# 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<br>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.

### *2.2.4 FDA Name Simulation Studies*

Sixty-nine (69) practitioners participated in DMEPA's prescription studies. Five participants in the prescription studies [outpatient (1), voice (1) and inpatient (3)], interpreted the name as "Abilify" and did not include the modifier "MyCite" in their response. We discuss the risk associated with the omission of the modifier in Section 2.2.5.

Appendix B contains the results from the verbal and written prescription studies.

### *2.2.5 Safety assessment of the modifier, MyCite*

The modifier "MyCite" was previously assessed[d] and a determination was made that a modifier is necessary and that the modifier "MyCite" is appropriate for this product. We have no outstanding concerns with the modifier and we continue to find the proposed modifier acceptable because of the following reasons:

An external name study by (b) (4) was submitted in support of the name Abilify MyCite with the initial name submission in 2015 and again in support of the current name submission. We previously evaluated the external study and concurred with (b) (4) conclusion. For the current name submission, (b) (4) conducted a gap analysis and name safety evaluation to assess whether any new potential conflicts had arisen in the interim period between their initial primary research (2013) and the present (February 2017). The drug name Mytesi was identified in their gap search.

We evaluated the risk of confusion between Abilify MyCite and the name Mytesi that was identified in the (b) (4) external study as having similarity to the modifier MyCite. (b) (4) determined that although there is moderate orthographic and phonetic similarity between Abilify MyCite and Mytesi, Mycite will be linked to the root name Abilify, which significantly limits the potential for confusion. Also, differences in product characteristics will limit the potential for confusion and medication errors. Thus, (b) (4) concluded that Abilify MyCite and Mytesi do not have a high probability of medication errors due to proprietary name confusion. We agree with (b) (4) assessment and find that the names Abilify MyCite and Mytesi can safely coexist in the marketplace.

In our evaluation, we also considered the risk of name confusion if the modifier "MyCite" is dropped. We note that omission and oversight of modifiers is cited in literature as a common cause of medication errors.[e] Although modifiers may be omitted, when used, they can assist in differentiating products and may help to prevent potential product selection errors. Postmarket experience shows that the introduction of product line extensions may result in medication errors if the modifier is omitted and the product characteristics are similar or overlap. An alternative to using a modifier to distinguish this product from the currently marketed products is to use a different root name. However, marketing the new product under a unique proprietary name also

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[d] 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.

[e] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

carries a risk of medication errors, such as therapeutic duplication and overdoses. These errors may have greater associated safety risks than the omission or oversight of the modifier as discussed above.

Thus, given the totality of factors considered above, we conclude that the modifier "Mycite" is acceptable for the proposed product.

### *2.2.6 Medication Error Data Selection of Cases*

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving the proprietary name, Abilify, that would be relevant for this review.

| **Table 2. FAERS Search Strategy** | |
|---|---|
| **Search Date** | June 21, 2017 |
| **Drug Name** | Product name: Abilify, Abilify Discmelt, Abilify Maintena<br>Active Ingredient: aripiprazole<br>Product Verbatim: Abilify |
| **Event (MedDRA Terms)** | **DMEPA Official PNR Name Confusion Search Terms Event List:**<br>Preferred Terms:<br>CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR<br>DRUG ADMINISTRATION ERROR<br>DRUG DISPENSING ERROR<br>DRUG PRESCRIBING ERROR<br>INTERCEPTED DRUG DISPENSING ERROR<br>INTERCEPTED DRUG PRESCRIBING ERROR<br>INTERCEPTED MEDICATION ERROR<br>MEDICATION ERROR<br>PRODUCT NAME CONFUSION<br>TRANSCRIPTION MEDICATION ERROR<br><br>Lower Level Terms:<br>INTERCEPTED PRODUCT SELECTION ERROR<br>INTERCEPTED WRONG DRUG PRODUCT SELECTED<br>INTERCEPTED WRONG DRUG SELECTED<br>PRODUCT SELECTION ERROR<br>WRONG DEVICE DISPENSED<br>WRONG DRUG ADMINISTERED<br>WRONG DRUG DISPENSED<br>WRONG DRUG PRESCRIBED<br>WRONG DRUG PRODUCT SELECTED |

| Table 2. FAERS Search Strategy | |
|---|---|
| | WRONG DRUG SELECTED<br>WRONG PRODUCT SELECTED<br>**PREFERRED TERM:**<br>MEDICATION ERROR |
| **Date Limits** | Gap Search: January 26, 2016 (end date of our previous search in OSE Review #2015-2180714) to June 21, 2017 |

