DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021303/S-020/S-022 **SUPPLEMENT APPROVAL**

Shire Development Inc.
Attention: Jennifer Pavillard
Regulatory Affairs Manager
725 Chesterbrook Boulevard
Wayne, PA 19087-5637

Dear Ms. Pavillard:

Please refer to your Supplemental New Drug Applications (sNDAs), received November 12, 2009 and March 18, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Adderall XR® (dextroamphetamine mixed salts of a single-entity amphetamine product) 5mg, 10mg, 15mg, 20mg, 25mg, and 30mg Capsules.

We also acknowledge receipt of your submission dated February 16, 2010.

These supplemental new drug applications provide for:

- Changes Being Effected Supplement S-020: The addition of Proton Pump Inhibitors to the **PRECAUTIONS, Drug Interactions** section and
- Prior Approval Supplement S-022: Labeling revisions for Adderall XR to meet the "Physician Labeling Rule" (PLR) requirements as defined under 21CFR § 201.56 and 201.57.

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 enclosed, agreed upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

REPORTING REQUIREMENTS

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 your Regulatory Project Manager at Juliette.Toure@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: Product Labeling & Medication Guide

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
11/12/2010