CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207202Orig1s000

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:	July 14, 2017
Application Type and Number:	NDA 207202
Product Name and Strength:	Abilify MyCite (aripiprazole + ingestible event marker) tablets 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Otsuka Pharmaceutical Company, Ltd.
Panorama #:	2017-14615908
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Abilify MyCite, 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 submitted an external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The Applicant, Otsuka Pharmaceutical Company, Ltd., previously submitted the proposed proprietary name, Abilify MyCite***, on December 2, 2015. The name was found conditionally acceptable in OSE Review #2180714, dated February 22, 2016. [a] However, the NDA application received a Complete Response (CR) action on April 26, 2016. On April 21, 2017, Otsuka submitted a Class II resubmission of the NDA as well as a Request for Proprietary Name Review of Abilify MyCite.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 21, 2017 proprietary name submission.

- Intended Pronunciation: Abilify *MY-site*
- Active Ingredient: aripiprazole
- Indication of Use: Abilify MyCite is a combination of Abilify (an atypical antipsychotic) embedded with an Ingestible Event Marker (IEM) that communicates with a Patch (wearable sensor) and a medical software application. (b) (4) is indicated for the treatment of:
  - Schizophrenia
  - Acute Treatment of Manic and Mixed Episodes associated with Bipolar I Disorder
  - Adjunctive Treatment of Major Depressive Disorder
- Route of Administration: Oral
- Dosage Form: Tablets
- Strengths: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg
- Dose and Frequency: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, or 30 mg orally once daily
- How Supplied: 30-count bottles of aripiprazole + IEM tablets and (b) (4) wearable sensors
- Storage: Tablets: Store at 25°C (77°F); excursions permitted betwe n 15°C to 30°C (59°F to 86°F); Wearable Sensor: Store between 15°C and 30°C (59°F to 86°F), 15% to 93% relative humidity.

[a] Holmes L. Proprietary Name Review for Abilify MyCite (NDA 207202). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Feb 22. RCM No.: 2015-2180714.

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 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.[b]

2.2.2 Components of the Proposed Proprietary Name

The name Abilify MyCite is comprised of the root name, Abilify (an FDA approved proprietary name) and the modifier "MyCite". The Applicant also indicated the following in their submission:

The proposed proprietary name for the three-part medical device system is ABILIFY MYCITE. The modifier MYCITE is the proposed name for the three-part medical device system and it will be used in combination with the drug ABILIFY.

The modifier MYCITE (pronounced MY-site) is meant to subtlety suggest "my information", which communicates that the aripiprazole + IEM combination drug-device and associated system provides patients with a view of their personalized medical information, providing (b) (4) *biometric data, and supporting communication between patients, caregivers and HCPs.*

The root name "Abilify" was previously assessed[c] and a determination was made that it is appropriate for this product. We have no outstanding concerns with the root name and we continue to find the proposed root name acceptable. Our analysis of the appropriateness of the modifier is discussed in Section 2.2.5.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 5, 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.

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[b] USAN stem search conducted on May 16, 2017.

[c] Holmes L. Proprietary Name Review for Abilify MyCite (NDA 207202). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Feb 22. RCM No.: 2015-2180714.

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