Our search retrieved 38 cases. Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, these 38 cases were excluded from final analysis because they did not describe confusion between the name Abilify and another US drug name. Thus, we continue to find the use of the root name, Abilify, acceptable for the proposed product.

#### *2.2.7 Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on July 7, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on July 14, 2017, they stated no additional concerns with the proposed proprietary name, Abilify MyCite.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Alycia Anderson, OSE Project Manager, at 240-402-4270.

### 3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Abilify MyCite, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your April 21, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES


1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [f]

[f] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

| | Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance. |
|---|---|
| **Y/N** | **Is the proposed name obviously similar in spelling and pronunciation to other names?** |
| | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products. |
| **Y/N** | **Are there inert or inactive ingredients referenced in the proprietary name?** |
| | Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)). |
| **Y/N** | **Does the proprietary name include combinations of active ingredients?** |
| | Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)). |
| **Y/N** | **Is there a United States Adopted Name (USAN) stem in the proprietary name?** |
| | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem. |
| **Y/N** | **Is this proprietary name used for another product that does not share at least one common active ingredient?** |
| | Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name. |
| **Y/N** | **Is this a proprietary name of a discontinued product?** |
| | Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients. |

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the checklist (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[g]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

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[g] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

**Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).**

| Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose. | | | |
|---|---|---|---|
| Orthographic Checklist | | Phonetic Checklist | |
| **Y/N** | Do the names begin with different first letters?<br>*Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.* | **Y/N** | Do the names have different number of syllables? |
| **Y/N** | Are the lengths of the names dissimilar* when scripted?<br>**FDA considers the length of names different if the names differ by two or more letters.* | **Y/N** | Do the names have different syllabic stresses? |
| **Y/N** | Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? | **Y/N** | Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? |
| **Y/N** | Is there different number or placement of cross-stroke or dotted letters present in the names? | **Y/N** | Across a range of dialects, are the names consistently pronounced differently? |
| **Y/N** | Do the infixes of the name appear dissimilar when scripted? | | |
| **Y/N** | Do the suffixes of the names appear dissimilar when scripted? | | |

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).**

| | |
|---|---|
| Step 1 | Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential |

| | |
|---|---|
| | for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>• Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.<br><br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>• Similar sounding doses: 15 mg is similar in sound to 50 mg |
| Step 2 | Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses. |

| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>*FDA considers the length of names different if the names differ by two or more letters.<br>• Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?<br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<br>• Do the suffixes of the names appear dissimilar when scripted? | Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• Across a range of dialects, are the names consistently pronounced differently? |

**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).**

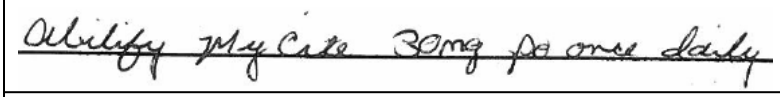
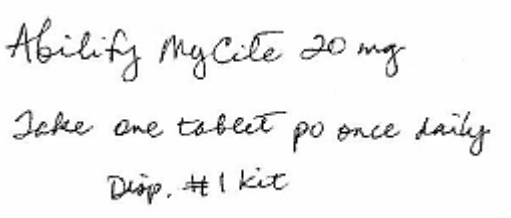
| |
|---|
| Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist. |

## Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

**Appendix B:** Prescription Simulation Samples and Results

**Figure 1. Abilify MyCite Study (Conducted on May 15, 2017)**

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Abilify MyCite 20 mg<br>Take one tablet by mouth once daily<br>Dispense: 1kit |
| Outpatient Prescription:<br>  <br> | |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

| | | | 296 People Received Study<br>69 People Responded | |
|---|---|---|---|---|
| **Study Name: Abilify MyCite** | | | | |
| **Total** | **22** | **18** | **29** | |
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| ABILFY MISITE | 0 | 1 | 0 | 1 |
| ABILIFY | 1 | 1 | 3 | 5 |
| ABILIFY MCCILE | 1 | 0 | 0 | 1 |
| ABILIFY MGCITE | 2 | 0 | 1 | 3 |
| ABILIFY MICITE | 1 | 0 | 0 | 1 |
| ABILIFY MY CITE | 0 | 0 | 4 | 4 |
| ABILIFY MY SIGHT | 0 | 2 | 0 | 2 |
| ABILIFY MYCATE | 0 | 0 | 2 | 2 |
| ABILIFY MYCILE | 1 | 0 | 0 | 1 |
| ABILIFY MYCIRE | 0 | 0 | 1 | 1 |
| ABILIFY MYCITE | 16 | 3 | 16 | 35 |
| ABILIFY MYLATE | 0 | 0 | 1 | 1 |
| ABILIFY MYSIDE | 0 | 1 | 0 | 1 |
| ABILIFY MYSIGHT | 0 | 3 | 0 | 3 |
| ABILIFY MYSITE | 0 | 5 | 0 | 5 |
| ABILIFYMY CITE | 0 | 0 | 1 | 1 |
| ABILIFYMY SIGHT | 0 | 1 | 0 | 1 |
| ABILITY MYSITE | 0 | 1 | 0 | 1 |

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/s/

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LORETTA HOLMES
07/14/2017

LOLITA G WHITE
07/14/2017

**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:** | February 22, 2016 |
| **Application Type and Number:** | NDA 207202 |
| **Product Name and Strength:** | Abilify Mycite (aripiprazole plus ingestible event marker) Tablets<br>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 #:** | 2015-2180714 |
| **DMEPA Primary Reviewer:** | Loretta Holmes, BSN, PharmD |
| **DMEPA Team Leader:** | Danielle Harris, PharmD, BCPS |

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 (Otsuka Pharmaceutical Company, Ltd) submitted an external name study, conducted by [redacted], for this product.

## 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, [redacted]*** on July 29, 2014 under IND 115927 and on July 1, 2015 under NDA 207202. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, [redacted]*** acceptable in Panorama Reviews #2014-25972 and #2015-887015 under the IND and NDA, respectively. On September 15, 2015, the Applicant indicated the name [redacted]*** was no longer being considered and requested a review of the proposed proprietary name, [redacted]***. The name [redacted] was withdrawn by the Applicant on September 21, 2015. The name [redacted]*** was found unacceptable in Panorama Review #2015-5661660 because it would misbrand the product.

Subsequently, on December 2, 2015, the Applicant submitted the name, Abilify Mycite***, for review.

## 1.2 PRODUCT INFORMATION

**Table 1. Relevant Product Information for Abilify Mycite (aripiprazole plus ingestible event marker), Abilify (aripiprazole), Abilify Discmelt (aripiprazole), and Abilify Maintena Kit (aripiprazole)**

| Product Name | Abilify Mycite *** | Abilify | Abilify Discmelt | Abilify Maintena Kit |
|---|---|---|---|---|
| **Initial Approval Date** | N/A | 2002 | 2006 | 2013 |
| **Active Ingredient** | aripiprazole + ingestible event marker (IEM) | aripiprazole | aripiprazole | aripiprazole |
| **Proposed Pronunciation** | a bil' i fye MY-cite | a bil' i fye | Not available | a bil' i fye main-TEN-a |

