CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date:	January 9, 2013
Reviewer:	Loretta Holmes, BSN, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Abilify Maintena (Aripiprazole) for Extended-release Injectable Suspension
Application Type/Number:	NDA 202971
Applicant:	Otsuka Pharmaceutical Co., Ltd.
OSE RCM #:	2012-2183

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CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Abilify Maintena is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Abilify Maintena, acceptable in OSE Review 2012-492, dated May 21, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see Section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-492. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded one new name, (b) (4)***, thought to look or sound similar to Abilify Maintena and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the name (b) (4)*** could potentially be confused with Abilify Maintena and lead to medication errors. This analysis determined that the name similarity between Abilify Maintena and the identified name was unlikely to result in medication errors for the reasons presented in Appendix A.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of December 17, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on November 27, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Abilify Maintena, did not identify any vulnerability that would result in medication errors with the additional name noted in this review. Thus, DMEPA has no objection to the proprietary name, Abilify Maintena, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Psychiatry Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Sandra Rimmel, OSE Project Manager, at 301-796-2445.

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4 REFERENCES

1. OSE Reviews

Holmes, Loretta. Abilify Maintena Proprietary Name Review, OSE Review 2012-492, dated May 21, 2012.

2. Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

3. 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.

4. Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: Risk of medication errors due to product confusion minimized by dissimilarity of the name and/or use in clinical practice for the reasons described.

	Proposed name: **Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection**	**Strengths:** **300 mg/vial and 400 mg/vial**	**Usual Dose:** **160 mg, 200 mg, 300 mg, or 400 mg intramuscularly once monthly**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
1.			(b) (4)

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/s/

LORETTA HOLMES
01/11/2013

IRENE Z CHAN
01/11/2013

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

Proprietary Name Review

Date:	May 21, 2012
Reviewer:	Loretta Holmes, BSN, PharmD Division of Medication Error Prevention and Analysis
Team Leader	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Division Director	Carol A. Holquist, RPh Division of Medication Error Prevention and Analysis (DMEPA)
Drug Name and Strength:	Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection 300 mg and 400 mg
Application Type/Number:	NDA 202971
Applicant:	Otsuka Pharmaceutical Company, Ltd.
OSE RCM #:	2012-492

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Abilify Maintena, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

The name Abilify (b) (4) was initially proposed for this NDA. However, the Applicant was notified in a letter dated December 23, 2011 that the name was unacceptable from a promotional perspective because it was misleading. Thus, the Applicant submitted the alternate name, Abilify Maintena, for our review.

1.2 PRODUCT INFORMATION

The following product information is provided in the February 24, 2012 proprietary name submission.

- **Active Ingredient:** Aripiprazole
- **Indication of Use:** Maintenance treatment of schizophrenia in adults
- **Route of administration:** Intramuscular
- **Dosage form:** Extended-release Suspension for Injection
- **Strength:** 300 mg and 400 mg
- **Dose and Frequency of Administration:** 200 mg, 300 mg, or 400 mg every month
- **How Supplied:** Kits containing a 300 mg or 400 mg vial, one vial of diluent containing 2 mL, one 3 mL Luer Lock syringe with 21-gauge, 1.5 inch, pre-attached needle, one 3 mL BD syringe, one vial adapter, one 21-gauge, 1.5 inch needle, and one 21-gauge, 2 inch needle
- **Storage:** Store below 30ºC (86ºF). Avoid freezing.
- **Intended Pronunciation of the Name:** a bil' i fye mayn ten' a
- **Derivation of Name:** Abilify is an FDA approved proprietary name.
- **Intended Meaning of the Modifier:** Blank canvas

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Psychiatry Products (DPP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The April 24, 2012 search of the United States Adopted Name (USAN) stems did not identify a USAN stem present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

This proprietary name contains two components: 1) the root name, Abilify, and 2) a modifier, Maintena. In the proprietary name submission, the Applicant stated the root name is derived from, "Abilify", an FDA approved proprietary name and the modifier has no intended meaning. Therefore, we have evaluated whether the proposed modifier "Maintena" is appropriate for this product (see Discussion in Section 3).

