

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205353Orig1s000

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:	June 18, 2014
Application Type and Number:	NDA 205353
Product Name and Strength:	Farydak (Panobinostat) Capsules, 10 mg, 15 mg, 20 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis
Submission Date:	March 24, 2014
Panorama #:	2014-17130
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

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

1 INTRODUCTION

This review evaluates the proposed proprietary name, Farydak, 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. The Applicant did not submit an external name study for this proposed proprietary name for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) to IND 069862, which was found acceptable in OSE Review 2007-1366, dated October 22, 2008. The Applicant changed the product characteristics and thus submitted another proprietary name request for (b) (4) was denied in OSE Review 2010-1240, dated November 22, 2010, for concerns of name confusion with (b) (4). Subsequently, on August 4, 2011, the Applicant submitted, *Farydak*, for proprietary name review which was found acceptable in OSE Review 2011-3037, dated January 25, 2012.

In accordance with the Guidance Contents of a Complete Submission for the Evaluation of Proprietary Names, the applicant is submitting the name, Farydak, for re-review on March 24, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 24, 2014 proprietary name submission.

- Intended Pronunciation: Fa-ry-dak
- Active Ingredient: panobinostat
- Indication of Use: In combination with bortezomib and dexamethasone is indicated for the treatment of patients with multiple myeloma who have received at least one prior therapy
- Route of Administration: Oral
- Dosage Form: Capsules
- Strength: 10 mg, 15 mg, 20 mg
- Dose and Frequency: 20 mg, taken once a day, on days 1, 3, 5, 8, 10 and 12, of a 21 days cycle
- How Supplied: PVC/PCTFE blister packs with 6 capsules in each blister pack
- Storage: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)

2 RESULTS

The following sections provide information obtained and considered in the overall 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 Hematology Products (DHP) concurred with the findings of OPDP's promotional 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 name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Farydak, is a coined name with a gentle reference to the mechanism of the drug via the –DAK suffix as this loosely refers to the deacetylase inhibition (commonly referenced as DAC) property of the drug. 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

One hundred and eleven practitioners participated in DMEPA's prescription studies. Twenty-four participants interpreted the name correctly (outpatient n=20, inpatient n=4). The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Examples of misinterpretations seen in the data are listed below:

- “F” omitted
- “F” misinterpreted as “V”
- “a” misinterpreted as “e”, “o”
- “r” misinterpreted as “n”
- “y” misinterpreted as “i”
- “k” misinterpreted as “q”

We have considered these variations in our look-alike and sound-alike searches and analysis. Appendix B contains the results from the verbal and written prescription studies.

¹USAN stem search conducted on June 11, 2014.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 2, 2014 e-mail, the Division of Hematology Products (DHP) 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

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	121
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 122 names contained in Table 1 determined that none of the names will pose a risk for confusion as described in Appendices C through G.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on June 11, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products on June 18, 2014, they stated no additional concerns with the proposed proprietary name, Farydak.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Kevin Wright, OSE project manager, at 301-796-3621.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 24, 2014 submission are altered, 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).

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 considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment:** For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE 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 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.²

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

² National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

- 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 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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

- 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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to 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 do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	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>	Y/N	Do the names have different number of syllables?
Y/N	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>	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 $\geq 50\%$ to $\leq 69\%$).

Step 1	<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 have a higher potential for confusion and should be evaluated further (see Step 2).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, 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"> ○ 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	<p>Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names with overlapping or similar strengths or doses.</p>

<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <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"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • 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/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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as 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 ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Farydak Study (Conducted on April 4, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Farydak 20mg M, W, F</i></p>	<p>Farydak 10 mg 2 tabs po M, W, F #12</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Farydak 10mg</i> <i>2 tabs po MWF</i> <i>#12</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

275 People Received Study
111 People Responded

Study Name: Farydak

Total	40	33	38	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ARIDAQ	0	1	0	1
FANYDAK	4	0	0	4
FARIDEQ	0	1	0	1
FARYDAH	0	0	13	13
FARYDAK	19	0	4	23
FARYDAK TABLETS	1	0	0	1
FARYDALE	9	0	0	9
FARYDUH	0	0	12	12
FARYDUK	0	0	5	5
FARYHAK	2	0	0	2
FARYKAH	0	0	1	1
FARYNAK	2	0	0	2
FARYRAK	1	0	0	1
FAVYDAK	2	0	0	2
FERIDAC	0	1	0	1
FERIDECK	0	1	0	1
FERIDEK	0	1	0	1
FERYDAC	0	1	0	1
FERYDEC	0	1	0	1
FERYDEK	0	1	0	1
FOREIDAC	0	1	0	1
FORIDAC	0	2	0	2
FORIDACK	0	1	0	1
FORIDAK	0	1	0	1
FORIDECK	0	1	0	1
FORIDEK	0	1	0	1
FORYIDAK	0	1	0	1
FRIDAC	0	1	0	1