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

| **Table 1. Relevant Product Information for Abilify Mycite (aripiprazole plus ingestible event marker), Abilify (aripiprazole), Abilify Discmelt (aripiprazole), and Abilify Maintena Kit (aripiprazole)** | | | | |
|---|---|---|---|---|
| **Product Name** | **Abilify Mycite ***** | **Abilify** | **Abilify Discmelt** | **Abilify Maintena Kit** |
| **Indication** | (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 | Oral: Schizophrenia, Acute Treatment of Manic and Mixed Episodes associated with Bipolar I, Adjunctive Treatment of Major Depressive Disorder, Irritability Associated with Autistic Disorder, and Treatment of Tourette's disorder<br><br>Injection: Agitation associated with schizophrenia or bipolar mania | Schizophrenia, Acute Treatment of Manic and Mixed Episodes associated with Bipolar I, Adjunctive Treatment of Major Depressive Disorder, Irritability Associated with Autistic Disorder, and Treatment of Tourette's disorder | Treatment of schizophrenia |
| **Route of Administration** | Oral | Oral; Intramuscular | Oral | Intramuscular |
| **Dosage Form(s)** | Tablets | Tablet<br>Oral solution<br>Injection<br>*(oral solution and injection have been discontinued)* | Disintegrating tablets<br>*(discontinued)* | Extended-release suspension for injection |

**Table 1. Relevant Product Information for Abilify Mycite (aripiprazole plus ingestible event marker), Abilify (aripiprazole), Abilify Discmelt (aripiprazole), and Abilify Maintena Kit (aripiprazole)**

| Product Name | Abilify Mycite *** | Abilify | Abilify Discmelt | Abilify Maintena Kit |
|---|---|---|---|---|
| **Strengths** | 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg | Tablets:<br>2 mg, 5 mg, 10 mg, 15 mg 20 mg, and 30 mg<br>Oral solution *(discontinued)*:<br>1 mg/mL<br>Injection *(discontinued)*:<br>9.75 mg/1.3 mL single dose vial | 10 mg and 15 mg (discontinued) | 300 mg and 400 mg single use vials and dual chamber syringes |
| **Dose and Frequency** | 2 mg to 30 mg once daily | Oral:<br>2 mg to 30 mg once daily<br>IM injection:<br>5.25 mg to 15 mg | The dosing for is the same as for the oral tablets | 160 mg, 200 mg, 300 mg or 400 mg once per month |
| **How Supplied** | Kits:<br>30-count bottle of aripiprazole tablets embedded with ingestible event marker (IEM) and (b) (4) Proteus Patches | Tablets:<br>Bottles of 30; Blisters of 100 | Product has been discontinued | Vial Kits:<br>300 mg or 400 mg vial, one vial of diluent , 3 needles (1 inch, 1.5 inch, and 2 inch)<br>Dual Chamber Syringe Kits:<br>300 mg or 400 mg pre-filled dual chamber syringe containing lyophilized powder and sterile water for injection; 3 needles (1 inch, 1.5 inch and 2 inch) |

| Table 1. Relevant Product Information for Abilify Mycite (aripiprazole plus ingestible event marker), Abilify (aripiprazole), Abilify Discmelt (aripiprazole), and Abilify Maintena Kit (aripiprazole) | | | | |
|---|---|---|---|---|
| **Product Name** | **Abilify Mycite ***** | **Abilify** | **Abilify Discmelt** | **Abilify Maintena Kit** |
| **Storage** | Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) | Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) | *Product has been discontinued.* | Vial:<br>Store at 25°C (77°F), excursions permitted between 15°C and 30°C (59°F to 86°F)<br><br>Dual Chamber Syringe:<br>Store below 30°C [86°F]. Do not freeze. Protect the syringe from light by storing in the original package until time of use |

## 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[1].

#### *2.2.2 Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the proposed name, Abilify Mycite, is comprised of the root name, Abilify, and the modifier "Mycite". The Applicant provided the following information:

[1]USAN stem search conducted on February 1, 2016.

1. The root name is derived from, "Abilify", an FDA approved proprietary name.

2. The modifier "Mycite" (pronounced MY-cite) 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.

Our evaluation of the root name and modifier is discussed in Sections 2.2.7 and 2.2.8, respectively.

