CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210806Orig1s000
210807Orig1s000

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:	June 22, 2018
Application Type and Number:	NDA 210807
Product Name and Strength:	Delstrigo (doravirine, lamivudine, and tenofovir disoproxil fumarate) Tablets, 100 mg/300 mg/ 300 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck Sharp & Dohme Corporation
Panorama #:	2018-21898059
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD
DMEPA Deputy Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review responds to a March 27, 2018 request from Merck Sharp & Dohme Corporation (Merck) to reconsider the proposed proprietary name, Delstrigo, for NDA 210807.

1.1 REGULATORY HISTORY

The proposed proprietary name, Delstrigo, was previously reviewed under NDA 210807 and found to be unacceptable due to orthographic similarities and overlapping product characteristics with the currently marketed product, Delestrogen.[a] Merck was informed of our decision in writing on February 7, 2018.[b]

Thus, Merck submitted a request for reconsideration of the proposed proprietary name, Delstrigo, on March 27, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 27, 2018.

- Intended Pronunciation: del-STREE-go
- Active Ingredient: doravirine, lamivudine, and tenofovir disoproxil fumarate
- Indication of Use: A complete regimen for the treatment of HIV-1 infection in treatment-naïve patients
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 100 mg/300 mg/300 mg
- Dose and Frequency: 1 tablet by mouth once daily
- How Supplied: Bottles of 30 tablets
- Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

2 MATERIALS REVIEWED AND METHODS

We considered the safety concerns described in our previous review of the proposed proprietary name, Delstrigo, as well as information provided by Merck, which included an external name study conducted by (b) (4) new information on the packaging, prescribing, and distribution of Delstrigo, and 2017 sales data for Delestrogen.

In the March 27, 2018 request for reconsideration, Merck stated:

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[a] Wilson, V. Proprietary Name Review for Delstrigo NDA 210807. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Feb 06. Panorama No. 2017-19081976.

[b] Chaudhry, A. Proprietary Name Denied for Delstrigo. Silver Spring (MD): FDA, CDER, OSE (US); 2018 Feb 07. NDA 210807.

1. Delstrigo and Delestrogen feature key phonetic, orthographic, and product characteristic differences that will help distinguish the two drugs in the marketplace, thus minimizing the risk of medication errors;
2. The indications for use of Delestrogen are very different from the proposed indication for Delstrigo
3. Delstrigo will be prescribed by infectious disease/HIV specialists with little to no overlap between the prescribing physician specialties for Delestrogen (obstetrician/gynecologists, endocrinologists, or oncologists);
4. The packaging and product appearance will differ significantly from Delestrogen. No secondary packaging (outer box) will be used for Delstrigo further distinguishing it from Delestrogen, which is supplied as a vial in a box;
5. Delstrigo will be used primarily in outpatient settings (e.g., physician offices, clinics, and health care systems), along with some use in inpatient/hospital settings. Retail pharmacies will be the primary dispensers of Delstrigo, with some dispensing by specialty pharmacies;
6. Delestrogen is rarely prescribed in the U.S., with only about (b) (4) units sold in 2017. This relatively low frequency of prescribing and dispensing of Delestrogen minimizes the risk of medication errors due to confusion between Delstrigo and Delestrogen; and
7. Delstrigo falls on the threshold between moderately similar and highly similar name pairs.

3 DISCUSSION

This section summarizes our evaluation of the information provided by the Applicant in support of a reconsideration of the proposed proprietary name, Delstrigo.

PHONETIC AND ORTHOGRAPHIC DIFFERENCES

We find there are sufficient phonetic differences between Delstrigo and Delestrogen. We previously determined the proposed proprietary name, Delstrigo, to be unacceptable due in part to orthographic similarity with Delestrogen, and we maintain that there are orthographic similarities between this name pair.

The Applicant acknowledges that both names begin with the same first three letters, D-e-l, but believes the names, Delstrigo and Delestrogen, have distinct endings that will help distinguish the two names in all circumstances except when rendered in extremely bad handwriting. The Applicant proposes the names are visually distinct because 1) the names differ in length by two letters making Delstrigo look shorter than Delestrogen both in script and print; 2) the additional letter "e" in the infix causes the upstroke letter "t" and downstroke letter "g" to be placed further out in the name; 3) the letter "o" in the infix of Delestrogen (-estro-) looks rounder when scripted when compared to an "i"; and 4) the letter "n" makes the suffix extend further and look different.

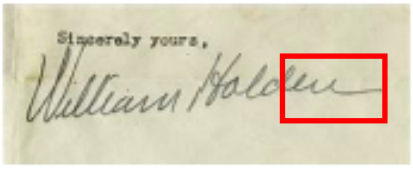
While a difference of two letters may provide visual differences in some cases, this can be influenced by the two letters in question. Additionally, the relative size of a name assumes there is an existing comparator name that an interpreter of a prescription has in mind. A person's ability to identify whether a name is longer or shorter may depend on whether there is another name immediately next to it against which it is compared. If a pharmacist is interpreting a proprietary name written on a prescription, it is unlikely that both Delestrogen and Delstrigo would be included on the same script to allow for this visual difference to be easily identified.

We note that one inpatient handwritten prescription result from (b) (4) name simulation studies, interpreted Delstrigo as Delsitrigo, which places the upstroke letter "t" and downstroke letter "g" in identical positions when compared to Delestrogen. Thus, based on the evidence provided by the Applicant, the additional letter "e" in Delestrogen may not always provide a sufficient difference. In this example, a person interpreting the prescription would not necessarily identify that the placement of the upstroke letter "t" and downstroke letter "g" is further out in the name.

