DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-522/S-034 and S-037
NDA 21-303/S-013

Shire Development, Inc.
Attention: Elisa Schneider
Manager, Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087

Dear Ms. Schneider:

Please refer to your new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adderall (mixed salts of a single-entity amphetamine product) Tablets (NDA 11-522) and Adderall XR (mixed salts of a single entity amphetamine product) Extended-Release Capsules (NDA 21-303).

We acknowledge receipt of your supplemental new drug application dated December 29, 2005, and amended on April 11, 2006, and May 3, 2006 (NDA 11-522/S-034).

We additionally acknowledge receipt of your submissions dated June 20, 2006, to applications 11-522/S-037 and 21-303/S-013. Your June 20, 2006 submissions constituted a complete response to our May 22, 2006 action letter.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 20, 2006, and enclosed to this letter.

These supplemental applications provide for the following revisions to product labeling.

NDA 11-522/S-034

- Revisions throughout the Adderall Package Insert to align the content and format with the package insert for Adderall XR (mixed salts of a single-entity amphetamine product) Extended-Release Capsules (NDA 21-303).

NDA 11-522/S-037 and NDA 21-303/S-013

- Changes to the **WARNINGS** section to incorporate class labeling revisions, as requested in the Agency letter dated May 22, 2006, to the CNS stimulant products to treat Attention-Deficit Hyperactivity Disorder (ADHD).

- The deletion of the subsections entitled **Effects on Weight** and **Hypertension** from the **PRECAUTIONS** section as they are described in the new **WARNINGS** section.

- For Adderall XR only, the pre-existing "hypertension" language was moved to the **ADVERSE EVENTS** section with a reference to the **WARNINGS** section. Under ADVERSE EVENTS section

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Felecia Curtis, Regulatory Project Manager, at (301) 796-0877.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
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
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