### *2.2.3 FDA Name Simulation Studies*

Seventy-two 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, December 22, 2015 e-mail, the Division of Psychiatry Products (DPP) had the following comments: *Is "Mycite" the only name, or is it "Abilify Mycite"? Will other IEM-embedded products also have the "Mysite" name attached, or will they get their own proprietary name as well? And, if it's not going to be "Abilify Mycite," how will prescribers and patients know that it's just Abilify with a chip.* These questions were answered by DMEPA in a follow-up email response and no further concerns or questions were forwarded by DPP.

### *2.2.5 Medication Error Data Selection of Cases*

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving the proprietary name, Abilify, that would be relevant for this review.

**Table 2. FAERS Search Strategy**

| | |
|---|---|
| **Search Date** | February 16, 2016 |
| **Drug Name** | Abilify, Abilify Discmelt, Abilify Maintena, aripiprazole, and aripiprazole lauroxil |
| **Event (MedDRA Terms)** | **DMEPA Official Proprietary Name Review Search Terms Event List:**<br>Product name confusion (PT)<br>Medication error (PT)<br>Intercepted medication error (PT)<br>Drug dispensing error (PT) |

| | |
|---|---|
| | Intercepted drug dispensing error (PT)<br>Circumstance or information capable of leading to a medication error (PT) |
| **Date Limits** | Gap Search: October 24, 2014 (date of previous search in Panorama Review #2014-25972) to January 26, 2016 |

Our search identified 52 cases. Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, these 52 cases were not analyzed further because they did not describe confusion between Abilify and another US drug name.

### *2.2.6 Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on February 17, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on February 18, 2016, they stated no additional concerns with the proposed proprietary name, Abilify Mycite.

### *2.2.7 Safety Analysis of the root name "Abilify"*

In our evaluation of the proposed name, Abilify Mycite, we considered whether the use of the root name, Abilify, is appropriate for this product. The proposed product is identical (in active ingredient, strength, dose, route of administration, frequency of administration, and psychiatric indications) to the currently marketed Abilify tablets with the difference being the fact that the proposed product contains the Ingestible Event Market (IEM). The currently marketed Abilify products contain aripiprazole. Since the proposed product also contains aripiprazole and is identical in all other product characteristics, the use of the root name Abilify seems reasonable.

The root name Abilify has been in the marketplace since 2002 when Abilify was initially approved. We conducted FAERS searches in previous reviews for Abilify products[2] and while there have been previous cases of name confusion between Abilify and names such as Actos and Aricept, our gap FAERS search for this review did not identify any new cases of name confusion between the root name Abilify and other US drug names. No new cases of confusion with a US drug name have been received since 2009. We also reviewed the Institute for Safe Medication Practices' list of confused drug names and note that Abilify is not on the list.

We also considered that the root name will indicate to prescribers that Abilify Mycite has the same active ingredient as Abilify. This is also important for patients to know since some may be transitioned from Abilify without the IEM to Abilify Mycite and the use of

[2] OSE Review Numbers 04-0091, 04-0091-1, 05-0198, 06-0002, 2007-979 and 2012-492 and Panorama Review #2014-25972

the root name will help patients to know that they are still receiving the same active ingredient that is in Abilify.

Given the totality of factors considered above, we believe that the root name "Abilify" is acceptable to use for this product.

### *2.2.8 Safety Analysis of the Modifier "Mycite"*

Otsuka proposes the proprietary name, Abilify Mycite, to represent the three-part medical device system (aripiprazole + IEM, Proteus patch, and mobile application). In their external name study, (b) (4) identified the following drug names that have the potential to either look or sound like Abilify Mycite or Mycite: Mycelex, Mysoline, Mag Citrate, Trilyte, and Aldactazide. We considered this information in our safety assessment below.

(b) (4) concluded that the proprietary name, Abilify Mycite, is an acceptable proprietary name candidate and that it exhibits minimal orthographic/phonetic and/or product similarities with existing proprietary names and does not suggest an inappropriate or promotional connotation.

