DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-977

New River Pharmaceuticals Inc.
Attention: Suma Krishnan, M.S., M.B.A., R.A.C.
2200 Kraft Drive, Suite 2050
Blacksburg, VA 24060

Dear Ms. Krishnan:

Please refer to your new drug application (NDA) dated December 6, 2005, received December 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vyvanse (lisdexamfetamine dimesylate) 30 mg, 50 mg, and 70 mg Capsules.

We acknowledge receipt of your submissions dated December 22, 2006, and January 22 and 24 and February 1, 7, 8, and 16, 2007.

Your submission dated December 22, 2006, constituted a complete response to our December 21, 2006, action letter.

This new drug application provides for the use of Vyvanse (lisdexamfetamine dimesylate) Capsules for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6-12 years of age.

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 agreed-upon labeling text enclosed to this letter.

Additionally, we have the following comments and recommendations:

Labeling

1. Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide, immediate container and carton labels). Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "SPL for approved NDA 21-977". Approval of this submission by FDA is not required before the labeling is used.

2. Vyvanse requires the distribution of a Medication Guide under 21 CFR 208 in order to prevent serious adverse effects, inform patients of information concerning risks that could affect their decision to use or continue to use the drug, and/or assure effective use of the drug.

3. Submit as described above, a Medication Guide that is identical in content and format to the enclosed Medication Guide. Under 21 CFR 208, you are responsible for ensuring that the Medication Guide is available for every patient who is dispensed Vyvanse. Therefore, format the proposed Medication Guide in a manner that will assure its appropriate distribution to patients and include a plan to ensure distribution. In addition, submit proposed container and/or carton labels for Vyvanse that include a prominent and conspicuous instruction to provide the Medication Guide to each patient dispensed the drug. The label must state how the Medication Guide is provided (e.g., affixed on the container, provided with the product, etc.).

Chemistry Manufacturing and Controls

1. A retest period of [redacted] for drug substance batches manufactured at both manufacturing sites, [redacted] is granted.

2. An expiration date of 24 months for Vyvanse capsules, 30 mg (manufactured using [redacted]), 50 mg and 70 mg packaged as 100 count in 60 cc/[redacted] bottles is granted.

Office of Clinical Pharmacology

We acknowledge your agreement to adopt the following final dissolution method and specifications for all three capsule strengths, 30 mg, 50 mg, and 70 mg:

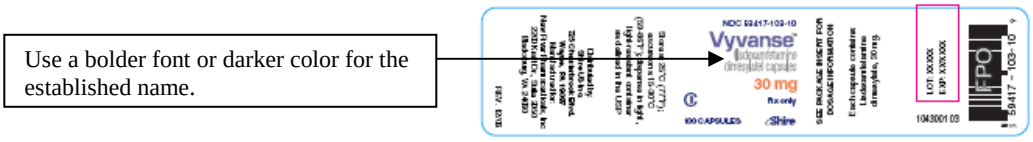
Apparatus:	USP Apparatus 2 (paddle)
Paddle Speed:	50 RPM
Medium:	900 ml of 0.1 N HCL
Specification:	Q=[redacted]% in 15 minutes

Division of Medication Errors and Technical Support

The Division of Medication Errors and Technical Support (DMETS) acknowledges your revisions to the labels and labeling as per our previous recommendations. However, we have the following additional recommendation for the revised label.

<u>Container Labels</u>

The established name is printed in a light grey color that is difficult to read. Please use a bolder font or darker color for the established name in order to improve visibility and readability.



Pediatric Research Equity Act (PREA) Requirements-Studies Waived and Deferred

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages 0 to 5 years (neonates and young children). We are deferring submission of your pediatric studies for ages 13 to 17 years (children and adolescents) until three years from the date of approval of this NDA.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

Post Marketing Commitments

1. Deferred Pediatric Studies Under PREA

You are required to assess the safety and effectiveness of lisdexamfetamine dimesylate as a treatment for Attention Deficit Hyperactivity Disorder in pediatric patients ages 13 to 17.

Final Report Submission: three years from the date of this letter

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Psychiatry Products and two copies of both the promotional materials and the package insert directly 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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The Med Watch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details atwww.fda.gov/medwatch/report/mmp.htm.

The final scheduling of this product by the Drug Enforcement Administration under the Controlled Substances Act is in progress, but not yet complete as of the date of this letter. We note your

commitment dated February 16, 2007, not to market this drug product until scheduling is finalized. We further note that, upon final scheduling, appropriate revisions should be made as necessary to the package insert, the patient-package insert, and the product labeling by submitting a supplement to your NDA.

If you have any questions, call LT Felecia Curtis, R.N., Regulatory Project Manager, at (301) 796-0877.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attachment (Labeling)

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

/s/

Robert Temple

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