



NDA 21-303/S-010

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

Dear Ms. Schneider:

We acknowledge receipt of your supplemental new drug application dated December 29, 2005, received December 30, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adderall XR® (mixed salts of single-entity amphetamine products) 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg Capsules.

We additionally acknowledge receipt of your submission dated May 3, 2006.

This “Changes Being Effected” supplemental new drug application provides for the following revisions to product labeling:

1. The addition to the **ADVERSE EVENTS** (associated with amphetamine use) section of the terms “rash, hypersensitivity reactions including angioedema and anaphylaxis”.
2. Minor editorial changes to the **DRUG ABUSE AND DEPENDENCE** section.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 3, 2006, and enclosed to this letter.

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
6/16/2006 10:04:13 AM