***Safety Assessment of the Modifier***

Abilify Mycite, if approved, will represent an extension of the currently marketed Abilify product line. Therefore, in our evaluation of the proposed name, Abilify Mycite, we considered the following:

- Whether a modifier is necessary
- Whether the proposed modifier is appropriate

1. We considered whether a modifier is necessary. The Applicant proposes to use the modifier, Mycite, to help differentiate Abilify Mycite from the currently marketed Abilify tablets. Abilify Mycite, if approved, will represent an extension of the currently marketed Abilify product line. Abilify Mycite consists of the three part medical/device system which differs from the currently marketed Abilify tablets which do not contain the IEM or associated system. Abilify Mycite and Abilify tablets have overlapping product characteristics such as strength, dose, route of administration, and frequency of administration. Because of these similarities, it may be difficult to distinguish between the two products throughout the entire medication use process if the root name Abilify is used alone. For example, during procurement of the drug, ordering by the name Abilify alone would not provide enough information to distinguish between the Abilify tablets without the IEM and Abilify tablets with the IEM. Therefore, we believe a modifier is necessary to help differentiate the two products given their product characteristic similarities and differences. Furthermore, the use of the modifier may indicate to healthcare practitioners that this product is different from the currently marketed Abilify tablets and prompt them to consult the full prescribing information.

We recognize there are limitations to this approach since there is postmarketing evidence that modifiers have been omitted or overlooked. However, in this circumstance, we believe the addition of a modifier could add an incremental measure of safety. Thus, we believe a modifier added to the root name, Abilify, is an acceptable naming convention in this case.

2. We considered whether the proposed modifier is appropriate. According to the Applicant, *the modifier "Mycite" 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*. We note that the modifier can be interpreted as "my site" or "my sight". However, the rationale and definition provided do not convey a meaning that is inappropriate or misleading. Additionally, we did not identify any marketed products that contain the modifier "Mycite" that could be confused with Abilify Mycite or convey a different meaning of the modifier.

   We evaluated the risk of confusion between Abilify Mycite and the names Mycelex, Mysoline, Mag Citrate, Trilyte, and Aldactazide that were identified in the (b) (4) external study as having look-alike and/or sound-alike similarities to Abilify Mycite or Mycite. (b) (4) determined that Mag Citrate, Trilyte, and Aldactazide are either sufficiently visually/phonetically distinctive and/or have significantly different product characteristics from Abilify Mycite, limiting the potential for an actual medication error to occur because of proprietary name confusion. We agree with their assessment of these names which is supported by the fact that the combined orthographic and phonetic POCA score that they obtained in their search was less than 50% for each of these names when compared to Abilify Mycite and Mycite, which indicates low similarity. The names Mycelex and Mysoline were further assessed by (b) (4) Although the combined POCA score for each of these names was 59%, indicating moderate similarity, (b) (4) determined that based on their orthographic, phonetic, and product characteristic differences and the fact that Abilify will be used in conjunction with the name Abilify Mycite, that these names are differentiated and can safely co-exist. We agree that the names can safely coexist in the marketplace.

   We also considered whether practitioners might misinterpret the word "Mycite" on a prescription as the word "Maintena" due to familiarity with the latter marketed formulation (as seen in the external name study). There is numerical similarity between strengths (30 mg vs. 300 mg); however, we determined the orthographic and phonetic differences between Maintena and Mycite, combined with differences in frequency and route of administration between the two products minimizes the risk for confusion.

   Given the totality of factors considered above, we believe that the modifier "Mycite" is acceptable for this drug.

