DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208510

NDA APPROVAL

Shire Development, LLC
Attention: Peggy Sung
Manager, Global Regulatory Affairs
300 Shire Way
Lexington, MA 02421

Dear Ms. Sung:

Please refer to your New Drug Application (NDA) dated March 31, 2016, received March 31, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vyvanse (lisdexamfetamine dimesylate) 10, 20, 30, 40, 50 and 60 mg chewable tablets.

This new drug application provides for the use of Vyvanse (lisdexamfetamine dimesylate) chewable tablets for the treatment of Attention Deficit Hyperactivity Disorder and the treatment of Binge Eating Disorder per the attached content of labeling.

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 text.

WAIVER OF HIGHLIGHTS SECTION

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 23, 2016, submission containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirement for ages 0 to less than 4 years because necessary studies are impossible or highly impracticable. This is because the diagnostic criteria and assessment measures for determining efficacy for the treatment of ADHD in children less than 4 years old are not well defined and studies in this age group are a challenge with regard to patient safety and study validity. Pharmaceutical treatment in this age group is uncommon and non-medication interventions are preferred treatment for behavioral disorders such as ADHD in very young children (e.g., less than 4 years of age).

We are deferring submission of your pediatric studies for ages 4 to less than 6 years for this application because pediatric studies should be delayed until additional safety or effectiveness data have been collected. At the current time, FDA has limited experience with the study of ADHD in younger children (4 to less than 6 years old), so we will defer studies in this younger age group for drugs seeking a claim in ADHD.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(C) of the FDCA. These required studies are listed below.

3149-1 Deferred pediatric study under PREA in children ages 4 to less than 6 years with a diagnosis of ADHD to obtain pharmacokinetic, safety, and tolerability data to inform dose selection for efficacy and safety studies in pediatric patients with ADHD.

Final Protocol Submission:	06/2017
Study/Trial Completion:	12/2018
Final Report Submission:	06/2019

3149-2 A randomized, double-blind, placebo-controlled efficacy study of VYVANSE (lisdexamfetamine dimesylate) chewable tablets in children ages 4 to less than 6 years diagnosed with ADHD.

Final Protocol Submission:	06/2019
Study Completion:	09/2022
Final Report Submission:	06/2023

3149-3 A 12-month open-label safety study of patients age 4 to less than 6 years (at the time of entry into PMR 3149-1 or PMR 3149-2, or at the time of enrollment if directly enrolled into PMR 3149-3) diagnosed with ADHD treated with VYVANSE (lisdexamfetamine dimesylate) chewable tablets.

Final Protocol Submission:	06/2019
Study Completion:	09/2022
Final Report Submission:	06/2023

We acknowledge that you are conducting pediatric studies with lisdexamfetamine dimesylate capsules; because you have demonstrated bioequivalence between this product and the capsule formulation, we can consider data from those trials in support of the deferred pediatric studies listed above.

Submit the protocols to your IND 67482, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

This product is appropriately labeled for use in ages 6 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

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, Medication Guide, and patient PI (as applicable) to:

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

/s/

MITCHELL V Mathis
01/28/2017