DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21977/S-013 **SUPPLEMENT APPROVAL**

Shire Pharmaceuticals
Attention: Kyna Williams
Global Regulatory Strategy- ADHD
Shire Pharmaceuticals
725 Chesterbrook Blvd.
Wayne, PA 19087-5637

Dear Ms. Wiliams:

Please refer to your supplemental new drug application dated, and received November 2, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vyvanse (lisdexamfetamine dimesylate) Capsules 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg.

This "Prior Approval" supplemental new drug application provides for the revision of Section 9.2 Abuse and Dependence language describing the results of Study NRP104, deleting all information pertinent to secondary endpoints and adding a reference in labeling to a published paper by Jasinski, et al that fully describes the results of this study.

We have completed our review of this application. It is 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-013".

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, call Shin-Ye Sandy Chang, Regulatory Project Manager, at (301) 796-3971.

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-13	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
12/02/2009