FURYDAK	0	1	0	1
HIRIDECK	0	1	0	1
ILLEDGIBLE	0	0	1	1
ORIDAC	0	1	0	1
ORIDAK	0	1	0	1
ORIDAQ	0	1	0	1
ORIDAT	0	1	0	1
ORIDEC	0	1	0	1
PERIDEC	0	1	0	1
PYRIDIC	0	1	0	1
RIDAC	0	1	0	1
TARYDAH	0	0	1	1
TARYDUH	0	0	1	1
VERIDACK	0	1	0	1
VERIDEK	0	1	0	1
VIRIDAK	0	1	0	1
VORIDAC	0	2	0	2
VYDEK	0	1	0	1

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

No.	Proposed name: Farydak Strength(s): 10 mg, 15 mg, 20 mg Usual Dose: 20 mg taken once a day, on days 1, 3, 5, 8, 10 and 12, of a 21 days cycle	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.			

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

No.	Proposed Name	POCA Score (%)
1.	Fulyzaq	60
2.	Paremyd	60
3.	Ferralet/90	55
4.	Varivax	55
5.	Cardec	54
6.	Fiorpap	54
7.	Foradil	54
8.	Fortabs	54
9.	Kerydin***	54
10.	Terak	54
11.	Fortamet	52
12.	Phenytek	52
13.	Varizig	52
14.	Ceretec	51
15.	Erymax	51
16.	Surelac	51
17.	DryMax	50
18.	Predator	50
19.	Erytab	50
20.	Fareston	50

21.	Ferate	50
22.	Larotid	50
23.	Percodan	50
24.	Pred-G	50
25.	Prevpac	50
26.	Sele-Pak	50
27.	Trymex	50
28.	Xerac AC	50

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

No.	Proposed name: Farydak Strength(s): 10 mg, 15 mg, 20 mg Usual Dose: 20 mg taken once a day, on days 1, 3, 5, 8, 10 and 12, of a 21 days cycle	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.	Peridex	57	Phonetic: The prefixes of this name pair sound differently. Ortho: The second syllable of this name pair have sufficient differences.
2.	Ferndex	56	Phonetic: The prefixes of this name pair sound differently. In addition, the names have different number of syllables (3 vs.2). Ortho: The second syllable of this name pair have sufficient differences.
3.	Fortaz	56	Phonetic: The suffixes of this name pair sound differently. In addition, the names have different number of syllables (3 vs.2). Ortho: The second syllable and suffixes of this name pair have sufficient differences.
4.	Therevac	56	Phonetic: The prefixes of this name pair sound differently. Ortho: The second syllable and suffixes of this name pair have sufficient differences. Routes of Administration: Farydak is an oral product, whereas Therevac is given rectally.
5.	Zartan	55	Phonetic: The suffixes of this name pair sound differently. In addition, the names have different number of syllables (3 vs.2). Ortho: The prefixes and second syllable of this name pair have sufficient differences.
6.	Parnate	54	Phonetic: The suffixes of this name pair sound differently. In addition, the names have different number of syllables (3 vs.2). Ortho: The second syllable of this name pair have

			sufficient differences.
7.	Farxiga	53	Phonetic: The suffixes of this name pair sound differently. Ortho: The infix and the suffix of this name pair have sufficient differences.
8.	Prozac	51	Phonetic: This name pair has sufficient phonetic differences. In addition, the names have different number of syllables (3 vs.2). Ortho: This name pair has sufficient orthographic differences.
9.	Loryna	50	Phonetic: This name pair has sufficient phonetic differences Ortho: This name pair has sufficient orthographic differences.
10.	Pradaxa	50	Phonetic: This name pair has sufficient phonetic differences. Ortho: This name pair has sufficient orthographic differences.

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

No.	Name	POCA Score (%)
1.		

