



4/10/00

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

RE: Docket No. 99D-4809 – Guidance for Industry: Applications Covered by Section 505(b) (2)

One comment to otherwise a well-written, clear and comprehensive guidance:

My comment relates to the bullet “BIOEQUIVALENCE” on page #5. A farther clarification is required for the term “bioequivalent” and the statistical approach to establishing of it.

Basically, you only have to add a phrase to say that the same statistical requirements for 505 (J) apply to 505 (B)(2), i.e. AUC for the generic has to be within 80-120% of the RLD’s AUC. Based on our experience, we’ve seen that the term is not clear to the people at the new drug division, being accustomed to the term “equivalence” not “bioequivalence”. They are not aware of the fact that the generic companies are, at the end of the process, trying to get “AB” rating in the orange book in order to be able to sell their product as “substitutable” generic in the pharmacies.

Including such a phrase will eliminate a lot of misunderstanding on both sides. Thanks for the opportunity to respond to your suggested draft guidance.

Respectfully,

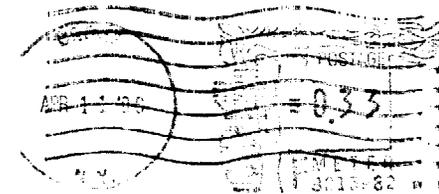
  
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99D-4809

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