



NDA 021977/S-034
NDA 208510/S-002

SUPPLEMENT APPROVAL

Shire Development LLC
Attention: Peggy Sung
Manager, Global Regulatory Affairs
300 Shire Way
Lexington, MA 02421-2101

Dear Ms. Sung:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 5, 2014, and your amendments, for NDA 021977/S-034 as well as your sNDA dated and received July 26, 2017, for NDA 208510/S-002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vyvanse (lisdexamfetamine dimesylate) 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg Capsules (NDA 021977) and Vyvanse (lisdexamfetamine dimesylate) 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg chewable tablets (NDA 208510).

We acknowledge receipt of your amendment to supplemental application 021977/S-034 dated July 25, 2016, which constituted a complete response to our July 29, 2015, action letter.

These Prior Approval supplemental new drug applications provide for an update to the Adverse Reactions section of the United States Package Insert (USPI) because you have identified discrepancies between the USPI and Brazilian Health Care Professional Leaflet as a result of a labeling update for Brazil.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your July 26, 2017, submission includes final printed labeling (FPL) for your package insert, Medication Guide. We have not reviewed this FPL. You are 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.

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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 and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, please email Simran Parihar, PharmD, at simran.parihar@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
Division Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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
07/31/2017