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ANDA Suitability Petition vs. 505 (B) 2 Applications

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Two routes are well known for filing the variation from the approved RLD as a generic player in the US market that is, filing an Abbreviated New Drug Application (ANDA) following the approval of Suitability Petition (SP) filing and another is filing New Drug Application (NDA) inline with 505(b)(2) of the act. The SP process is addressed in 21 CFR part 10.20 and 10.30, 314.54, 314.93. Most of the times it become confusing in selecting the appropriate route of filing and evaluating their common and uncommon requirements. Underlining information in this article helps in understating the filing requirement of each route and the way in which the US Food and Drug Administration (FDA) has recently begun using its authority for variations is critical for choosing the appropriate path. The differences between the SP and the 505(b)(2) NDA submission are also discussed in FDA.

Biography

Pandya Hardik P.is currently pursuing his 2nd year M. Pharm in Regulatory Affairs from JSS University, Mysore. He has done his graduation from KLE's college of pharmacy Belgaum. He has attended 63rdIPC and presented a poster on "Regulatory Requirements for approval of a new drug in India under Section 122-E" and also attended Indo-American Pharmaceutical Regulatory Symposium- 2011 and presented a poster on "NewAdverse-event reporting policy by FDA during clinical trials: obliging an eloquent practice!".

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Comparison of labelling requirement and review process as per EMA and US FDA

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European Union (EU) Countries and United States of America (USA) are priority markets for pharmaceutical companies for their product. Regulation followed by European Medical Agency (EMA) and United States Food Drug Administration (US FDA) are similar in some cases but different in various region specific requirement. Labelling requirement is recommended to describe in MODULE – I of COMMON TECHNICAL DOCUMENT (CTD). Review process of label information carry out by working group of Quality Review of Document (QRD) of EMA and Centre for Drug Evaluation and Research (CDER). In this paper we compare regulatory requirement of label and review process in EMA and US FDA, under Labelling requirement like, Name, Text, Language, Format, Pictograms, Symbols and other region specific requirements. Our Objective for this comparative study is to identify different regulatory requirement of both, EMA and US FDA, e.g. requirement of BLUE BOX in EMA and BOX WARNING in US FDA. By considering all requirement at an early stage pharma company can avoid revisions and save time & money to launch their product in market. We believe, High standard regulation which is regulated by EMA and US FDA through their expertise in relevant field which helps to control the duplicity, misbranded and counterfeit medicine in the market. High standard and stringent regulation helps both company and patient, also better availability of product in market.

Biography

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