DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022063

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 July 21, 2006, received July 21, 2006, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mydayis (mixed salts of a single-entity amphetamine product) extended-release capsules 12.5 mg, 25 mg, 37.5 mg, and 50 mg.

We acknowledge receipt of your amendment dated December 20, 2016, which constituted a complete response to our May 18, 2007, action letter.

This new drug application provides for the use of Mydayis (mixed salts of a single-entity amphetamine product) extended-release capsules for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

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. Content of labeling must be identical to the enclosed labeling (text for the package insert and 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 June 20, 2017, submission containing final printed carton and container labels.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Latrice Wilson, PharmD
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 4111
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

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 study requirement for ages 0 to 3 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 pharmaceutical treatment in this age group is uncommon.

We are deferring submission of your pediatric studies for ages 4 to 5 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act 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 Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

3224-1 A single-dose, open-label, randomized pharmacokinetic study of MYDAYIS (mixed salts of a single-entity amphetamine product) extended-release in male and female children (4 to less than 6 years of age) with ADHD.

Final Protocol Submission: 09/01/2017
Study/Trial Completion: 12/31/2018
Final Report Submission: 06/30/2019

3224-2 A 4-week randomized, double-blind, placebo-controlled, fixed -dose study of MYDAYIS (mixed salts of a single-entity amphetamine product) extended-release 6.25 mg in 4 to 5 year olds diagnosed with ADHD.

Final Protocol Submission: 09/01/2017
Study/Trial Completion: 12/31/2018
Final Report Submission: 06/30/2019

3224-3 Because of adverse reactions identified during your development program, it is not apparent from the studies you have conducted in 6 to 12 year old patients with ADHD that the lowest effective dose of MYDAYIS (mixed salts of a single-entity amphetamine product) extended-release has been identified. Conduct a 4-week randomized, double-blind, placebo-controlled, dose optimization study of MYDAYIS (mixed salts of a single-entity amphetamine product) extended-release 6.25 mg and 12.5 mg in 6 to 12 year olds diagnosed with ADHD.

Final Protocol Submission: 09/01/2017
Study/Trial Completion: 12/31/2018
Final Report Submission: 06/30/2019

3224-4 A one year Pediatric Open-Label Safety Study for patients age 4 to 12 years (at the time of entry into PMR 3224-1, PMR 3224-2, or PMR 3224-3) with ADHD.

Final Protocol Submission: 09/01/2018
Study/Trial Completion: 12/31/2019
Final Report Submission: 06/30/2020

Submit the protocols to your IND 066329, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (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.

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:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, contact Latrice Wilson, PharmD, Regulatory Project Manager, at latrice.wilson@fda.hhs.gov or (240) 402-5317.

Sincerely,

{See appended electronic signature page}

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

Enclosures:
Content of Labeling
Carton and Container Labeling

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