2.2.3 Medication Error Data Selection of Cases

Since Abilify is a currently marketed product, DMEPA searched the FDA Adverse Event Reporting System (AERS) database for medication errors involving Abilify which would be relevant for this review (i.e., wrong drug errors that may indicate name confusion involving Abilify products).

The March 26, 2012 search of the FDA Adverse Event Reporting System (AERS) database used the following search terms: active ingredient "aripiprazole", trade names "Abilify" and "Abilify Discmelt", and verbatim terms "Abil% and "arip%" The reaction terms used were the MedDRA High Level Group Terms (HLT) "Maladministrations" and "Medication Errors NEC" and the "Preferred Terms (PT) "Product Label Confusion", "Drug Label Confusion", "Product Name Confusion" and "Drug Name Confusion". The search was limited to the following dates, February 2, 2008 through March 26, 2012, in order to retrieve those reports submitted since our last review of Abilify (OSE Review 2007-979).

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, 62 reports were not included in the final analysis for the following reason: they did not involve wrong drug errors. Following exclusions, the search yielded three relevant cases.

2.2.4 FDA Name Simulation Studies

Thirty-three practitioners participated in DMEPA's prescription studies. One of the interpretations in the Inpatient study overlapped with the currently marketed product "Abilify". In this case, the practitioner omitted the modifier "Maintena" and wrote the route of administration instead (i.e., "Abilify IM"). Abilify is currently marketed in an injection dosage form that is administered intramuscularly. Only two practitioners interpreted the name correctly as "Abilify Maintena". The remaining interpretations in

the studies were variations of the root name "Abilify" and the modifier "Maintena". See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE April 2, 2012 e-mail, the Division of Psychiatry Products (DPP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Abilify Maintena. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Abilify Maintena, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation or by the (b) (4) external name study that were not identified by DMEPA but require further evaluation.

Table 1: Collective List of Potentially Similar Names [EPD, Primary Safety Evaluator, and (b) (4) (External Name Study)]

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Ablavar	EPD	Mesafem***	EPD	(b) (4) ***	Primary Safety Evaluator
Altabax	EPD	(b) (4) ***	EPD	Maintain	Primary Safety Evaluator
Abelcet	EPD	Mesalamine	EPD	Concerta	(b) (4)
Mestinon	EPD	Abilify (b) (4) ***	EPD	Mannitol	(b) (4)
Menactra	EPD	Marezine	Primary Safety Evaluator	Metformin	(b) (4)
Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
None					

Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Abilify	EPD and (b) (4)	Invega Sustenna	EPD	Mitotane	(b) (4)
Abilify Discmelt	EPD and (b) (4)	Makena	EPD and (b) (4)	Mytelase	(b) (4)
Memantine	EPD and (b) (4)	Materna	Primary Safety Evaluator		

Our analysis of the 23 names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics. We determined these names will not pose a risk for confusion as described in Appendices D and E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Psychiatry Products via e-mail on April 24, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Psychiatry Products on April 26, 2012, they stated no additional concerns with the proposed proprietary name, Abilify Maintena.

3 DISCUSSION

Our discussion includes an assessment of the root name and modifier.

3.1 ROOT NAME "ABILIFY"

In our evaluation of the proposed name, Abilify Maintena, we considered whether the use of the root name, Abilify, is appropriate for this product. The root name Abilify has been in the marketplace since 2002 when Abilify was initially approved. Abilify is currently available in three dosage forms: tablets, oral solution, and injection. Additionally, Abilify Discmelt which was approved in 2006 is an orally disintegrating tablet. Thus, there are two names; Abilify and Abilify Discmelt currently in the marketplace (see Appendix D for product comparisons).

