

# **APPENDIX NO. 3**

### Appendix 3

Transcript and Slide from FDA CDER December 2004 On-line Training Seminar entitled "The FDA Process for Approving Generic Drugs," Dale Conner, Pharm.D., Director, Division of Bioequivalence, Office of Generic Drugs, CDER, FDA

See also FDA CDER Website Link:

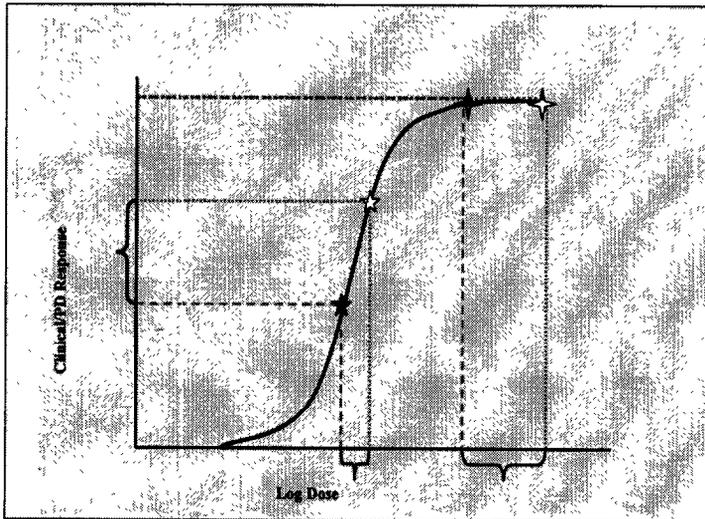
<http://www.connectlive.com/events/genericdrugs/GenericsScriptFINAL.doc>

#### Excerpt from End of SLIDE 17 Transcript (Dale Conner, Pharm.D):

If we consider clinical effects, the pattern of a clinical response, if we remember our pharmacology, is usually an S-shaped or sigmoidal dose response curve. What we're really looking for when we look at differences in bioequivalence is if two pharmaceutically equivalent products, containing the same amount of a drug, effectively deliver a different dose. What we're looking for ideally for a bioequivalent product is that the product should deliver the same dose at the same rate to the body. So putting it on a dose-response curve is valid. We see that the response that we're getting in a therapeutic response is not linear related to a change in dose. It's more S-shaped.

Slide 18 and Excerpt from Beginning of Slide 18 Transcript (Dale Conner, Pharm.D):

### **Clinical/PD Dose-Response**



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If we go to the next slide (i.e., Slide 18 above) and see that relationship blown up, in effect you will see two different situations. What should be evident from the slide is that the dose that you