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

No.	Name	POCA Score (%)	Failure Prevention
1.	(b) (4)	92	This proposed name was withdrawn by the applicant on

			(b) (4)
2.	Feridex***	64	<p>This name was identified in RxNorm.</p> <p>However, this product will be withdrawn FR and is listed as discontinued in Facts and Comparison.</p>
3.	Pro Red AC	60	<p>This name was identified in Rx Norm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
4.	Ferratab	59	<p>This name was identified in Rx Norm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
5.	Tri-Dec	58	<p>This name was identified in Rx Norm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p> <p>This is an over-</p>

			the-counter (OTC) product
6.	BF-Paradac	57	This name was identified in Rx Norm database. However, this is an over-the-counter (OTC) and international product marketed in Hong Kong.
7.	Aridex	56	This name was identified in Rx Norm database. However, we were unable to find complete product characteristics in commonly used drug databases.
8.	Farbital	56	This name was identified in Rx Norm database. However, we were unable to find complete product characteristics in commonly used drug databases.
9.	(b) (4)	56	This proposed name was found unacceptable for NDA 21997. The product was approved under the name Zolpidem tablets.
10.	Peri-D.O.S.	56	This name was identified in Rx Norm.

			However, we were unable to find product characteristics in commonly used drug databases.
11.	Pharmaf	56	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
12.	Predate-50	56	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases. This product is listed as deactivated in RedBook.
13.	Teronac	56	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
14.	(b) (4)	55	This is a secondary proposed proprietary name for NDA 201739.

			The product was approved under the proprietary name Auvi-Q (epinephrine) Auto-Injector.
15.	Mooredec	55	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases. This product is listed as deactivated in RedBook.
16.	(b) (4) ***	55	This is a secondary proposed proprietary name for NDA (b) (4) and this product was not approved.
17.	Threda	55	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
18.	(b) (4)	54	This proposed name for ANDA 065461 was withdrawn by the applicant on 12/10/09. The product was approved under

			the name tacrolimus.
19.	Ferra-TD	54	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
20.	Ferro DSS	54	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases. This product is listed as deactivated in RedBook.
21.	Fruity C	54	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases. This is an over-the-counter (OTC) product.
22.	Peri-DS	54	This name was identified in Rx Norm. However, we were unable to

			find product characteristics in commonly used drug databases.
23.	(b) (4)	54	Proposed proprietary name withdrawn on (b) (4). NDA (b) (4) received complete response.
24.	Trynate	54	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
25.	Formate	53	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
26.	Kuretek	53	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
27.	Parmid	53	This name was identified in Rx Norm. However, we

			were unable to find product characteristics in commonly used drug databases.
28.	(b) (4) ***	53	This proposed name was found unacceptable for IND-078781. The product was approved under the name Naloxegol tablets.
29.	Urobak***	53	This name was identified in Drugs at FDA database. However, this product is listed as discontinued in Drugs at FDA and has been withdrawn FR effective on 7/29/1992.
30.	Zodryl DAC	53	This name was identified in Rx Norm. However, this product is listed as discontinued in Redbook.
31.	Sirturo***	52	This is a secondary proposed name for NDA 204384. This product was approved under the name Sirturo.
32.	Ceredase***	52	This name was identified in Drugs at FDA database and

			<p>RxNorm.</p> <p>However, this product is listed as discontinued in Drugs at FDA and has been withdrawn FR effective on 4/18/2012.</p>
33.	Farlutal	52	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
34.	Farnesal	52	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
35.	(b) (4) ***	52	<p>This proprietary name was found acceptable by DMEPA in OSE# (b) (4). The product is currently under review.</p>
36.	Frumax	52	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find product characteristics in commonly used</p>

			drug databases.
37.	(b) (4)	52	This proposed name for ANDA 079221 was withdrawn by the applicant on 8/25/09. The product was approved under the name drospirenone and ethinyl estradiol tablet.
38.	Permax	52	This name was identified by Drugs at FDA and RxNorm. However, this product is listed as discontinued in Drugs at FDA and has been withdrawn pending FR notice on 4/8/2009.
39.	Predef	52	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
40.	Pro1tek	52	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used

			drug databases.
41.	Protac	52	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases. This product is listed as discontinued in Redbook.</p>
42.	(b) (4)	52	<p>This proposed name was withdrawn by the applicant on 6/18/10. This product was approved as Omeprazole 25 mg/Amoxicillin 500 mg/clarithromycin 500 mg capsule.</p>
43.	(b) (4)***	52	<p>This name was reviewed by DMEPA and found acceptable in OSE# (b) (4) (b) (4) IND (b) (4) is still under review.</p>
44.	(b) (4)***	52	<p>This name was reviewed by DMEPA and found unacceptable in OSE# (b) (4) (b) (4) NDA- (b) (4) is (b) (4) approvable as (b) (4)</p>