We searched the AERS database to determine if there has been name confusion involving the name Abilify that would impact this review. We identified three cases of name confusion that occurred between the period February 2, 2008 and March 26, 2012:

- ISR # 5705888: Abilify 10 mg was ordered but Aricept 10 mg was dispensed. The reporter stated the causality as similar name, nearby location on the shelf and blister card (prepack).
- ISR # 6495049: Donepezil (established name for Aricept) was prescribed but Aripiprazole 5 mg was dispensed. The cause of the error was not stated.
- ISR # 7986818: Folic acid 1 mg was ordered but Aripiprazole 30 mg was dispensed. The cause of the error was not stated.

Additionally, we reviewed previous DMEPA Abilify and Abilify Discmelt reviews (OSE Review #'s 04-0091, 04-0091-1, 05-0198, 06-0002, and 2007-979) for AERS searches and a discussion of name confusion involving the root name "Abilify".

Our review of these previous OSE reviews identified one other case (n=1) where Abilify and Aricept were confused. We also identified name confusion between Abilify and Actos (n=2), Adderal XR (n=1), and Zyprexa (n=1). The causality in these cases was not stated, however, we note these products overlap in strength with Abilify, which may have contributed to some of the errors. The use of the modifier "Maintena" would likely minimize the potential for confusion with the aforementioned names. We also acknowledge there has been name confusion between "Aripiprazole" the established name for Abilify, and proton pump inhibitors due to the USAN stem for antiulcer agents ("-prazole") contained in the established names of these products. However, that source of name confusion is not relevant to this review, and thus, will not be discussed further.

Although there has been confusion between the name Abilify and other products, the name has been in the marketplace for 10 years and we have not identified any alarming trends that warrant regulatory action. Additionally, the root name Abilify is not on the Institute for Safe Medication Practices' (ISMP) List of Confused Drug Names. Thus, we have no objections to the use of the root name Abilify for this product.

3.2 MODIFIER "MAINTENA"

The Applicant proposes to use the modifier "Maintena" to help differentiate Abilify Maintena from the currently available Abilify injection which is also administered by the intramuscular route. Abilify Maintena, if approved, will represent an extension of the currently marketed Abilify product line. Therefore, in our evaluation of the proposed name, Abilify Maintena, we considered whether a modifier is necessary, whether the modifier "Maintena" is appropriate, and whether the use of a dual proprietary name is warranted.

Abilify Maintena is an extended-release suspension for injection intended for chronic administration monthly, which differs from the currently marketed Abilify Injection which is an immediate release product intended for multiple dosing in a day. Abilify injection and Abilify Maintena also differ in indication of use, strength, and dose. However, these differences will not be enough to differentiate the products throughout the entire medication use process if the root name Abilify were used alone. For example, during procurement of the drug, ordering by the name Abilify alone would not provide enough information to distinguish between the immediate release and extended-release formulations available. Therefore, we believe a modifier is necessary to help differentiate these two formulations since they contain the same active ingredient and are given by the same route of administration (see Table 2 for a comparison of the two injectable products). 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.

Table 2: Product Comparison

Proprietary Name:	Indication of Use:	Dosage Form:	Strength(s):	Usual dose:
Proposed Proprietary Name: Abilify Maintena (Aripiprazole)	Maintenance treatment of schizophrenia in adults	Extended-release Suspension for Injection	300 mg per vial and 400 mg per vial	200 mg, 300 mg or 400 mg intramuscularly every month
Abilify (Aripiprazole)	Agitation associated with schizophrenia or bipolar mania	Injection	9.75 mg/1.3 mL (7.5 mg/mL)	5.25 mg to 15 mg intramuscularly every 2 hours as needed (maximum of 30 mg per day). If ongoing aripiprazole therapy is clinically indicated, oral aripiprazole in a range of 10 mg per day to 30 mg per day should replace aripiprazole injection as soon as possible.

Although the Applicant did not state there was a meaning for the modifier "Maintena", the modifier "Maintena" suggests the word "maintenance". Since Abilify Maintena is recommended for the maintenance treatment of schizophrenia as compared to the currently marketed Abilify injection which is not recommended for maintenance treatment, the modifier "Maintena" appears to be appropriate and not misleading. Additionally, the use of this modifier may indicate to practitioners that this product is different from the currently marketed injection and trigger practitioners to consult the full prescribing information. We did not identify any marketed products that contain the modifier "Maintena" that could cause confusion with Abilify Maintena.

