CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208082Orig1s000

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:	January 10, 2017
Application Type and Number:	(b) (4) and NDA 208082
Product Name and Strength:	Austedo (deutetrabenazine) Tablets 6 mg, 9 mg, and 12 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Teva Pharmaceuticals, Inc.
Panorama #:	2016-10567133 and 2016-10808890
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION 1
1.1 Regulatory History 1
1.2 Product Information 1
2 RESULTS 2
2.1 Misbranding Assessment 2
2.2 Safety Assessment 2
3 CONCLUSIONS 4
3.1 Comments to the Applicant 4
4 REFERENCES 5
APPENDICES 6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Austedo, 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 proposed proprietary name, Austedo was previously submitted to IND 112975 on November 18, 2014 and NDA 208082 on May 29, 2015 for the treatment of chorea associated with Huntington's disease (these applications are covered by the Division of Neurology Products). The Division of Medication Error Prevention and Analysis found the name conditionally acceptable in OSE Review #2014-43007, dated February 24, 2015[a] and OSE Review #2015-650424, dated June 22, 2015[b], under the IND and NDA, respectively. The NDA application received a Complete Response (CR) action on May 27, 2016.

Teva most recently submitted a proprietary name review request for Austedo to (b) (4) on October 4, 2016 for (b) (4) (this application is covered by the Division of Psychiatry Products) and to NDA 208082 on October 17, 2016 for the treatment of chorea associated with Huntington's disease (the NDA was resubmitted on October 3, 2016 in response to the May 27, 2016 CR action).

1.2 PRODUCT INFORMATION

The following product information is provided in the October 4, 2016 (b) (4) and October 17, 2016 (NDA 208082) proprietary name submissions.

- Intended Pronunciation: ah-STED-oh
- Active Ingredient: deutetrabenazine
- Indication of Use: Treatment of chorea associated with Huntington's Disease; (b) (4)
- Route of Administration: Oral
- Dosage Form: Tablets
- Strengths: 6 mg, 9 mg, and 12 mg
- Dose and Frequency: The usual dosage for this product is 6 mg to 24 mg. The frequency of administration is once to twice daily. Daily doses of 12 mg and higher per day should be given in two divided doses. The maximum daily dose is 48 mg.

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[a] Harris, J. Proprietary Name Review for Austedo (IND 112975). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Feb 24. 19 p. OSE RCM No.: 2014-43007.

[b] Harris, J. Proprietary Name Review for Austedo (NDA 208082). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Jun 22. 2 p. OSE RCM No.: 2015-650424.

- How Supplied: 60-count bottles
- Storage: Store at 25º C (77º F); excursions permitted to 15-30ºC (59-86º F)
- Container and Closure Systems: (b) (4) bottle (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Psychiatry Products (DPP) and the Division of Neurology Products (DNP) 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[c].

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

Eighty-three (83) practitioners participated in DMEPA's prescription studies. One participant in the verbal prescription study interpreted the name as "Astero" which is phonetically similar to the name of the currently marketed product, Astepro. However, we believe that Austedo and Astepro are unlikely to be confused due to product characteristic differences (see Appendix C).

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, October 14, 2016 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.

[c] USAN stem search conducted on December 13, 2016.

In response to the OSE, October 21, 2016 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

We had identified and evaluated 60 names in our previous proprietary name review.[d] Our new POCA search identified 64 names with the combined score of ≥55%. In this review, we re-evaluated one of the names identified in the previous review because the combined POCA score with the revised POCA algorithm is now ≥70% whereas a lower combined score was retrieved in the previous review. Additionally, we re-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 name. We acknowledge the addition of a new indication (b) (4) since our previous review of the proprietary name; however, the strengths, dosages and other product characteristics have not changed. We agree with the findings from our previous review for the names evaluated previously. Therefore, Table 1 lists the 28 names not previously analyzed with the combined orthographic and phonetic score of ≥55% retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation. In addition to these 28 names, Table 1 also includes:

- one name from our previous proprietary name review which now has a combined score of ≥70% as a result of the POCA update
- four names identified by (b) (4) but not retrieved in our POCA search

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	28
Low similarity name pair: combined match percentage score ≤54%	4

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Austedo, will be available in strengths of 6 mg, 9 mg, and 12 mg. Since 9 mg is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Austedo that were not identified in POCA.

