# 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*****

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| **Date of This Review:** | January 10, 2017 |
| **Application Type and Number:** | (b) (4) and NDA 208082 |
| **Product Name and Strength:** | Austedo (deutetrabenazine) Tablets<br>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 |

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# 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.

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