

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**761029Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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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<b>Date of This Review:</b>	June 10, 2015
<b>Application Type and Number:</b>	BLA 761029
<b>Product Name and Strength:</b>	Zinbryta (daclizumab) Injection 150 mg/mL
<b>Product Type:</b>	Drug-Device Combination Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	AbbVie Inc
<b>Panorama #:</b>	2015-114367
<b>DMEPA Primary Reviewer:</b>	Justine Harris, BS, RPh
<b>DMEPA Team Leader:</b>	Danielle Harris, PharmD, BCPS

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Zinbryta, 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 [REDACTED]<sup>(b) (4)</sup>, for this product; however, this study appears to be identical to the previous external study submitted December 16, 2013.

### 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary names, Zinbryta and [REDACTED]<sup>(b) (4)</sup> under IND 012120 on December 16, 2013. The Division of Medication Error Prevention and Analysis (DMEPA) found the names, Zinbryta and [REDACTED]<sup>(b) (4)</sup>, conditionally acceptable in OSE Review # 2013-16715 and 2013-16714, dated June 4, 2014.

Subsequently, the Applicant submitted the name, Zinbryta, for review under BLA 761029 on April 10, 2015. Zinbryta is proposed for the prefilled syringe (PFS) configuration.

[REDACTED]<sup>(b) (4)</sup>

### 1.2 PRODUCT INFORMATION

The following product information is provided in the April 10, 2015 proprietary name submission.

- Intended Pronunciation: Zin-BRY-tuh
- Active Ingredient: daclizumab
- Indication of Use: indicated for the treatment of patients with relapsing forms of multiple sclerosis
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 150 mg/1 mL
- Dose and Frequency: 150 milligrams injected subcutaneously once a month
- How Supplied: a carton containing a single-dose prefilled syringe providing 150 mg/mL.
- Storage: Store in the closed original carton to protect from light until ready for injection.
- Store in a refrigerator between 2°C to 8°C (36°F to 46°F). Do not freeze.

Discard if frozen. Once removed from the refrigerator, ZINBRYTA should be allowed to warm to room temperature (about 30 minutes) prior to injection. Do not use external heat sources such as hot water to warm ZINBRYTA.

If refrigeration is unavailable, ZINBRYTA may be stored up to 30°C (86°F) for a period up to 30 days, protected from light. Do not place ZINBRYTA back into the refrigerator after warming to room temperature. If ZINBRYTA is at room temperature (up to 30°C/86°F) for more than 30 days, it should be discarded

- Container and Closure Systems: prefilled syringe is made of glass (Type 1) with a (b) (4) rubber plunger stopper and (b) (4) rigid needle shield. The rubber plunger stopper and rigid needle shield are not made with natural rubber latex (b) (4). A 29 gauge, 0.5 inch staked needle is pre-affixed to the syringe.

## **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 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<sup>1</sup>.

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

The Applicant did not provide a derivation or intended meaning for the proposed name, Zinbryta in their submission. 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.

#### ***2.2.4 FDA Name Simulation Studies***

Eighty-one practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

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<sup>1</sup>USAN stem search conducted on May 15, 2015.

### 2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 21, 2015 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.

### 2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of  $\geq 50\%$  retrieved from our POCA search<sup>2</sup> organized as highly similar, moderately similar, or low similarity for further evaluation. Table 1 also includes names identified from the external study (b) (4).

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	75
Low similarity name pair: combined match percentage score $\leq 49\%$	7

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

Our analysis of the 84 names contained in Table 1 determined none of the names would 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 June 5, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on June 7, 2015, they stated no additional concerns with the proposed proprietary name, Zinbryta.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

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<sup>2</sup> POCA search conducted on May 20, 2015.

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your April 10, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. **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.

### **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](http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological)).

### **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#>).

### **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.

## 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 DNCE. OPDP or DNCE 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 DNCE 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.

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
<b>Y/N</b>	<b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
<b>Y/N</b>	<b>Are there medical and/or coined abbreviations in the proprietary name?</b>
	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.
<b>Y/N</b>	<b>Are there inert or inactive ingredients referenced in the proprietary name?</b>
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
<b>Y/N</b>	<b>Does the proprietary name include combinations of active ingredients?</b>
	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)).
<b>Y/N</b>	<b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
<b>Y/N</b>	<b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
<b>Y/N</b>	<b>Is this a proprietary name of a discontinued product?</b>
	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  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 50\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 49\%$ .

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of  $\geq 70$  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  $\geq 70\%$ ).**

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

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 50\%$  to  $\leq 69\%$ ).**

<p>Step 1</p>	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg, which may potentiate confusion between a name pair with moderate similarity.</li> <li>○ Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
<p>Step 2</p>	<p>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 <b><u>with</u></b> overlapping or similar strengths or doses.</p>

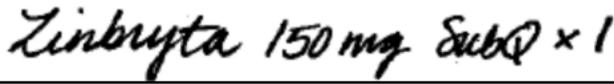
	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters?</li> </ul> <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> <li>• Are the lengths of the names dissimilar* when scripted?</li> </ul> <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/down stroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 49\%$ ).**

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. Zinbryta Study (Conducted on April 27, 2015)**

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> 	Zinbryta UAD Disp # 1
<u>Outpatient Prescription:</u> 	

