DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-303/S-009

Shire Development, Inc.
Attention: Charles LaPree, RAC
Senior Director, Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087

Dear Mr. LaPree:

Please refer to your supplemental new drug application dated and received September 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adderall XR (mixed salts of a single-entity amphetamine product) Extended-Release Capsules.

We acknowledge receipt of your additional submissions dated:

October 27, 2004	December 17, 2004	December 22, 2004	January 11, 2005	March 8, 2005
October 29, 2004	December 21, 2004	January 7, 2005	January 13, 2005	May 27, 2005

Your submission of May 27, 2005 constituted a complete response to our March 15, 2005 action letter.

This supplemental new drug application provides for the use of Adderall XR in the treatment of adolescents with attention-deficit hyperactivity disorder.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-303/S-009**." Approval of this submission by FDA is not required before the labeling is used.

Pediatric Research and Equity Act (PREA)
All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

Promotional Materials
In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Psychiatry Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,
{See appended electronic signature page}

Thomas Laughren, M.D.
Acting Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Thomas Laughren
7/21/05 03:17:47 PM