CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208255Orig1s000

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)

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Date of This Review:	October 18, 2017
Application Type and Number:	NDA 208255 and NDA 22142
Product Name and Strength:	Symfi Lo (efavirenz, lamivudine, and tenofovir disoproxil fumarate) Tablet, 400 mg/300 mg/300 mg Symfi (efavirenz, lamivudine, and tenofovir disoproxil fumarate) Tablet, 600 mg/300 mg/300 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Mylan Pharmaceuticals, Inc. and Mylan Laboratories Limited
Panorama #:	2017-16575934 and 2017-16639499
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary names, Symfi and Symfi Lo, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed names are outlined in the reference section and Appendix A respectively. The Applicants submitted external name studies conducted by (b) (4), for these products.

1.1 PRODUCT INFORMATION

The following product information is provided in the July 25, 2017 and July 27, 2017 proprietary name submissions.

Proprietary Name Requested	**Symfi**	**Symfi Lo**
Intended Pronunciation	SIM-fee	SIM-fee LOW
Active Ingredient	efavirenz, lamivudine, and tenofovir disoproxil fumarate	
Indication of Use	Treatment of HIV-1 infection	
Route of Administration	Oral	
Dosage Form	Tablet	
Strength	600 mg/300 mg/300 mg	400 mg/300 mg/300 mg
Dose and Frequency	1 tablet once daily	
How Supplied	Bottles of 30	Bottle count not provided
Storage	Store below 30°C (86°F)	(b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed names would not misbrand the proposed products. DMEPA and the Division of Antiviral Products (DAVP) concurred with the findings of OPDP's assessment of the proposed names.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the names.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary names[a].

2.2.2 Components of the Proposed Proprietary Names

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

Additionally, according to the July 25, 2017 cover letter submitted to NDA 208255, the Applicant proposes that the low dose formulation of efavirenz, lamivudine, and tenofovir disoproxil fumarate tablets (400 mg/300 mg/300 mg) includes the modifier 'Lo' with the root name, Symfi (i.e. Symfi Lo). We assess the modifier, Lo, in section 2.2.8.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 10, 2017 e-mail, the Division of Antiviral Products (DAVP) did not forward any comments or concerns relating to the proposed proprietary names at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Symfi

Sixty-three practitioners participated in DMEPA's prescription studies for Symfi. One participant in the verbal prescription study misinterpreted the prescription as, Cimfi, an international product currently marketed in India. Given that Cimfi is not marketed in the United States (US), we find there is low risk of confusion with Symfi as outlined in Appendix C.

Symfi Lo

Sixty-eight practitioners participated in DMEPA's prescription studies for Symfi Lo. Four participants in the written inpatient prescription study misinterpreted the prescription as, Synti Lo, which sounds like an international product, Synti, that was formerly marketed in Malaysia. Given that Synti was never marketed in the US, we find there is low risk for confusion with Symfi Lo as outlined in Appendix C.

Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 61names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70**.** These names are included in Table 1 below.

[a] USAN stem search conducted on (August 22, 2017).

[b] POCA search conducted on (August 28, 2017) in version 4.2.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, FDA Prescription Simulation Study, and the [redacted] (b) (6) external study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	59
Low similarity name pair: combined match percentage score ≤54%	11

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

Our analysis of the 72 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 Safety Assessment of the Modifier "Lo"

The Applicant indicated "Lo" is intended to identify Symfi Lo as the low dose formulation of efavirenz, lamivudine, and tenofovir disoproxil fumarate. We recognize the modifier, "Lo," is included on ISMP's *List of Products with Drug Name Suffixes.* According to the list, the modifier, "Lo," means "low dose," which is consistent with the Applicant's intended meaning for the use of the modifier, "Lo."

We assessed whether the modifier, "Lo" could be misinterpreted for a medical abbreviation. We identified several definitions for the medical abbreviation "Lo", which include lateral oblique, lenticular opacity, leucine oxidation, linguo occlusal, loss, low lumbar orthosis, lipoxygenase, and limes zero; however, these terms are not typically used in prescribing and dispensing medications.

During the DMEPA written prescription simulation studies, one practitioner misinterpreted "Lo" as the number "10." We note that the number "10" does not overlap with the strength or dose of Symfi or Symfi Lo. Additionally, this modifier has been utilized in the market previously and we are not aware of it contributing to medication errors.

Although we recognize that omission or oversight of modifiers is cited in literature as a common cause of medication error[c], we also recognize that it has been an accepted naming convention to use a modifier to distinguish products in a product line. [redacted] (b) (4)

[c] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults. Therefore, we find the use of the modifier "Lo" appropriate for this product.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antiviral Products (DAVP) via e-mail on October 17, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAVP on October 18, 2017, they stated no additional concerns with the proposed proprietary names, Symfi and Symfi Lo.

