DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-977/S-006/S-007

Shire Development Inc.
Attention: Jennifer Pavillard
Associate Director, Regulatory Affairs, Global Regulatory Strategy
725 Chesterbrook Boulevard
Wayne, PA 19087-5637

Dear Ms. Pavillard:

Please refer to your supplemental new drug applications dated July 15, 2008 (S-006), and July 31, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Vyvanse (lisdexamfetamine dimesylate) 20mg, 30mg, 40mg, 50mg, 60mg, 70mg capsules.

We acknowledge receipt of your amendment dated August 28, 2008.

These supplemental new drug applications provide for the following changes to product labeling:

S-006

- The addition of a Postmarketing Reports section under 6.2 and revisions to the Adverse Reactions sections (6.1 and 6.3).

S-007

- Revisions to the Clinical Studies section (14) to denote an increased efficacy range from 1.5 hours through 13 hours after receiving a dose of Vyvanse.

We have completed our review of these applications. 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, please submit the content of labeling [21 CFR 314.50(l)] 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 and Medication Guide). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-977/S-006/S-007."

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Juliette Touré, PharmD, Senior 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 Laughren
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