CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206111Orig1s000

PROPRIETARY NAME REVIEW(S)

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)

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Date of This Review:	August 7, 2015
Application Type and Number:	NDA 206111
Product Name and Strength:	Synjardy (empagliflozin and metformin HCl) tablets, 5 mg/500 mg, 5 mg/1000 mg 12.5 mg/500 mg, 12.5 mg/1000 mg
Product Type:	Multiple Ingredients
Rx or OTC:	Rx
Applicant/Sponsor Name:	Boehringer Ingelheim
Panorama #:	2015-887595
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

1 INTRODUCTION

The proposed proprietary name, Synjardy, was found conditionally acceptable in OSE Review # 2014-26096, under NDA 206111, dated October 20, 2014. We note that the product characteristics are the same. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Synjardy, is acceptable from both a misbranding and safety perspective.

If you have further questions or need clarifications, please contact Terrolyn Thomas, OSE project manager at 301-796-1637.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 2, 2015 submission are altered, the name must be resubmitted for review.

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

/s/

SARAH K VEE
08/07/2015

YELENA L MASLOV
08/07/2015

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)

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Date of This Review:	October 20, 2014
Application Type and Number:	NDA 206111
Product Name and Strength:	Synjardy (empagliflozin/metformin) tablets 5 mg/500 mg, (b) (4) 5 mg/1000 mg 12.5 mg/500 mg, (b) (4) 12.5 mg/1000 mg
Product Type:	Multi-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Boehringer Ingelheim
Submission Date:	August 8, 2014
Panorama #:	2014-26096
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Synjardy, 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 submitted an external name study for this proposed proprietary name, conducted by Omega Insights, for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the August 8, 2014 proprietary name submission.

- Intended Pronunciation: sin-JAR-dee
- Active Ingredient: empagliflozin/metformin
- Indication of Use: combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (b) (4)
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 5 mg/500 mg, (b) (4) 5 mg/1000 mg, 12.5 mg/500 mg, (b) (4) 12.5 mg/1000 mg
- Dose and Frequency: 1 tablet twice daily
- How Supplied: Bottles of 60 or 180 (b) (4) tablets
- Storage: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature]
- Container and Closure Systems: The container closure system is a multidose plastic bottl (b) (4)

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 Metabolic and Endocrinology Products (DMEP) 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 name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Synjardy, is an abstract name, with no intended meaning, which is considered to be dynamic and encouraging in style. This proprietary name is comprised of a single 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

Seventy practitioners participated in DMEPA's prescription studies. One practitioner misinterpreted the inpatient prescription as "Singular", which is a close variation of the marketed product, Singulair. See section 2.2.6 for further discussion for this name. Voice prescription had the most varied interpretations with almost no duplicate interpretations. 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, August 19, 2014 e-mail, DMEP forwarded one sound alike name (Synagis) 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 ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation and by Omega Insights.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	75[3]

[1]USAN stem search conducted on August 18, 2014.

[2] POCA search conducted on August 14, 2014.

[3] Synagis and Singulair are included in this category for further analysis due to DMEP response (see Section 2.2.4) and an Rx Study hit (see Section 2.2.6 and Appendix B).

Low similarity name pair: combined match percentage score ≤49%	7

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

An FDA Rx Study participant misinterpreted the inpatient prescription for Synjardy (b) (4) as "Singular", which is a close variation to the marketed product "Singulair". Despite this misinterpretation in the FDA Rx Study, we do not think that the name pair, Synjardy and Singulair, has a potential for confusion in the actual use environment for the following reasons:

1. Synjardy and Singulair (Orthographic POCA 47%) have significant orthographic differences. Synjardy has three down strokes in the second, fourth and eighth positions (i.e. 'y', 'j' and 'y') compared to one down stroke in Singulair (i.e. 'g').

2. The second and third syllables of the name pair (Phonetic POCA 43%) have notable phonetic differences when spoken (i.e. 'jar-dy' vs. 'gu-lair").

3. Although one strength and dose of 5 mg is common in Synjardy and Singulair, strengths of both components for Synjardy must be specified (e.g. 5 mg/500 mg, (b) (4) 5 mg/1000 mg) on a prescription. Thus, it is unlikely that a prescription for Synjardy would be written as "Synjardy 5 mg"

Our analysis of the 83 names contained in Table 1 determined 83 names will not 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 DMEP via e-mail on October 2, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DMEP on October 14, 2014, they stated no additional concerns with the proposed proprietary name, Synjardy.

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 Lyle Canida, OSE project manager, at 301-796-1637.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 8, 2014 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).

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. [4]

***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?

[4] 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤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 ≥ 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).			
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 ≥50% 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 have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, 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: o 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. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	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.

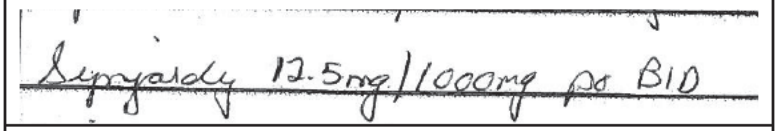
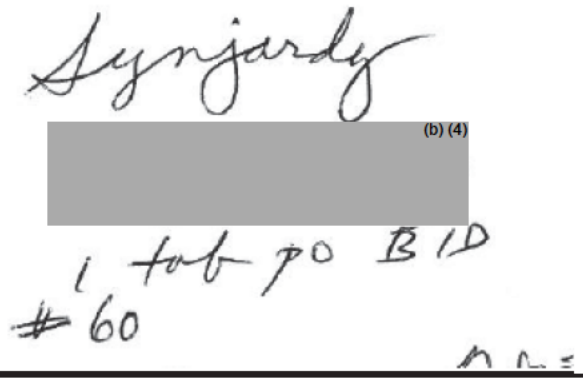
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤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. Synjardy Study (Conducted on 8/22/2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Synjardy (b) (4) 1 tab po BID #60

