DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021977/S-010/S-015 **SUPPLEMENT APPROVAL**

Shire Pharmaceuticals, Inc.
Attention: Jennifer Pavillard
Global Regulatory Strategy, US Regulatory Lead
725 Chesterbrook Boulevard
Wayne, PA 19087-5637

Dear Ms. Pavillard:

Please refer to your supplemental new drug application dated and received June 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vyvanse (lisdexamfetamine dimesylate) 20mg, 30mg, 40mg, 50mg, 60mg, 70mg capsules.

We acknowledge receipt of your submissions dated July 30, 2009, August 26, 2009, and March 17, 2010. This supplemental new drug application (sNDA) proposes to add information to section **14 Clinical Studies** based on findings from a new clinical trial, SPD489-316, entitled "A Phase IIIb Randomized, Double-Blind, Multicenter, Placebo-controlled, Dose Optimization, Crossover, Safety and Efficacy Workplace Environment Study of Lisdexamphetamine Dimesylate (LDX)" in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)" to product labeling.

We also refer to your "Changes Being Effected" supplemental application submitted on December 21, 2009 (S-015), adding "Stevens-Johnson Syndrome" to **6.2 Postmarketing Reports**.

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.

CONENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 21977/S-010".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the

proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21977	SUPPL-15	SHIRE DEVELOPMENT INC	VYVANSE (LISDEXAMFETAMINE DIMESYLATE)
NDA-21977	SUPPL-10	SHIRE DEVELOPMENT INC	VYVANSE (LISDEXAMFETAMINE DIMESYLATE)

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
04/05/2010