# 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE Project Manager, at 240-402-5035.

## 3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Abilify Mycite, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your December 2, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES


1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Drugs@FDA***

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

[3] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

| | Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance. |
|---|---|
| **Y/N** | **Is the proposed name obviously similar in spelling and pronunciation to other names?** |
| | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products. |
| **Y/N** | **Are there medical and/or coined abbreviations in the proprietary name?** |
| | Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning. |
| **Y/N** | **Are there inert or inactive ingredients referenced in the proprietary name?** |
| | Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)). |
| **Y/N** | **Does the proprietary name include combinations of active ingredients?** |
| | Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)). |
| **Y/N** | **Is there a United States Adopted Name (USAN) stem in the proprietary name?** |
| | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem. |
| **Y/N** | **Is this proprietary name used for another product that does not share at least one common active ingredient?** |
| | Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name. |
| **Y/N** | **Is this a proprietary name of a discontinued product?** |
| | Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients. |

b. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

c. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

## Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

**Appendix B:** Prescription Simulation Samples and Results

**Figure 1. Abilify Mycite Study (Conducted on December 21, 2015)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>Abilify Mycite 5mg po once daily<br><br>Outpatient Prescription:<br>Abilify Mycite 2mg<br>Take 1 tablet po daily<br>#1 kit | Abilify Mycite 2 mg<br>Take 1 tablet by mouth daily<br>Dispense: 1 kit |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

| | |
|---|---|
| | **239 People Received Study** |
| | **72 People Responded** |

**Study Name: Abilify Mycite**

| Total | 26 | 24 | 22 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| ABILIFY MICYTE | 0 | 1 | 1 | 2 |
| ABILIFY MY SIGHT | 0 | 4 | 0 | 4 |
| ABILIFY MY SITE | 0 | 3 | 0 | 3 |
| ABILIFY MYCITE | 25 | 0 | 19 | 44 |
| ABILIFY MYCITI | 0 | 0 | 1 | 1 |
| ABILIFY MYCYTE | 0 | 3 | 0 | 3 |
| ABILIFY MYFITE | 0 | 1 | 0 | 1 |
| ABILIFY MYOCITE | 0 | 1 | 0 | 1 |
| ABILIFY MYSIGHT | 0 | 2 | 0 | 2 |
| ABILIFY MYSITE | 0 | 5 | 0 | 5 |
| ABILIGY MYCITE | 1 | 0 | 0 | 1 |
| ABILITY MISCITE | 0 | 1 | 0 | 1 |
| ABILITY MY SIGHT | 0 | 1 | 0 | 1 |
| ABILITY MYCITE | 0 | 1 | 0 | 1 |
| ABILITY MYSITE | 0 | 1 | 0 | 1 |
| AMBILIFY MYCITE | 0 | 0 | 1 | 1 |

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LORETTA HOLMES
02/22/2016

DANIELLE M HARRIS
02/22/2016

**Department of Health and Human Services**
**Public Health Service**
**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Surveillance and Epidemiology**
**Office of Medication Error Prevention and Risk Management**
**Division of Medication Error Prevention and Analysis**

# Proprietary Name Review

| | |
|---|---|
| Date: | November 4, 2015 |
| Application Type/Number: | NDA 207202 |
| Product Name and Strength: | (b) (4) (aripiprazole + IEM) tablets<br>2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg |
| Applicant/Sponsor: | Otsuka Pharmaceutical Development & Commercialization, Inc. |
| Panorama #: | 2015-5661660 |
| Reviewer(s): | Deborah Myers, RPh, MBA |
| Team Leader: | Danielle Harris, PharmD, BCPS |
| Deputy Director: | Irene Z. Chan, PharmD, BCPS |
| Director: | Todd Bridges, RPh |

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DEBORAH E MYERS
11/04/2015

DANIELLE M HARRIS
11/04/2015

IRENE Z CHAN
11/06/2015

TODD D BRIDGES
11/06/2015

**PROPRIETARY NAME MEMORANDUM**

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 16, 2015 |
| **Application Type and Number:** | NDA 207202 |
| **Product Name and Strength:** | (b) (4) (aripiprazole + IEM) Tablets<br>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 #:** | 2015-887015 |
| **DMEPA Primary Reviewer:** | Loretta Holmes, BSN, PharmD |
| **DMEPA Team Leader:** | Danielle Harris, PharmD, BCPS |

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