DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-303

Shire Laboratories
Attention: Debra Aleknavage, RAC
Senior Regulatory Affairs Manager
U.S. Research and Development
1801 Research Boulevard, Suite 600
Rockville, MD 20850

Dear Ms. Aleknavage:

Please refer to your correspondence dated June 4, 2004, requesting changes to FDA's Written Request issued on May 6, 2003 (amended September 17, 2003 and May 7, 2004) for pediatric studies for Adderall XR (mixed slats of a single-entity amphetamine product) Extended-Release Capsules.

We have reviewed your proposed changes and are amending the below listed sections of the Written Request. All other terms stated in our Written Request, issued on May 6, 2003 (amended September 17, 2003 and May 7, 2004) remain the same.

We are amending the "Format of reports to be submitted" section of your Written Request, which states the specific information on racial and ethnic minorities to be included in the final study report in accordance with Section 18 of the BPCA. Please note that we are changing the word "must" to "should" twice. All other terms stated in our original Written Request or any subsequent amendments remain the same.

Format of reports to be submitted:
In addition, the reports are to include information on the representation of pediatric patients of ethnic and racial minorities. All pediatric patients enrolled in the study(s) should be categorized using one of the following designations for race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander or White. For ethnicity one of the following designations should be used: Hispanic/Latino or Not Hispanic/Latino.

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, **"PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY"** in large font, bolded type at the beginning of the cover letter of the submission. Notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, **"PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission.

Submit reports of the studies as a **supplement to your approved NDA** with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director,

Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions, call Richardae Taylor, Pharm.D., Regulatory Project Manager, at 301-594-5793.

Sincerely,
{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Temple

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