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

246 People Received Study  
81 People Responded

Study Name: Zinbryta

	Total	26	27	28	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
CIMBRYSA	0	1	0	1	
CYMBRISSA	0	1	0	1	
CYMBRIZA	0	1	0	1	
FINBRYTA	2	0	0	2	
FINKRYTA	1	0	0	1	
LINBRYTA	0	0	11	11	
SIMBRAZA	0	1	0	1	
SIMBRISA	0	2	0	2	
SIMBRITA	0	1	0	1	
SYMBRIATA	0	1	0	1	
SYMBRISA	0	2	0	2	
SYMBRITA	0	1	0	1	
SYMBRIZA	0	1	0	1	
SYMBRYTA	0	1	0	1	
ZEMBRISA	0	2	0	2	
ZIMBRIGHTZA	0	1	0	1	
ZIMBRISA	0	2	0	2	
ZIMBRISSA	0	1	0	1	
ZIMBRITA	0	1	0	1	
ZIMBRITZA	0	2	0	2	
ZIMBRYSSA	0	1	0	1	
ZIMBRYTA	1	0	0	1	
ZIMBRYZA	0	1	0	1	
ZIMPRYZA	0	1	0	1	
ZINBRYTA	20	0	17	37	
ZINBRYTE	1	0	0	1	
ZYMBRISA	0	1	0	1	
ZYMBRYTA	0	1	0	1	
ZYNBRYTA	1	0	0	1	

**Appendix C: Highly Similar Names (e.g., combined POCA score is  $\geq 70\%$ )**

No.	<b>Proposed name: Zinbryta</b> <b>Established name: daclizumab</b> <b>Dosage form: Injection</b> <b>Strength(s): 150 mg/ mL</b> <b>Usual Dose: 150 mg injected subcutaneously once a month</b>	<b>POCA Score (%)</b>	<b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</b>  <b>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</b>
1.	Zinbryta	100	subject of this review
2.	(b) (4)		

**Appendix D:** Moderately Similar Names (e.g., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)***	54
2.	Inlyta	59
3.	Lemtrada	50
4.	Penbritin	60
5.	Penbritin-S	54
6.	Viibryd	52
7.	Zebeta	62
8.	Zenatane	51
9.	(b) (4)**	60
10.	*	50
11.	***	55
12.	Zinca-pak	54
13.	Zincate	57
14.	Zincfrin	58
15.	Zinecard	51
16.	Zinotic	53
17.	Zodryl AC	50
18.	Zodryl DAC	50
19.	Zometa	50
20.	Zonegran	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ )  
with overlap or numerical similarity in Strength and/or Dose

No.	<b>Proposed name:</b> <b>Zinbryta***</b>  <b>Established name:</b> <b>daclizumab</b>  <b>Dosage form: Injection</b>  <b>Strength(s): 150 mg/ mL</b>  <b>Usual Dose: 150 mg injected subcutaneously once a month</b>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
1.	Zenedi	52	<p>The infixes of this name pair have sufficient orthographic differences</p> <p>The second and third syllables of this name pair sound different.</p>
2.	(b) (4)***	52	<p>The infixes of this name pair have sufficient orthographic differences</p> <p>The first and second syllables of this name pair sound different.</p>
3.	Zyprexa	55	<p>The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different.</p>
4.	Zantac	50	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The second syllables of this name pair sound different. Zinbryta name contains an extra syllable.</p>
5.	Semprana***	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The second syllables of this name pair sound different.</p>
6.	Zanryl	56	<p>The suffixes of this name pair have sufficient orthographic differences</p> <p>The second syllables of this name pair sound different. Zinbryta name contains an extra syllable.</p>
7.	Zerit	50	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound</p>

			different. Zinbryta name contains an extra syllable
8.	Zembrace***	61	The suffixes of this name pair have sufficient orthographic differences The second syllables of this name pair sound different. Zinbryta name contains an extra syllable.
9.	Zorblisa***	51	The infixes and suffixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
10.	Dendrid	51	The infixes of this name pair have sufficient orthographic differences The second syllables of this name pair sound different. Zinbryta name contains an extra syllable.
11.	Zebutal	51	The infixes and suffixes of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
12.	Zilretta***	66	The infixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.

**Appendix F:** Low Similarity Names (e.g., combined POCA score is  $\leq 49\%$ )

No.	Name	POCA Score (%)
1.	Zetia	43
2.	Zovirax	40
3.	Zyban	37
4.	Centrax	46
5.	Femtrace	49
6.	Isentress	46
7.	Xarelto	40

**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.	Sandrena	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	(b) (4)***	57	This is a secondary proposed proprietary name and the product was approved under proprietary name (b) (4).
3.	Vinbarbital	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	(b) (4)***	51	Proposed proprietary name found unacceptable in DMEPA review OSE # 2014-205474. Product approved under proprietary name Obredon.
5.	Zentrip	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
6.	Zinc Citrate	52	International product marketed in Great Britain.
7.	Zinc Orotate	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
8.	Zinc Picrate	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases

9.	Zincaf	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
10.	Zinc-DTPA	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
11.	Zinnat	50	International product marketed in numerous foreign countries.

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

No.	Name	POCA Score (%)
1.	Benlysta	52
2.	Cinryze	52
3.	Cymbalta	53
4.	(b) (4)***	52
5.	Imbruvica	52
6.	Infalyte	50
7.	(b) (4)**	50
8.	(b) (4)***	50
9.	Pimtrex	50
10.	Simbrinza	60
11.	Synapryn	50
12.	(b) (4)***	50
13.	Vibra-tabs	53
14.	(b) (4)**	52
15.	(b) (4)***	51

16.	(b) (4)***	52
17.	Diabeta	51
18.	Endrate	52
19.	Entresto***	50
20.	Fybranta	55
21.	Intron A	54
22.	Kineret	50
23.	Libritabs	53
24.	Linjeta***	58
25.	Lynparza	50
26.	Qinprezo***	50
27.	(b) (4)***	50
28.	Tanabid DA	50
29.	Tenoret	52
30.	(b) (4)***	54
31.	Vincrex	50
32.	(b) (4)***	62

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/s/  
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06/10/2015

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