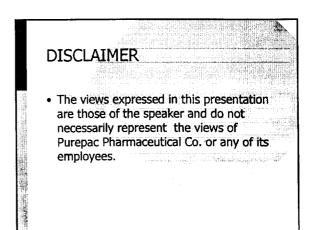
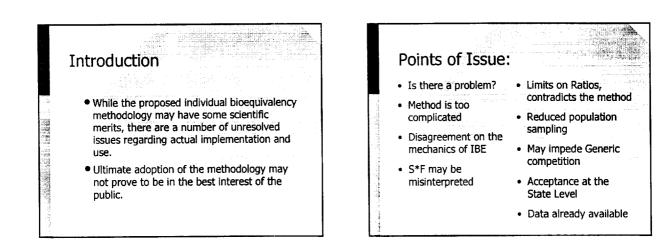
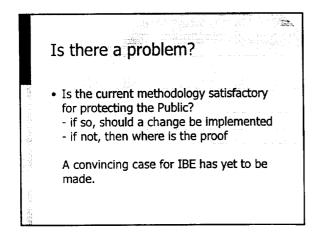
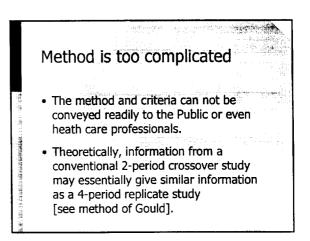
Individual Bioequivalence ... Are we ready for it? Russell J. Rackley, Ph.D.



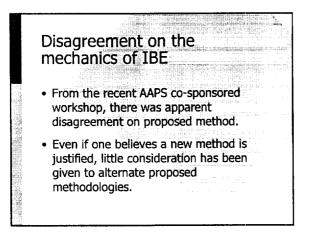


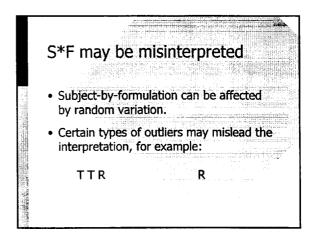


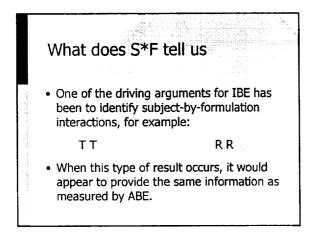


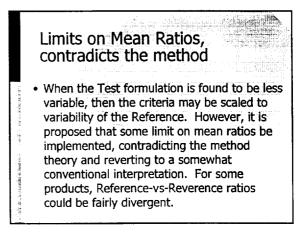
Individual Bioequivalence . . . Are we ready for it?

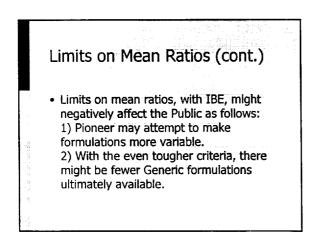
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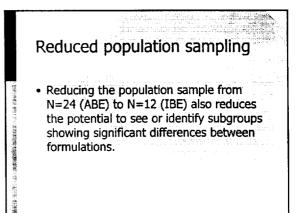












May impede Generic competition

- For variable Pioneer drug formulations, there may be cases where only PBE passes.
- If we move forward with this method, then Pioneer should be held to similar requirements for any significant formulation changes, relative to clinical formulation, pre- or post- approved. IBE results should appear in labeling.

Acceptance at the State Level

 In certain states, where Formularies for substitution of Generic drugs exist, it is already a sometimes tenuous task to gain approval. How will these Formularies react to approvals under the proposed method.

