



NDA 21-977/S-001

NDA APPROVAL

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

Dear Ms. Schneider:

Please refer to your supplemental new drug application (NDA) dated June 29, 2007, received on June 29, 2007, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Vyvanse (lisdexamfetamine dimesylate) 30 mg, 50 mg, 70 mg tablets.

We acknowledge receipt of your submissions dated October 5, 2007, October 31, 2007, December 20, 2007, January 31, 2008 (2), February 15, 2008, March 14, 2008 and April 3, 2008.

This supplemental new drug application provides for the use of Vyvanse (lisdexamfetamine) for the treatment of attention deficit hyperactivity disorder in the adult population.

We have completed our review of this application, as amended. It is approved effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. You are also responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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. 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 supplement 21-977/S-001.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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)

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 www.fda.gov/cder/ddmac.

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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 LCDR Janet Cliatt, Regulatory Project Manager, at (301) 796-0240.

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

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Enclosure

**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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