(b)(2) pathway. Which products are appropriate for this pathway, typical features of 505(b)(2) development programs, and when a bio waiver is appropriate will be discussed. Further, a review of products that gained approval based on studies reported in the literature is provided.

Conclusions & Significance: The 505(b)(2) regulatory pathway allows a Sponsor to rely on existing data and therefore reduce the size or scope of the development program. BA/BE studies are often the tenet of a 505(b)(2) approval, and have distinct goals compared with pharmacokinetic studies conducted for 505(b)(1) or generic products. It is therefore critical that BA/BE studies be designed with the nuances of the 505(b)(2) pathway in mind, and to collect additional data that will further reduce the number of studies required for approval. When BA/BE studies are well designed and conducted, and with FDA feedback and input at the appropriate times, a sponsor can expect reduced cost and time to market.

Biography

Angela Drew is a Product Ideation Consultant at Camargo Pharmaceutical Services. Angela has an academic background in inflammatory diseases and cancer, and a regulatory background in FDA submissions for approval via the 505(b)(2) regulatory pathway. Angela has industry experience with US and Australian regulatory submissions, and experience with global clinical program oversight. She is experienced in Product Ideation and design of drug development programs.

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