

725 Chesterbrook Blvd.  
Wayne PA 19087-5637 USA  
866 744-7362  
Fax 484 595-8653



December 6, 2005

Nancy E. Boocker, J.D.  
Director, DRPI  
Office of Regulatory Policy (HFD-007)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Rockwall II  
5515 Security Lane  
Rockville, MD 20852

Re: **Citizen Petition: Adderall XR<sup>®</sup>**  
**Docket 2005P-0420/CP1**

Dear Ms. Boocker:

The above-referenced Citizen Petition, submitted by Eliseo O. Salinas, M.D., Chief Scientific Officer, Shire Pharmaceuticals Group, plc, was docketed on October 18, 2005.

The Petition requests that FDA establish therapeutic equivalence requirements for any generic or follow-on drug product referencing Shire's ADHD prescription drug Adderall XR<sup>®</sup>, especially a requirement that the plasma concentration-time pharmacokinetic profile in any bioequivalence study be shown to be identical to (i.e., superimposable upon) the plasma concentration-time pharmacokinetic profile associated with Adderall XR<sup>®</sup> under the once-daily dosing described in the approved labeling for Adderall XR<sup>®</sup>.

We understand that, procedurally, pertinent FDA personnel are consulted in connection with the review of Citizen Petitions. We respectfully request that CDER's Division of Psychiatry Products and Division of Neurology Products be consulted on, and have substantive input into, FDA's consideration of this Petition.

If you have any questions please contact me at 484-595-8373

Sincerely yours,

A handwritten signature in black ink that reads "Charles A. LaPree".

Charles A. LaPree, RAC  
Senior Director, Regulatory Affairs

cc: Thomas Laughren, M.D. (HFD-120)  
Paul J. Andreason, M.D. (HFD-120)  
Richardae Taylor, Pharm.D. (HFD-120)  
Russell G. Katz, M.D. (HFD-120)  
Gary J. Buehler, R.Ph. (HFD-600)