DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-303 / S-015

Shire US Inc.
Attention: Elisa Schneider
Manager, Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087-5637

Dear Ms. Schneider:

Please refer to the supplemental new drug application 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.

This "Changes Being Effected" supplemental new drug application provides for the addition of a Medication Guide as requested in our letter of February 21, 2007 (clarified in our March 19, 2007 email correspondence).

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the submitted labeling text. 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, email Felecia Curtis, RN, Regulatory Project Manager, at Felecia.Curtis@FDA.HHS.GOV.

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 (labeling)

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
5/22/2007 10:19:12 AM