CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

11-522/S-030

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 11-522/S-030

Shire Pharmaceutical Development, Inc.
Attention: Rick Lilley, PhD
Senior Vice President
1901 Research Blvd., Suite 500
Rockville, MD 20850

Dear Dr. Lilley:

We acknowledge receipt on July 8, 2002, of your July 8, 2002, resubmission to your supplemental new drug application for ADDERALL ™ (Mixed Salts of a Single-Entity Amphetamine Product) Tablets, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg and 30 mg.

With this amendment, we have received a complete response to our action letter.

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}

John Purvis
Chief
Project Management Staff
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-522/S-030

PRIOR APPROVAL SUPPLEMENT

Shire Pharmaceutical Development, Inc.
Attention: Tami T. Martin, R.N., Esq., Vice-President, Regulatory Affairs
1901 Research Boulevard
Suite 500
Rockville, MD 20850

Dear Ms. Martin:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Adderall® CII (Mixed Salts of a Single-Entity Amphetamine Product) Tablets 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, and 30 mg

NDA Number: 11-522

Supplement number: 030

Date of supplement: November 20, 2001

Date of receipt: November 20, 2001

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act January 19, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Attention: Division Document Room, 4008
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Attention: Division Document Room, 4008
1451 Rockville Pike

Rockville, Maryland 20852-1420

If you have any questions, call Anna Marie Homonnay, Regulatory Project Manager, at (301) 594-5535.

Sincerely yours,

Robert H. Seevers, Ph.D.
Chemistry Team Leader
Psychiatric Drugs for the
Division of Neuropharmacological Drug Products
HFD-120
DNDC 1, Office of New Drug Chemistry
Center for Drug Evaluation and Research