[d] Harris J. Proprietary Name Review for Austedo IND 112975. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 Feb 24. 17 p. OSE Review No.: 2014-43007.

Table 1A. eDRLS Search Results[e]	POCA Score (%)
N/A	

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 33 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on January 4, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNP on January 6, 2017, they stated no additional concerns with the proposed proprietary name, Austedo.

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on January 4, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on January 10, 2017, they stated no additional concerns with the proposed proprietary name, Austedo.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE Project Manager, at 240-402-4232 (for DNP concerns) or Alycia Anderson, OSE Project Manager, at 240-402-4270 (for DPP concerns).

3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Austedo should be submitted once the NDA for the (b) (4) indication is submitted.

If any of the proposed product characteristics as stated in your October 4, 2016 (b) (4) and October 17, 2016 (NDA 208082) submissions are altered prior to approval of the marketing application, the name must be resubmitted for review.

[e] eDRLS search conducted on December 12, 2016.

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

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

3. ***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).

4. ***RxNorm***

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

5. ***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.

6. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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]

***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

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

	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 50% 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 check list (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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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.

   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? *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? **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. For single strength products, also consider circumstances where the strength may not be expressed. 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. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • 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. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • 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) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • 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? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Austedo Study (Conducted on December 16, 2016)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Austedo 9mg po twice daily	Austedo 12 mg Take 1 tablet by mouth twice daily Disp. #60
Outpatient Prescription: Austedo 12mg Take one tablet po bid #60	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

			307 People Received Study 83 People Responded	
Study Name: Austedo				
Total	**26**	**27**	**30**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ACEADO	0	1	0	1
ARUSTEDO	0	0	1	1
ASTERO	0	1	0	1
ASTETTO	0	1	0	1
AULTEDO	0	0	1	1
AULTIDO	0	0	2	2
AURSTEDO	0	0	1	1
AURTEDO	0	0	2	2
AUSTEDO	4	2	13	19
AUSTETO	0	1	0	1

AUSTETTO	0	1	0	1
AUSTIDO	0	0	2	2
DIUSTEDO	0	0	1	1
DRULTIDO	0	0	1	1
DURSTEDO	0	0	1	1
LUSTEDO	1	0	0	1
ORUSTEDO	0	0	2	2
OSTEADO	0	1	0	1
OSTEDO	0	6	0	6
OSTELLO	0	1	0	1
OSTENO	0	1	0	1
OSTETO	0	6	0	6
OSTETTO	0	5	0	5
OURITEDO	0	0	1	1
OURSTEDO	0	0	1	1
SURITIDO	0	0	1	1
SUSTEDO	21	0	0	21

Appendix C: Highly Similar Names (e.g., combined or individual POCA score is ≥70%)

No.	**Proposed name:** **Austedo** **Established name:** **deutetrabenazine** **Dosage form:** **Tablets** **Strengths:** **6 mg, 9 mg, and 12 mg** **Usual Dose:** **6 mg to 24 mg once to twice daily. Daily doses of 12 mg and higher per day should be given in two divided doses. The maximum daily dose is 48 mg.**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Astepro	70	The suffixes of this name pair ("-do" vs. "-pro") have sufficient orthographic differences due to the upstroke letter "d" in Austedo vs. the downstroke letter "p" and adjacent letter "r" in Astepro. The onset of the third syllables of this name pair ("-do" vs. "-pro") sound different. The products differ in dosage form (tablet vs. nasal spray); strengths (6 mg, 9 mg, and 12 mg vs. 0.15%); and dose (6 mg to 24 mg vs. 1 or 2 sprays). These differences will help to minimize the potential for confusion to occur.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)	56
2.	Antabuse	58
3.	Ascot	55
4.	Atuss DS	58
5.	Stendra	58

