

## 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 2<sup>nd</sup> 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 63<sup>rd</sup> IPC 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 "New Adverse-event reporting policy by FDA during clinical trials: obliging an eloquent practice!"

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## Emergent potential of *Stevia rebaudiana* as a natural excipient

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Natural sweetening agents are preferred over synthetic sweetening agents since they do not have any adverse impact on health. Non-saccharide natural sweetening agents are low calorific, nontoxic and super sweet in nature and can overcome the problems of sucrose and synthetic sweeteners. Natural sweeteners are useful sugar substitutes for diabetic patients. The most common endocrine disorder in human is Diabetes mellitus, a heterogeneous syndrome rather than a single disease entity which have hyperglycemia. Diabetes mellitus is a major health problem not only in urban but also in the rural areas. The natural sweeteners that can substitute for sucrose have caught great attention. The leaves of *Stevia rebaudiana* contain different steviol glycosides, the major constituent being stevioside. Stevioside is a diterpenoid glycoside, comprising an aglycone (steviol) and three molecules of glucose. In addition to stevioside several other sweet compounds such as steviobioside, rebaudioside A, B, C, D, E and ducoside A were isolated from *Stevia rebaudiana*. This review discusses the potential of medicinal and nutritional importance of this wild herb for health care management and also describes its as an alternative for diabetic patients.

### Biography

Mr. Pankaj A. Cheke, doing M.Pharm(Pharmaceutics) in Shivaji University, Kolhapur. Presented posters in various national and international conferences.

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