



SEP 7 2004

Food and Drug Administration  
Rockville MD 20857

Debra L. Bowen, M.D.  
Vice President, Research and Development  
McNeil Consumer and Specialty Pharmaceuticals  
7050 Camp Hill Road  
Fort Washington, Pennsylvania 19034-2299

Re: Docket No. 2004P-0139/CP1

Dear Dr. Bowen:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on March 19, 2004. Your petition requests that the Agency apply additional bioequivalence metrics other than the average bioequivalence parameters to ensure that the approval of generic versions of Concerta (methylphenidate HCl) extended-release tablets are both bioequivalent and clinically equivalent to the innovator product.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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