We also considered whether practitioners might misinterpret the word "Maintena" on a prescription as the word "maintenance". There is numerical similarity between oral Abilify doses of 20 mg and 30 mg with injection doses for Abilify Maintena of 200 mg and 300 mg; however, the doses required for intramuscular injection of Abilify, used in agitation, and Abilify Maintena do not overlap. A prescription for Abilify Maintena would have to include both the dose and the frequency of administration, which would help to prevent confusion since there is no direct overlap between these two products.

We further considered the fact that the modifier "Maintena" is not typical of other modifiers which usually consist of shortened abbreviated forms such as XR, ER, and EC. As such, the modifier "Maintena" may be misinterpreted as a stand-alone name and prescribers may write prescriptions for "Maintena" without specifying the root name. This may lead to medication errors due to confusion with the use of the name "Maintena" alone. Postmarketing experience has shown this type of scenario to occur with Zyprexa

Zydis where Zyprexa Zydis was prescribed or referred to as "Zydis". Thus, we evaluated the modifier "Maintena" alone from a safety perspective for the potential to cause confusion with other names currently in the marketplace. We did not identify any names currently in the marketplace with the potential to cause confusion with the name "Maintena" if the root name "Abilify" was omitted from a prescription.

We also considered whether the use of a different name, a dual proprietary name (one that does not include the root name Abilify) would be appropriate for this product. The use of a dual proprietary name introduces the potential for patients to be inadvertently placed on multiple aripiprazole products concomitantly if the proprietary names are not recognized as having the same active ingredient. This may lead to overdose and other safety issues. Based on our assessment of the root name, modifier, and product characteristics, we believe the use of a dual proprietary name is unwarranted for this product.

Given the totality of the factors considered above, we believe that the use of a modifier is appropriate for this drug, and the proposed modifier, "Maintena" is acceptable.

4 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective. Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA.

If you have further questions or need clarifications, please contact Sandra Griffith, OSE Project Manager, at 301-796-2445.

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Abilify Maintena, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your February 24, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. Additionally, this proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

5 REFERENCES

1. Arnwine, Kristina C. Abilify Discmelt Name Review, OSE Review 04-0091, dated August 12, 2004.

2. Pedersen, Kimberly. Abilify Discmelt Name Review, OSE Review 04-0091, 05-0198, dated May 31, 2006.

3. Arnwine, Kristina C. Abilify (injection) Label and Labeling Review, OSE Review 06-0002, dated March 23, 2006.

4. Park, Judy. Abilify Medication Errors Postmarketing Safety Review, OSE Review 2007-979, dated August 13, 2004.

5. ***Micromedex Integrated Index (http://csi.micromedex.com)***

   Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

6. ***Phonetic and Orthographic Computer Analysis (POCA)***

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

7. ***Drug Facts and Comparisons, online version, St. Louis, MO (http://factsandcomparisons.com)***

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

8. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

9. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

10. Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. U.S. Patent and Trademark Office (http://www.uspto.gov)

USPTO provides information regarding patent and trademarks.

8. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. Access Medicine (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)

USAN Stems List contains all the recognized USAN stems.

13. Red Book Pharmacy's Fundamental Reference

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. Medical Abbreviations Book

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

16. CVS/Pharmacy (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

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

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2]

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

[2] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

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.

