DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-303/S-001

Shire Laboratories, Inc.
Attention: Rick Lilley, Ph.D.
Senior Vice President, Regulatory Affairs
1901 Research Blvd., Suite 500
Rockville, MD 20850

Dear Dr. Lilley:

Please refer to your supplemental new drug application dated October 26, 2001, received October 26, 2001, 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 amendments dated February 22 and 27, 2002.

This supplemental new drug application provides for three additional strengths: 5 mg, 15 mg and 25 mg.

We also refer to the May 20, 2002, teleconference between representatives of Shire and members of this division, and to the May 22, 2002, telephone conversation between Ms. Debbie Aleknavage and Ms. Anna Marie H. Weikel, during which agreement was reached on the approved labeling for this supplement.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text attached to this letter. Accordingly, the supplemental application is approved effective on the date of this letter.

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

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten 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-001". Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you should have any questions, please call Ms. Anna Marie H. Weikel, R.Ph., Regulatory Health Project Manager, at (301) 594-5535.

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
5/22/02 11:12:20 AM