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J. Mark Pohl, Esq.  
Pharmaceutical Patent Attorneys, LLC  
55 Madison Avenue, 4<sup>th</sup> Floor  
Morristown, NJ 07960-7397

Re: Docket No. 2005P-0237/CP1

Dear Mr. Pohl:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received June 15, 2005. Your petition requests that FDA make a determination that lamotrigine oral tablets in 50 mg and 250 mg strengths were not withdrawn due to safety or efficacy concerns. You also request that FDA determine that these tablet strengths are either exempt from the requirement for pediatric assessment or the requirement is waived.

FDA has been unable to reach a decision on your petition because of 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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

2005P-0237

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