3 CONCLUSIONS

The proposed proprietary names, Symfi and Symfi Lo, are acceptable.

If you have further questions or need clarifications, please contact Danyal Chaudhry, OSE project manager, at 301-796-3813.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Symfi and Symfi Lo, and have concluded that the names Symfi and Symfi Lo are acceptable.

If any of the proposed product characteristics as stated in your July 25, 2017 and July 27, 2017 submissions are altered prior to approval of the marketing applications, the names 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.

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

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [d]

[d] 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.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	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)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
   - Highly similar pair: combined match percentage score ≥70%.
   - Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
   - Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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.,

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg

<table>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>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?</td><td>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?</td></tr>
</table>

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

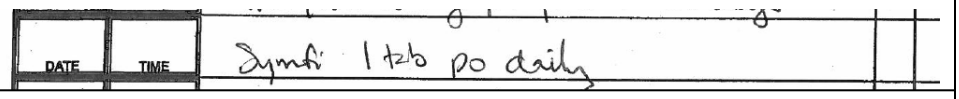
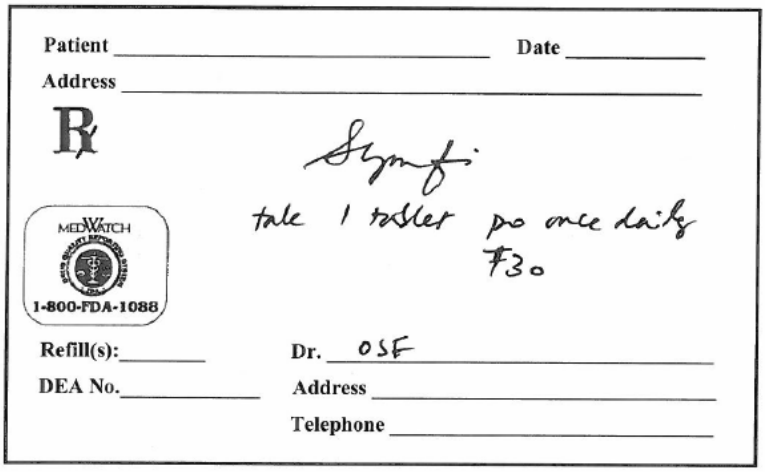
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Two prescription simulation studies were conducted for Symfi and Symfi Lo. Prescription samples and results for Symfi are listed in section B.1 and for Symfi Lo in section B.2.

B.1 Rx Study #1 for Symfi

Figure 1. Symfi Study (Conducted on August 4, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Symfi Take 1 tablet by mouth once daily Dispense #30

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

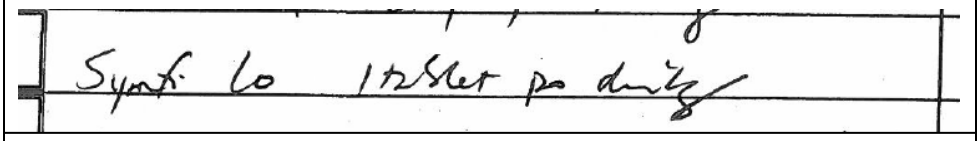
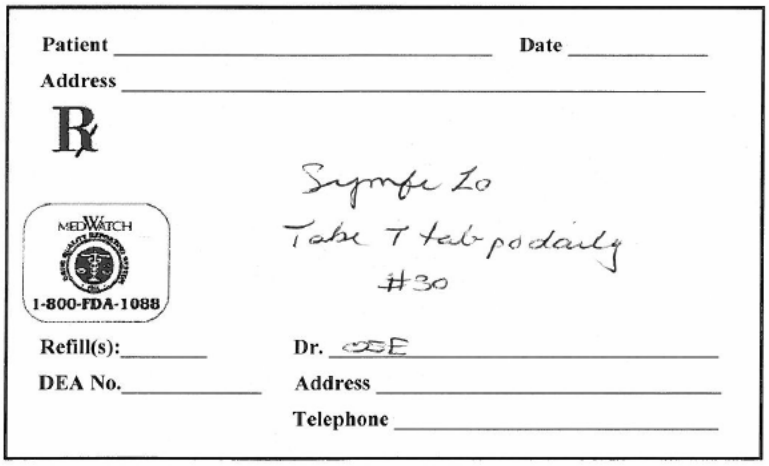
291 People Received Study
63 People Responded

Study Name: Symfi conducted on August 4, 2017

Total	24	14	25	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
CIMFI	0	1	0	1
SIMFI	0	2	0	2
SIMPHI	0	1	0	1
SIMPHY	0	1	0	1
SIMPI	0	1	0	1
SIMPTY	0	1	0	1
SIMVI	0	2	0	2
SIM-VI	0	1	0	1
SIMVY	0	1	0	1
SMYFI	1	0	0	1
SYMFE	0	1	0	1
SYMFI	21	0	24	45
SYMFY	0	1	0	1
SYMPFI	1	0	0	1
SYNFI	1	0	1	2
ZIMFI	0	1	0	1

