CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022063Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA) Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	April 13, 2017
Application Type and Number:	NDA 022063
Product Name and Strength:	Mydayis (mixed salts of a single-entity amphetamine product) extended-release capsules 12.5 mg, 25 mg, 37.5 mg, and 50 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Shire Development LLC
Panorama #:	2017-12614118
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Mydayis, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant resubmitted the 2014 external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The Applicant initially submitted the proposed proprietary name (b) (4) on July 21, 2006 for NDA 022063. DMEPA found the name conditionally acceptable in OSE Review 2007-21, dated May 2, 2007. The FDA issued an Approvable Letter to the NDA on May 18, 2007. The Applicant withdrew the name (b) (4) on December 17, 2014 and submitted the proposed name, Mydayis, on December 18, 2014 for our review. The name Mydayis was found conditionally acceptable in a memorandum appended to OSE Review 2014-46036, dated June 3, 2015. The Applicant submitted a Class 2 Resubmission of the NDA on December 20, 2016. Subsequently, the Applicant resubmitted the proposed name Mydayis for review on January 17, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 17, 2017 proprietary name submission.

- Intended Pronunciation: my-DAY-is
- Active Ingredient: mixed salts of a single-entity amphetamine product
- Indication of Use: Treatment of Attention Deficit Hyperactivity Disorder (ADHD)
- Route of Administration: Oral
- Dosage Form: Extended-release capsule
- Strengths: 12.5 mg, 25 mg, 37.5 mg and 50 mg
- Dose and Frequency: The recommended starting dose is 12.5 mg once daily in the morning. Dosage may be adjusted in increments of 12.5 mg no sooner than weekly to a maximum dose of 50 mg once daily.
- How Supplied: 100-count bottles
- Storage: Store at room temperature, 20ºC to 25ºC (68ºF to 77ºF). Excursions permitted between 15-30º C (59-86º F)
- Container and Closure Systems: HDPE bottle (b) (4).

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Division of Psychiatry Products (DPP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name.[a]

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Mydayis, is not derived from any one particular concept. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Eighty-five (85) practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 7, 2017 e-mail, the Division of Psychiatry Products (DPP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Safety Assessment of the Proposed product Mydayis and risk of confusion with currently marketed Adderall XR

The proposed product Mydayis contains the exact combination of mixed amphetamine salts found in the currently marketed Adderall XR, which is also a Shire product. We identified similarities that may lead to confusion or risk of prescribing errors between the two products if not adequately mitigated. Both products have the same established name and dosage form (mixed salts of a single-entity amphetamine product extended release capsule). Additionally, both products overlap in frequency of administration (once daily in the morning) and overlap in one strength (25 mg). Although, the products have similarities, they also have differences. One difference is in their pK profiles, specifically, in the duration of action. Mydayis has a duration of action of 16 hours whereas Adderall XR has a duration of action of 10 to 12 hours. We are concerned that health care practitioners and patients will not be aware that Mydayis is different

[a] USAN stem search conducted on March 10, 2017.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.