



JUL 19 2005

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Anthony Bruno  
Executive Vice President  
General Counsel  
Warner Chilcott  
100 Enteprise Drive  
Rockaway, New Jersey 07866

Re: Docket No. 2005P-0037/CP1

Dear Mr. Bruno:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated January 31, 2005. Your petition requests that FDA refrain from accepting for filing or approving ANDAs filed for estradiol vaginal cream, 0.01%, that use Estrace vaginal cream as the reference listed drug where 1) the bioequivalence data presented in the application rely on blood level data alone or 2) a showing of bioequivalence is not a well-controlled clinical end-point bioequivalence trial that demonstrates equivalent safety and therapeutic effect.

FDA has yet to reach a decision on your petition due to the need to address other Agency priorities. 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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