B.2 Rx Study #2 for Symfi Lo

Figure 2. Symfi Lo Study (Conducted on August 9, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Symfi Lo Take 1 tablet by mouth once daily Dispense #30

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

291 People Received Study
68 People Responded

Study Name: Symfi Lo conducted on August 9, 2017

Total	28	20	20	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
CENFILOW	0	1	0	1
SEVELO	0	1	0	1
SIM V LOW	0	1	0	1
SIMFELO	0	1	0	1
SIMFILOW	0	1	0	1
SIMVE LO	0	1	0	1
SIMVEE LO	0	1	0	1
SIMVI LO	0	1	0	1
SIMVILOW	0	1	0	1
SIMVLIOW	0	1	0	1
SIMVY LO	0	1	0	1
SINTHEE LOW	0	1	0	1
SINVIE-LO	0	1	0	1
SIVI-LO	0	1	0	1
SYMBI LO	1	0	0	1
SYMFE 10	1	0	0	1
SYMFE LO	9	0	0	9
SYMFEE LO	0	1	0	1
SYMFI LO	16	2	9	27
SYMFI ZO	1	0	0	1
SYMFILO	0	0	1	1
SYMPHI LO	0	1	0	1
SYMPHYLOW	0	1	0	1

291 People Received Study
68 People Responded

Study Name: Symfi Lo conducted on August 9, 2017

Total	28	20	20	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
SYNFI	0	0	1	1
SYNFI LO	0	0	4	4
SYNTHI-LO	0	1	0	1
SYNTI LO	0	0	4	4
SYONFI LO	0	0	1	1

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

No.	**Proposed name:** Symfi and Symfi Lo **Established name:** efavirenz, lamivudine, and tenofovir disoproxil fumarate **Dosage form:** Tablet **Strength(s):** 600 mg/300 mg/300 mg and 400 mg/300 mg/300 mg **Usual Dose:** 1 tablet once daily	**Symfi POCA Score (%)**	**Symfi Lo POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Cimfi	80	56	International product marketed in India.
2.	Synti	50	80	International product formerly marketed in Malaysia.

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

No.	Name	Symfi POCA Score (%)	Symfi Lo POCA Score (%)
3.	Femmesil	N/A	64
4.	Hemofil	N/A	62
5.	Qsymia	58	N/A
6.	Somophyllin	N/A	56
7.	Symmetrel	N/A	56
8.	Fem Ph	52	N/A

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

No.	**Proposed name:** Symfi and Symfi Lo **Established name:** efavirenz, lamivudine, and tenofovir disoproxil fumarate **Dosage form:** Tablet **Strength(s):** 600 mg/300 mg/300 mg and 400 mg/300 mg/300 mg **Usual Dose:** 1 tablet once daily	**Symfi POCA Score (%)**	**Symfi Lo 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**
9.	Symlin	64	N/A	The downstroke or cross-stroke of "f" in Symfi and the additional letter "n" in Symlin offers orthographic differences between the suffixes of this name pair when scripted. The second syllables of this name pair sound different. There is no numerical overlap in dose between these products (1 tablet vs 15 mcg to 120 mcg).
10.	[redacted] (b) (6) ***	N/A	63	This name pair has sufficient orthographic differences. There is no overlap in dose, route, or frequency between these products (1 tablet by mouth daily vs [redacted] (b) (6) .
11.	Sulfo-Lo	N/A	62	This name pair has sufficient orthographic and phonetic differences.
12.	Tensilon	N/A	62	This name pair has sufficient orthographic and phonetic differences.
13.	Sildaflo	N/A	60	This name pair has sufficient orthographic and phonetic differences.
14.	Symax	60	N/A	This name pair has sufficient orthographic and phonetic differences.
15.	Symax-SL	N/A	60	This name pair has sufficient orthographic and phonetic differences.
16.	Symtuza***	N/A	60	This name pair has sufficient orthographic and phonetic differences.
17.	Symdeko***	N/A	59	This name pair has sufficient phonetic differences. There is no numerical overlap in strength between these two products (400 mg/300 mg/300 mg vs 100 mg/150 mg & 150 mg). Symdeko*** will contain one dual ingredient tablet and one single ingredient tablet [redacted] (b) (4)

