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The vasoconstrictor assay for BE of topical corticosteroids, 20 years after issuance of the FDA guidance

It has been 21 years since the USFDA introduced its guidance "Topical Dermatologic Corticosteroids: *In vivo* Bioequivalence" (June 2, 1995). Much of the guidance was based on experiences with a previous, failed, 1992 interim guidance and a number of relatively small research studies funded by the FDA. Recently, the guidance has been accepted as a method to gain approval for generic topical corticosteroid products in regulatory jurisdictions outside the US, notably in the EU. Fairly significant changes in the guidance procedures have occurred in practice, with some required by the FDA. Despite this, there have not been official publications by the FDA of these changes. This presentation will briefly cover the historical background leading to the guidance, will describe the methodology in the early years following introduction of the guidance, and refinements to the method that have occurred over the last 20 years. The discussion will distinguish which changes to the guidance method are mandatory and which are not, but which the FDA has found acceptable. Some examples will be given of products that present unique challenges to the vasoconstrictor method.

Biography

Charles Bon is the President/Founder of Biostudy Solutions LLC. He served on FDA's Expert Panel for Bioequivalence of Topical Corticosteroids and FDA's Blue Ribbon Panel on Population and Individual Bioequivalence. He is co-author of the textbook "*Pharmaceutical Statistics*". He has contributed to, or written, a number of chapters in various pharmaceutical books, co-authored a number of scientific papers and regularly presents at scientific meetings.

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