4. 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.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

[3] Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name Abilify Maintena	Scripted May Appear as	Spoken May Be Interpreted as
A	Ce, Ci, Cl, O, U	Any vowel
a	el, ci, cl, d, o, u	Any vowel
b	l, h, k, v	p, v, d
i	e, l, j	Any vowel
l	b,e, s, A, P, i	
i	e, l, j	Any vowel
f	p, t	pf, ph
y	f, g, p, u, v, x, Z	Any vowel
fy		phy
M	M. V, ss	
m	rn, nn, n, v, w, wi, vi, onc, z	
a	el, ci, cl, d, o, u	Any vowel
i	e, l, j	Any vowel
n	m, u, x, r, h, s	dn, gn, kn, mn, pn
t	r, f, x, A	d
e	a, i, l, p	Any vowel
n	m, u, x, r, h, s	dn, gn, kn, mn, pn
a	el, ci, cl, d, o, u	Any vowel
"Abil"		"Abel"
"Main"		"Maine", "Maim"
"tena"		"taina"

Appendix C: Prescription Simulation Samples and Results

Figure 1. Abilify Maintena Study (Conducted on March 1, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
Inpatient Medication Order: Abilify Maintena 300mg IM once	"Abilify Maintena 400 mg Bring to clinic Dispense one kit"
Outpatient Prescription: Abilify Maintena 400mg Bring to Clinic # 1 kit	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

	84 People Received Study
	33 People Responded

Study Name: Abilify Maintena

Total	11	13	9	
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
ABILIFY IM	1	0	0	1
ABILIFY MAINTAINA	0	10	0	10
ABILIFY MAINTAINA KIT	0	1	0	1
ABILIFY MAINTAINER	0	2	0	2
ABILIFY MAINTENA	1	0	1	2
ABILIFY MAINTENANCE	1	0	0	1
ABILIFY MAINTENEN	1	0	0	1
ABILIFY MAINTENIA	1	0	0	1
ABILIFY MAINTENIR	1	0	0	1
ABILIFY MAINTENN	1	0	0	1
ABILIFY MANNTENA	1	0	0	1
ABILIFY MANTENA	1	0	0	1
ABILIFY MARITENA	0	0	1	1
ABILIFY MARNTENA	0	0	2	2
ABILIFY MARNTEVA	0	0	2	2
ABILIFY MARTEVA	0	0	1	1
ABILITY MAINTENANCE	1	0	0	1
ALILIFY MARTERA	0	0	1	1
ALRILIFY MARNTENA	0	0	1	1
AMBILIFY MAINTENIN	1	0	0	1

Appendix D: Proposed Product (Abilify Maintena) Compared to the Currently Marketed Abilify Products

	Proprietary Name:	Indication of Use:	Dosage Form:	Strength(s):	Usual dose:
	Abilify Maintena (Aripiprazole)	**Maintenance treatment of schizophrenia in adults**	**Extended-release Suspension for Injection**	**300 mg and 400 mg**	**200 mg, 300 mg or 400 mg intramuscularly every month**
1	Abilify (Aripiprazole)	Oral dosage forms Schizophrenia, bipolar 1 disorder, adjunctive treatment of major depressive disorder, irritability associated with autistic disorder	Tablets Oral Solution	Tablets 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg Oral Solution 1 mg/mL	Tablets: 2 mg to 30 mg once daily Oral Solution: The oral solution can be substituted for tablets on a mg-per-mg basis up to the 25 mg dose level. Patients receiving 30 mg tablets should receive 25 mg of the solution.
		Injection Agitation associated with schizophrenia or bipolar mania	Injection	Injection 9.75 mg/1.3 mL (7.5 mg/mL)	Injection: 5.25 mg to 15 mg intramuscularly every 2 hours as needed (maximum of 30 mg per day). If ongoing aripiprazole therapy is clinically indicated, oral aripiprazole in a range of 10 mg per day to 30 mg per day should replace aripiprazole injection as soon as possible.
2	Abilify Discmelt (Aripiprazole)		Orally Disintegrating Tablets	10 mg and 15 mg	Same as for the oral tablets (above)