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

260 People Received
Study
70 People Responded

Total	24	21	25	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
FENJARDI	0	1	0	1
FENZARTI	0	1	0	1
SENJARDI	0	2	0	2
SENJARDIE	0	1	0	1
SENJARNI	0	1	0	1
SENJARTY	0	1	0	1
SENZURNI	0	1	0	1
SEPJARDY	0	0	1	1
SEPYARDY	0	0	4	4
SINGARDI	0	1	0	1
SINGARDY	0	1	0	1
SINGIARDI	0	1	0	1
SINGULAR	0	0	1	1
SINGURNEY	0	1	0	1
SINJARDI	0	1	0	1
SINJARI	0	1	0	1
SINJARTY	0	1	0	1
SINJARTY TABLETS	0	1	0	1
SINJURNY	0	1	0	1
SINZARTI	0	1	0	1
SUPJARDAY	0	0	1	1
SYNGARDI	0	1	0	1
SYNJAIDY	0	0	1	1
SYNJARDY	23	0	16	39
SYNJARLY	1	0	0	1
SYNJARY	0	0	1	1
SYNJOURNEY	0	1	0	1
ZENGARDI	0	1	0	1

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

No.	Name	POCA Score (%)	Failure preventions
1.	Synjardy	100%	Subject of this review

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

No.	Name	POCA Score (%)
1.	Synalar N/Synalar-C/Synalar	64/62/58
2.	Synercid	61
3.	Synacort	59
4.	Centany	58
5.	Zinecard	58
6.	Synthroid	57
7.	Sansert	56
8.	Sincalide	56
9.	Sine-Aid Ib	56
10.	Synarel	56
11.	Synera	55
12.	Lynparza***	54
13.	Sensodyne	53
14.	(b) (4)***	52
15.	Fungi-Guard	51
16.	Striverdi	51
17.	Synovacin	51
18.	Adenocard	50
19.	Cymbalta	50
20.	Fentanyl	50
21.	Folgard	50
22.	Sensipar	50
23.	Simbrinza	50

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No.	Name	POCA Score (%)
24.	Symbicort	50
25.	Synribo	50

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

No.	**Proposed name: Synjardy** **Strengths:** 5 mg/500 mg, (b) (4) mg/1000 mg, 12.5 mg/500 mg, (b) (4) 12.5 mg/1000 mg **Usual Dose:** 1 tablet twice daily	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.	Synagis	49%	The infix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
2.	Singulair	45%	The prefix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Cimetidine	30%
2.	Cynara-SL	<30%
3.	Janumet	30%
4.	Glyburide	<30%
5.	Sitagliptin	<30%
6.	Symbyax	42%
7.	Synvisc	44%

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.	Centergy	64	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
2.	Sani Guard	64	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
3.	Syntaris	64	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
4.	Cyndal HD	60	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
5.	(b) (4) ***	60	Alternate name/withdrawn for BLA 125409. Approved under Perjeta.
6.	Sinus Aid	58	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
7.	Stangard	58	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
8.	(b) (4) ***	58	2011-3380 DDMAC denial for NDA 21669, dated 9/29/2011
9.	(b) (4) ***	56	NDA (b) (4) name withdrawn as of 3/8/2010
10.	Suscard	56	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.

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No.	Name	POCA Score (%)	Failure preventions
11.	Synandone	56	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
12.	Synapryn	56	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
13.	Lentard	55	NDA 18384 withdrawn FR Effective 9/25/1997
14.	Sine-Aid	55	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
15.	Synadrin	55	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
16.	(b) (4)	55	NDA 18384 withdrawn FR Effective 3/11/1987
17.	Cedocard	54	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
18.	Concordin	54	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
19.	(b) (4) ***	54	Alternate name for NDA 21217 (RCM #2006-959 dated 7/21/2006) acceptable but NDA 21217 approved under Exalgo
20.	(b) (4) ***	54	Proposed name for IND (b) (4) (RCM #2008-1809) DDMAC denial

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No.	Name	POCA Score (%)	Failure preventions
21.	Tonocard	53	NDA 18257 withdrawn FR effective 6/16/2006
22.	Cedocard IV	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
23.	Phencarb GG	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
24.	Phendal-HD	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
25.	Phendry	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
26.	Sanatos Day	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
27.	Sandrena	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
28.	Sensi-Care Body	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
29.	(b) (4)***	52	Found unacceptable RCM # 2010-1153, dated 11/3/2010 BLA 125431 approved under Tanzeum

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No.	Name	POCA Score (%)	Failure preventions
30.	Vascardin	52	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
31.	Semitard MC	51	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
32.	Sinarest	51	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
33.	(b) (4)***	51	Proposed name for NDA 22331, approved under Kapvay
34.	(b) (4)***	51	Proposed name for NDA 21332 approved under Symlin
35.	Symmetry	51	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
36.	Symtan A	51	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
37.	(b) (4)***	50	Proposed name for IND (b) (4) withdrawn 6/24/2009
38.	Cyndal	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
39.	Oxy Gard	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.

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No.	Name	POCA Score (%)	Failure preventions
40.	Safe-Guard	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
41.	Sennoside B	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
42.	Senormin	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
43.	Symtan	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
44.	Synkavite	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
45.	Syn-Rx	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
46.	Syntest	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
47.	Syscor MR	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
48.	Tandur DM	50	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.

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/s/

SARAH K VEE
10/20/2014

YELENA L MASLOV
10/20/2014