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

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** **Austedo** **Established name:** **deutetrabenazine** **Dosage form:** **Tablets** **Strengths:** **6 mg, 9 mg, and 12 mg** **Usual Dose:** **6 mg to 24 mg once to twice daily. Daily doses of 12 mg and higher per day should be given in two divided doses. The maximum daily dose is 48 mg.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Acetadote	56	The prefixes/suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different. Acetadote contains an extra syllable.
2.	Leustat	58	The prefixes/suffixes of this name pair have sufficient orthographic differences. The first/second syllables of this name pair sound different. Austedo contains an extra syllable.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Aspi-Cor	52
2.	Amisulpride	34
3.	Oseltamivir	30
4.	Azilect	28

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	Aquastan	56	International product marketed in Canada.
2.	(b) (4)	57	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
3.	Tustan	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Diastat	58
2.	Easotic	56
3.	Elastin	56
4.	Eskata	56
5.	Feostat	60
6.	Miostat	55
7.	Nasofed	56
8.	Orastat	56
9.	Pseudo-12	58
10.	Statuss	57
11.	Tavist DA	56
12.	Tavist-D	56
13.	Testred	60
14.	Tuss Tan	56
15.	Tusstat	58
16.	Uristat	55
17.	Vasaten	56
18.	Westadone	56

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Antimonium Tartaricum
2.	Apis Mellifica
3.	Arnica Montana
4.	Arnica Montana (Whole Plant)
5.	Arnicare Arnica
6.	Avedana Pain-Relieving
7.	Bacteriostatic Sodium Chloride
8.	BPO 9 Foaming
9.	Brace Relief
10.	By Pharmicell Lab Beaucell Dual Hydrogel Mask
11.	Cheiranthus Cheiri
12.	Codeinum
13.	Covergirl Aquasmooth
14.	Emsam
15.	Femur 9 Special Order
16.	Graphite
17.	Hanskin Hyaluron Skin Essence
18.	Hepar Sulphuris Calcareum
19.	Intense Care Snail
20.	Invega
21.	Lachesis Mutus
22.	Loesch HC-10 Anti-Itch Therapy
23.	Lycopodium Clavatum
24.	Minitran
25.	Morphinum
26.	Motto
27.	Naja Forte X
28.	Natroba
29.	Naturalth Goat Milk Moisture
30.	Neti Wash Flu
31.	Nitro-Time
32.	Obeo Hair
33.	Oral-B Neutra-Foam Mint
34.	Paliperidone
35.	Pamidronate Disodium
36.	Pleo Poly E
37.	Pleo Poly M
38.	Premium Natural BL Hydrogel Mask Pack
39.	Radium Bromatum
40.	Sepia Officinalis
41.	Shaving Factory

No.	Name
42.	Silicea
43.	Sodium Chloride
44.	Spinosad
45.	Symphytum Officinale
46.	Uceris
47.	Xtampza

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/s/

LORETTA HOLMES
01/10/2017

LOLITA G WHITE
01/10/2017

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:	June 22, 2015
Application Type and Number:	NDA 208082
Product Name and Strength:	Austedo (deutetrabenazine) tablets 6 mg, 9 mg, and 12 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Teva Pharmaceuticals, Inc.
Panorama #:	2015-650424
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

1 INTRODUCTION

The proposed proprietary name, Austedo, was found conditionally acceptable in OSE Review # 2014-43007, under IND 112975, dated February 24, 2015. We note that the product characteristics are the same for this NDA as the IND and have confirmed the absence of a USAN stem in the name. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Austedo, is acceptable from both a misbranding and safety perspective under the NDA 208082.

If you have further questions or need clarifications, please contact Ermias Zerislassie OSE project manager at 301-496-0097.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 29, 2015 submission are altered, the name must be resubmitted for review.

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/s/

JUSTINE HARRIS
06/22/2015

DANIELLE M HARRIS
06/22/2015