Appendix E: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

	Proprietary Name (Active Ingredient)	Similarity to Abilify Maintena	Failure preventions
3	Mesalamine Extended-release Capsules Delayed-release Tablets Suppositories Enema	Look	The pair have sufficient orthographic differences.
4	Invega Sustenna (Paliperidone Palmitate) Extended-release Suspension for Injection	Look and Sound	The pair have sufficient orthographic and/or phonetic differences.
5	Concerta (Methylphenidate HCl) Extended-release Tablets	Look	The pair have sufficient orthographic and/or phonetic differences.
6	Metformin Tablets Extended-release Tablets	Look	The pair have sufficient orthographic differences.
7	Mytelase (Ambenonium Chloride) Tablets	Look	The pair have sufficient orthographic differences.
8	Ablavar (Gadofesveset Trisodium) Injection	Look	The pair have sufficient orthographic differences.
9	Mannitol Injection Irrigation Inhalation	Look	The pair have sufficient orthographic differences.
10	Mesafem*** (Paroxetine Mesylate) Capsules	Look	This name was found unacceptable by DMEPA. The Applicant has since submitted two names for our review which were also found unacceptable. Also, the pair have sufficient orthographic differences
11	Abilify (b) (4) ***	Look and Sound	(b) (4)

	Proprietary Name (Active Ingredient)	Similarity to Abilify Maintena	Failure preventions
12	(b) (4)		
13	Maintain (Benzocaine)	Look	This product appears to have been discontinued. According to the SAEGIS database, the year of last recorded sales of this product was 2001.[4] Product characteristic information specific to this product was unavailable in our common databases. According to the US Patent and Trade Office (USPTO) database, the trademark is dead.

Appendix F: Summary Findings of the FMEA

	Proposed name: **Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection**	**Strengths:** **300 mg and 400 mg**	**Usual dose:** **200 mg, 300 mg or 400 mg intramuscularly every month**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
14	Altabax (Retapamulin) Ointment Strength: 1% Dosage: Apply a thin layer to the affected area twice daily for five days	Orthographic: The root name Abilify is orthographically similar to Altabax. Both names contain seven letters and begin with the letter "A" and have an upstroke letter in the second position. The ending letters "y" vs. "x" may look similar when written.	Orthographic: Although both names contain three upstroke letters, the second and third upstroke letters are in different positions in the names which help to differentiate them. Dose: 200 mg, 300 mg or 400 mg vs. a thin layer

[4] Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com). Accessed on April 4, 2012.

	Proposed name: **Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection**	**Strengths:** **300 mg and 400 mg**	**Usual dose:** **200 mg, 300 mg or 400 mg intramuscularly every month**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
15	Abelcet (Amphoteracin B Lipid Complex) Injection Strength: 5 mg/mL (20 mL vial) Dosage: 5 mg/kg intravenously once daily	Orthographic: Abilify is orthographically similar to Abelcet. Both names contain seven letters and begin with letters that may look similar "Abil" vs. "Abel". Dose: The products may overlap with a dose of 300 mg or 400 mg	Orthographic: The suffixes "ify" vs. "cet" do not look similar. Frequency of administration: Every month vs. once daily
16	Mestinon (Pyridostigmine Bromide) Tablets Extended-release Tablets Syrup Strength: *Tablets* 60 mg *Extended-release Tablets* 180 mg *Syrup* 60 mg/5 mL Dosage: *Tablets and Syrup* 600 mg per day spaced to provide maximum benefit (dosage range 60 mg to 1500 mg per day) *Extended-release Tablets* 180 mg to 540 mg orally once or twice daily	Orthographic: The modifier "Maintena" is orthographically similar to Mestinon. Both names contain eight letters and begin with the letter "M". Both names contain the upstroke letter "t" in a similar position. Dose: Abilify Maintena and Mestinon overlap with a 300 mg dose.	Orthographic: The infix letters "ain" vs. "es" look different which helps to differentiate the names. Although Maintena is the modifier, the possibility exists for prescribers to order Abilify Maintena by the modifier only, especially since there are no other modifiers by this name in the marketplace. Postmarketing experience has shown that this type of scenario has occurred. Frequency of administration: Every month vs. once daily or more Dosage form: Injection vs. tablets, extended-release tablets, and syrup Mestinon is available in multiple dosage forms so a prescription for it would likely indicate the dosage form. Additionally, Abilify Maintena and Mestinon do not have overlapping dosage forms.

