



NDA 022063/S-001

**SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING REQUIREMENTS**

Shire Development, LLC
Attention: Chayla Freeman, MS, JD
Associate Director, Global Regulatory Affairs
300 Shire Way
Lexington, MA 02421-2101

Dear Ms. Freeman:

Please refer to your supplemental new drug application (sNDA) dated March 13, 2019, received March 13, 2019, 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.

This Prior Approval supplemental new drug application provides for the addition of safety information in pediatric patients ages 12 years and younger with Attention Deficit Hyperactivity Disorder (ADHD).

APPROVAL & 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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

changes in pending “Changes Being Effected” (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 *SPL Standard for Content of Labeling Technical Qs and As*.²

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(I)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submissions dated March 13, 2019, and June 26, 2019, containing the final reports for the following postmarketing requirements listed in the June 20, 2017, approval letter and March 14, 2018, new postmarketing requirement letter.

- 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.

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

- 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.
- 3224-5 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 extended-release) has been identified. Conduct a 4-week randomized, double-blind, placebo-controlled, fixed-dose efficacy and safety study of MYDAYIS (mixed salts of a single-entity amphetamine extended-release) 6.25mg in 6 to 12 year-olds diagnosed with ADHD. (Study SHP465-309)

We have reviewed your submissions and conclude that the above requirements were fulfilled.

This completes all of your postmarketing requirements acknowledged in our June 20, 2017, and March 14, 2018, letters.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
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 *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

³ When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵ For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.⁶

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, RAC, Senior Regulatory Project Manager, at latrice.wilson@fda.hhs.gov or (240) 402-5317.

Sincerely,

{See appended electronic signature page}

Tiffany R. Farchione, MD
Director (Acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Medication Guide

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

⁶ <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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