No.	**Proposed name:** Symfi and Symfi Lo **Established name:** efavirenz, lamivudine, and tenofovir disoproxil fumarate **Dosage form:** Tablet **Strength(s):** 600 mg/300 mg/300 mg and 400 mg/300 mg/300 mg **Usual Dose:** 1 tablet once daily	**Symfi POCA Score (%)**	**Symfi Lo 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**
18.	Synemol	N/A	59	This name pair has sufficient orthographic and phonetic differences.
19.	Simliya***	N/A	58	This name pair has sufficient orthographic and phonetic differences. There is no numerical overlap in strength between these products (400 mg/300 mg/ 300 mg vs 0.15 mg/0.02 mg/0.01 mg).
20.	Symjepi	58	N/A	This name pair has sufficient orthographic and phonetic differences.
21.	Syncol	N/A	58	This name pair has sufficient orthographic and phonetic differences.
22.	Synribo	N/A	58	This name pair has sufficient orthographic and phonetic differences.
23.	Santyl	N/A	56	This name pair has sufficient orthographic and phonetic differences.
24.	Cenfol	N/A	55	This name pair has sufficient orthographic and phonetic differences. There is no numerical overlap in strength between these products (400 mg/300 mg/300 mg vs 24.5 mg/2,000 mcg/ 2.3 mg).
25.	Simponi	N/A	55	This name pair has sufficient orthographic and phonetic differences.
26.	Symproic	N/A	55	This name pair has sufficient orthographic and phonetic differences.
27.	Zensa	47	N/A	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	Symfi POCA Score (%)	Symfi Lo POCA Score (%)
28.	Onfi	46	35
29.	Simcor	48	53
30.	Simeprevir	34	38
31.	Simvastatin	33	34
32.	Soma	46	34
33.	Sovaldi	30	44
34.	Syeda	46	36
35.	Symbicort	44	50
36.	Symbyax	46	44
37.	Synthroid	42	45
38.	Synvisc	53	51

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

No.	Name	Symfi POCA Score (%)	Symfi Lo POCA Score (%)	Failure preventions
39.	Sno Pilo	N/A	66	International product marketed in Ireland and United Kingdom.
40.	Soni-Slo	N/A	65	International product formerly marketed in Ireland and United Kingdom.
41.	Symbioflor	N/A	64	International product formerly marketed in Germany and Switzerland
42.	Symbioflor 2	N/A	64	International product formerly marketed in Switzerland and Germany
43.	Sevoflo	N/A	63	Veterinary product.
44.	Symtan	63	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	(b) (4)	N/A	60	Proprietary name submitted to IND (b) (4) that was found unacceptable on (b) (6). Panorama #: (b) (6).
46.	Isoflo	N/A	60	Veterinary product.
47.	Symbioflor I	N/A	60	International product formerly marketed in Germany and Switzerland
48.	Cinnasil	N/A	58	Discontinued, withdrawn FR effective August 14, 2012.

No.	Name	Symfi POCA Score (%)	Symfi Lo POCA Score (%)	Failure preventions
49.	Simplet	N/A	58	Name identified in RxNorm and Redbook databases. Product is deactivated and no generic alternatives are available.
50.	Sympatol	N/A	58	International product formerly marketed in Germany, Italy, Switzerland, and Austria.
51.	Synflex	N/A	58	International product marketed in Canada, Indonesia, Hong Kong, Ireland, New Zealand, the UK, Australia, South Africa, Italy, Malaysia, Singapore, and Thailand.
52.	Zemcolo***	N/A	58	Proprietary name submitted to IND (b) (6) that was found unacceptable on (b) (6) . The Sponsor later submitted Aemcolo*** for proprietary name review, (b) (6)
53.	Panfil	N/A	57	Discontinued per RxNorm and not found in any other commonly used databases
54.	Emfib	56	N/A	International product formerly marketed in United Kingdom.
55.	Seffin	56	N/A	Discontinued, withdrawn FR effective 6/9/1994 with no generic equivalents available.
56.	Stimlor	N/A	56	International product formerly marketed in United Kingdom.
57.	Symtan A	N/A	56	Product withdrawn from the market due to safety concerns. Cough and cold product that contained the tannate salt form which is not generally recognized as safe and effective. FR notice 3/3/2011.
58.	Phenflu	N/A	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
59.	Pro-symbioflor	N/A	50	International product formerly marketed in Switzerland and Germany

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[f].

No.	Name	Symfi POCA Score (%)	Symfi Lo POCA Score (%)
60.	Zyflo	N/A	62
61.	Tymlos	N/A	60
62.	Esimil	N/A	60
63.	Thymus Oil	N/A	59
64.	Tamiflu	N/A	59
65.	Dymelor	N/A	58
66.	Zymafluor	N/A	56
67.	Tansy Oil	N/A	56
68.	Lamisil	N/A	56
69.	Timolol	N/A	56
70.	Konsyl	N/A	56
71.	Primsol	N/A	56
72.	Vansil	N/A	56

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

No.	Name
73.	N/A

[f] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/s/

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