DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-303/S-005

Shire Laboratories, Inc.
Attention: Stephen W. Sherman, JD
Senior Director, Regulatory Affairs
U.S. Research and Development
1801 Research Blvd., Suite 600
Rockville, MD 20850

Dear Mr. Sherman:

Please refer to your supplemental new drug application dated December 18, 2002, 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:

May 8, 2003	August 12, 2003	September 2, 2003	February 27, 2004
July 11, 2003	August 22, 2003	October 27, 2003	July 14, 2004
August 6, 2003	August 26, 2003	February 13, 2004	

Your submission of February 13, 2004 constituted a complete response to our October 17, 2003 action letter.

This supplemental new drug application provides for the use of Adderall XR in the treatment of adult attention deficient hyperactivity disorder (ADHD). (b)(4)----------

(b)(4)----------

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 the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-303/S-005." Approval of this submission by FDA is not required before the labeling is used.

In addition, you must submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5). Current guidance for industry specifies that the content of labeling should be provided in PDF file format. This new submission requirement was published on December 11, 2003 (68 FR

69009) and was effective June 8, 2004. For additional information, consult the following guidance for industry: *Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004).

Pediatric Research 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 are waiving the pediatric study requirement for ages less than 6 years and deferring pediatric studies for ages 13 to 17 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

LIST POSTMARKETING COMMITMENTS:
1. Deferred pediatric study under PREA for the treatment of ADHD in pediatric patients ages 13 to 17.

   Final Report Submission: May 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments**".

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 Neuropharmacological Drug 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

Medwatch
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 Taylor, Pharm.D., Regulatory Project Manager, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}
Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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/

Russell Katz
8/11/04 10:58:28 AM