			(b) (4)
45.	Tramake	52	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
46.	(b) (4) ***	52	<p>This name was reviewed by DMEPA and found unacceptable in OSE# (b) (4)</p> <p>ANDA (b) (4) is under review.</p> <p>This proposed name was withdrawn by the applicant on (b) (4).</p>
47.	(b) (4) ***	52	<p>This name was reviewed by DMEPA and found unacceptable in OSE# (b) (4)</p> <p>(b) (4) IND (b) (4) is under review.</p>
48.	Fero-Grad	51	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p> <p>This is an over-</p>

			the-counter (OTC) product.
49.	Ferronate	51	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases.
50.	(b) (4) ***	51	This name was reviewed by DMEPA and found acceptable in OSE# (b) (4). However, IND (b) (4) has been withdrawn.
51.	(b) (4) ***	51	This name was reviewed and found unacceptable by OPDP in OSE# (b) (4). NDA 22007 was approved under the proprietary name Performist.
52.	Pre Milk	51	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
53.	Tridane	51	This name was identified in Rx Norm. However, we

			were unable to find product characteristics in commonly used drug databases.
54.	(b) (4)***	51	This name was reviewed by DMEPA and found acceptable in OSE# (b) (4) (b) (4) IND (b) (4) is an over-the-counter (OTC) product under review.
55.	Acitak 200/400/800	50	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
56.	(b) (4)	50	This is a secondary proposed proprietary name for NDA 201739. This product was approved under the proprietary name Auvi-Q (epinephrine) Auto-Injector.
57.	(b) (4)***	50	This name was identified in 'Name entered by safety evaluator' database. However, we were unable to find product characteristics in

			commonly used drug databases. This name is a misspelling of a proposed proprietary name.
58.	(b) (4) ***	50	This proposed name for NDA (b) (4) was withdrawn by the applicant on (b) (4). The product received a complete response.
59.	Carbic D		This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
60.	Carbodec	50	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases.
61.	Cardec S	50	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used

			drug databases. This product is listed as deactivated in RedBook.
62.	(b) (4) ***	50	This name was reviewed by DMEPA and found unacceptable in OSE# (b) (4) NDA (b) (4) received a complete response.
63.	Dryvax	50	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases. This product is listed as discontinued in Facts and Comparisons.
64.	Fansidar***	50	This name was identified in Rx Norm. However, this product is listed as discontinued in Facts and Comparisons and has been withdrawn FR effective on 4/18/2012.
65.	(b) (4)	50	This name was reviewed by

			DMEPA and found acceptable in OSE# (b) (4) NDA (b) (4) received a complete response.
66.	FERIDEX I.V.***	50	This name was identified in Drugs at FDA database. However, this product will be withdrawn FR and is listed as discontinued in Facts and Comparison.
67.	Ferrimin/ Ferrimin 150	50	This name was identified in Rx Norm. However, we were unable to find complete product characteristics in commonly used drug databases.
68.	Fluorides	50	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
69.	Flura-Tab	50	This name was identified in Rx Norm. However, we were unable to find product

			characteristics in commonly used drug databases.
70.	(b) (4) ***	50	This is a proposed name for NDA (b) (4) that was withdrawn on (b) (4). DMEPA reviewed and found acceptable in OSE# (b) (4) an alternative name (b) (4). This application received a complete response.
71.	Furalan	50	This name was identified in Drugs at FDA database. However, we were unable to find complete product characteristics in commonly used drug databases. This product is listed as discontinued on Drugs at FDA.
72.	(b) (4) ***	50	This name was reviewed and found unacceptable by DMEPA in OSE# (b) (4). IND (b) (4) is active.
73.	Patty Cake	50	This name was identified in Rx Norm.

			However, we were unable to find product characteristics in commonly used drug databases.
74.	Periocheck	50	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
75.	Probax	50	This name was identified in Rx Norm. However, we were unable to find product characteristics in commonly used drug databases.
76.	(b) (4) ***	50	This name was reviewed by DMEPA in OSE# (b) (4) and was found unacceptable. This proposed name was withdrawn on 6/21/12. NDA 50786/S-007 was approved under proprietary name Pylera.
77.	Ryna C	50	This name was identified in Rx Norm. However, we were unable to

			find product characteristics in commonly used drug databases.
78.	Seradex	50	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>
79.	(b) (4)***	50	<p>This name was reviewed by DMEPA in OSE# (b) (4) and was found unacceptable. IND (b) (4) is active.</p>
80.	Zodryl AC	50	<p>This name was identified in Rx Norm.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases. This product is listed as discontinued in Redbook.</p>

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MICHELLE K RUTLEDGE
06/18/2014

LUBNA A MERCHANT on behalf of YELENA L MASLOV
06/18/2014