	Proposed name: **Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection**	**Strengths:** **300 mg and 400 mg**	**Usual dose:** **200 mg, 300 mg or 400 mg intramuscularly every month**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
17	Menactra (Meningococcal Polysaccharide Diphtheria Toxoid Conjugate Vaccine) Injection Strength: Not applicable Dosage: 0.5 mL intramuscularly once or once and repeat in 3 months	Orthographic: Menactra may look similar to the modifier "Maintena". Both names contain eight letters, begin with the letter "M" and end with the letter "a". Both names contain the upstroke letter "t" in similar positions.	Orthographic: The infixes "ain" vs. "enac" look different when scripted. The suffix "ena" which follows the letter "t" in Maintena appears longer in length as compared to the suffix "ra" that follows the letter "t" in Menactra. Dose: 200 mg, 300 mg or 400 mg vs. 0.5 mL
18	Memantine HCl (Established name marketed under the proprietary names: Namenda and Namenda XR) Strengths: *Tablets* 5 mg and 10 mg *Extended-release Tablets* 7 mg and 14 mg *Oral Solution* 2 mg/mL Dosage: *Tablets and Oral solution* Initially, 5 mg orally once daily; gradually increase to 10 mg twice daily *Extended-release Tablets* Initially, 7 mg once daily; gradually increase to 28 mg orally once daily	Orthographic: Memantine may look similar to the modifier "Maintena". Both names begin with the letter "M" and contain the upstroke letter "t" in a similar position. The suffixes "tena" vs. "tine" look similar when written. Phonetic: The syllables "Main-" vs. "-man-" and "-ten-" vs. "-tine" may sound similar.	Orthographic: The infix letter 'm" in Memantine elongates the beginning portion of the name ("Meman") that precedes the letter "t" which makes it appear longer in length as compared to the beginning portion of Maintena ("Main") which appears shorter in length. Although Maintena is the modifier, the possibility exists for prescribers to order Abilify Maintena by the modifier only, especially since there are no other modifiers by this name in the marketplace. Postmarketing experience has shown that this type of scenario has occurred. Phonetic: The sound alike syllables are in different portions of the names which helps to differentiate them phonetically (i.e., "Main-" is the first syllable in Maintena whereas "-man-" is the second syllable in Memantine; "-ten-" is the second syllable in Maintena whereas "-tine-" is the third syllable in Memantine. Dose: 200 mg, 300 mg, or 400 mg vs. 5 mg, 10 mg, 7 mg, 14 mg, 21 mg, or 28 mg

	Proposed name: **Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection**	**Strengths:** **300 mg and 400 mg**	**Usual dose:** **200 mg, 300 mg or 400 mg intramuscularly every month**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
19	Makena (Hydroxyprogesterone Caproate) Injection Strength: 250 mg/mL (5 mL) Dosage: 250 mg intramuscularly every week	Orthographic: The modifier Maintena is orthographically similar to Makena. Both names begin with the letters "Ma" and end with the letters "ena". Phonetic: The beginning syllables "Main-" vs. "Ma-" and the ending syllables "-a" vs. "-na" sound similar. Route of administration: Both products are administered intramuscularly	Orthographic: Maintena contains eight letters and appears longer in length when written as compared to Makena which contains six letters. Although Maintena is the modifier, the possibility exists for prescribers to order Abilify Maintena by the modifier only, especially since there are no other modifiers by this name in the marketplace. Postmarketing experience has shown that this type of scenario has occurred. Phonetic: The middle syllables "-tĕn-" vs. "-kē-" sound different. Dose: 200 mg, 300 mg, or 400 mg vs. 250 mg Frequency of administration: Every month vs. every week
20	Marezine (Cyclizine HCl) Tablets Strength: 50 mg Dosage: 25 mg to 50 mg orally every 4 to 6 hours as needed	Orthographic: The modifier Maintena may look similar to the name Marezine. Both names begin with the letters "Ma". The ending letters "tena" vs. "zine" may look similar, especially when the letter "z" is written with a cross stroke and without a downstroke.	Orthographic: Although Maintena is the modifier, the possibility exists for prescribers to order Abilify Maintena by the modifier only, especially since there are no other modifiers by this name in the marketplace. Postmarketing experience has shown that this type of scenario has occurred. Dose: 200 mg, 300 mg, and 400 mg vs. 25 mg to 50 mg Frequency of administration: Every month vs. every 4 to 6 hours

	Proposed name: **Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection**	**Strengths:** **300 mg and 400 mg**	**Usual dose:** **200 mg, 300 mg or 400 mg intramuscularly every month**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
21	Materna (Ascorbic Acid (Vitamin C), Biotin, Calcium, Cholecalciferol, Chromium, Cupric Oxide, Cyanocobalamin (Vitamin B12), Ferrous Fumarate, Folic Acid (Vitamin B9), Magnesium Oxide, Manganese Sulfate, Molybdenum, Niacinamide, Pantothenic Acid (Vitamin B5), Potassium Iodide, Pyridoxine (Vitamin B6), Riboflavin (Vitamin B2), Selenium, Thiamine Mononitrate (Vitamin B1), Vitamin A Acetate, Vitamin E Acetate, Zinc Oxide Tablets Strength: Not applicable Dosage: Unable to locate dosage information for this product which is a prenatal vitamin. The recommended dosage for prenatal vitamins is usually 1 tablet orally once daily.	Orthographic: The modifier "Maintena" may look similar to the name Materna. Both names begin with the letters "Ma", contain the upstroke letter "t" and end with the letters "na". Phonetic: Both names contain three syllables which may sound alike at each position ("Main-" vs. "Ma-"), ("-tain-" vs. "-ter-") and ("-na" vs. "-a").	Orthographic: The upstroke letter is in the fifth position in Maintena and the third position in Materna which helps to differentiate the names. Although Maintena is the modifier, the possibility exists for prescribers to order Abilify Maintena by the modifier only, especially since there are no other modifiers by this name in the marketplace. Postmarketing experience has shown that this type of scenario has occurred. Dose: 200 mg, 300 mg or 400 mg vs. 1 tablet Frequency of Administration: Every month vs. once daily

	Proposed name: **Abilify Maintena (Aripiprazole) Extended-release Suspension for Injection**	Strengths: **300 mg and 400 mg**	Usual dose: **200 mg, 300 mg or 400 mg intramuscularly every month**
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
22	(b) (4)		
23	Mitotane (Mitotane is an established name) Tablets Strength: 500 mg Dosage: Start at 2 g to 6 g per day in divided doses, either three or four times a day. Doses are usually increased incrementally to 9 g to 10 g per day	Orthographic: The modifier "Maintena" may look similar to the name Mitotane. Both names contain eight letters and begin with the letter "M". Both names contain the upstroke letter "t" in the fifth position. The suffixes "ena" and "ane" look similar.	Orthographic: Mitotane contains two upstroke letters whereas Maintena contains one which may help to differentiate the names. Although Maintena is the modifier, the possibility exists for prescribers to order Abilify Maintena by the modifier only, especially since there are no other modifiers by this name in the marketplace. Postmarketing experience has shown that this type of scenario has occurred. Dose: 200 mg, 300 mg, or 400 mg vs. 2 g to 10 g per day in divided doses, either three or four times per day Frequency of administration: Every month vs. three times per day or four times per day

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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

Proprietary Name Review

Date:	December 19, 2011
Reviewer:	Yelena Maslov, Pharm.D. Division of Medication Error Prevention and Analysis
Team Leader	Irene Chan, Pharm.D., BCPS Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, R.Ph. Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Abilify (b) (4) (Aripiprazole) Extended-release Suspension for Injection, 300 mg per vial and 400 mg per vial
Application Type/Number:	NDA 202971
Applicant/Sponsor:	Otsuka
OSE RCM #:	2011-3928

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/s/

YELENA L MASLOV
12/20/2011

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