The Applicant states the letter "o" in the infix of Delestrogen looks rounder than the letter "i" in the infix of Delstrigo, providing additional mitigation to prevent name confusion. We don't disagree that, in isolation, the letter "o" in the infix of Delestrogen (-estro-) can look rounder when scripted when compared to an "i"; however, this may not always be the case. For example, we note that handwritten sample #7 from (b) (4) name simulation studies, shown below, depicts a rounded letter "i" for Delstrigo. In light of the other similarities in the name pair, we are not convinced that this difference will always be identified.

Handwritten sample #7	

Furthermore, we previously stated the suffixes of this name pair, -go and -gen, can look similar if the letters "o" and "n" are written with a trailing tail. The Applicant provided an example of two writing samples in the form of autographs, one by Mario Cuomo and the other by William Holden to dispute our claim. We note in the examples provided, the "rio" in Mario looks similar to the "en" in Holden. Thus, the endings of this name pair can look similar when scripted, even when in one case the tail would be expected to occur at the top of the letter ("o" in Delstrigo) as opposed to the bottom of the letter ("n" in Delestrogen).

Mario Cuomo (politician):	William Holden (actor):
	 [Exhibit 3]

DIFFERENCES IN PRODUCT CHARACTERISTICS

We evaluated the product characteristic differences between the proposed product and Delestrogen, included in the Applicant's submission (see Appendix A), and the rationale provided for how those differences can prevent a medication error. Delstrigo will be available as a single strength, multi-ingredient tablet intended for oral administration once daily. Delestrogen is available as multi-dose vials, in multiple strengths, intended for intramuscular injection once every one to four weeks. Although there is some numeric overlap between the strengths of Delstrigo (100 mg/300 mg/300 mg) and Delestrogen (100 mg/5mL), there is no numeric overlap in dosage between the two products. A prescription for Delstrigo is likely to include dosage as "1

tablet" as opposed to Delestrogen, which is likely to indicate the dosage as "10-, 20-, or 30 mg." The lack of dose overlap and differences in routes of administration between Delstrigo and Delestrogen may minimize the risk of name confusion between these two products.

The Applicant further proposes in their submission that a patient who is instructed on self-administration for Delestrogen injection, but then receives Delstrigo tablets at the pharmacy would realize that she or he has not received the correct product. Moreover, the Applicant proposes that a patient who has not received instruction on the proper technique for intramuscular injection of Delestrogen, but receives a drug requiring the use of a syringe and needle would question whether a mistake has been made. We agree that in some instances, a patient may recognize that an error has occurred. However, post-marketing experience shows us that differences in product characteristics may not always prevent wrong drug errors from occurring even when numerous differences exist that might be expected to prevent the risk for confusion. Additionally, relying on the patient to catch an error that has occurred does not negate the fact that a medication error already occurred.

DIFFERENCE IN INDICATION AND PRESCRIBERS

The Applicant proposes that a prescriber who specializes in treating hormone deficiencies is unlikely to mistake Delstrigo for Delestrogen because Delestrogen contains the medical meaningful word, estrogen, and Delstrigo establishes no such connection to any particular medical concept. Given the connection between "estrogen" and hormone therapy, the Applicant indicates that an infectious disease doctor or other healthcare provider is unlikely to mistake a drug with "estrogen" in its name for an HIV treatment. We agree with the Applicant; thus, we find it unlikely that a prescriber intending to write for an HIV treatment would mistakenly order Delestrogen instead. However, we considered whether a person interpreting the prescription may always recognize that "estrogen" is embedded in the name (see our discussion above regarding orthographic similarity in the name pair). In the event that the person interpreting a prescription (e.g. pharmacy technician) does not see or read the word "estrogen" within the name, then a dispensing error may still occur.

DIFFERENCES IN PACKAGING

The Applicant proposes the packaging and product appearance of Delstrigo will differ significantly from Delestrogen thus minimizing the potential for medication errors. Delstrigo will be supplied in HDPE bottles of 30 tablets, which differs from the 5 mL vials of Delestrogen solution that is currently marketed. Furthermore, the Applicant proposes that no secondary packaging (outer box) will be used for Delstrigo which will further distinguish it from Delestrogen, which is supplied as a vial in a box (see Appendix B). The difference in packaging and product appearance may mitigate potential product selection errors; however, the product packaging and appearance is unlikely to impact the likelihood of misinterpretation that may occur during the transcription phase of the medication use system (e.g. when a technician is entering a prescription into the computer system).

SETTING OF USE

The Applicant proposes that Delstrigo will be used primarily in outpatient settings along with some use in inpatient/hospital settings. Retail pharmacies will be the primary dispensers of Delstrigo, with some dispensing by specialty pharmacies. Delestrogen is administered by a healthcare provider in a healthcare facility, but can also be self-administered in a patient's home according to the Delestrogen Prescribing Information[c]. Thus, this information suggests that both products, Delstrigo and Delestrogen, will share the same settings of use; thus, we do not find the Applicant's rationale compelling.

LOW USE OF DELESTROGEN

The Applicant supplied data demonstrating that Delestrogen is rarely prescribed in the U.S. and noted that only about (b) (4) units of Delestrogen were sold in 2017. Results from our search of drug use data suggests about (b) (4)% of Delestrogen was sold to retail channels of distribution, (b) (4)% was sold to non-retail channels of distribution, and (b) (4)% to mail-order in 2017.[d] There has been a gradual decrease in the number of Delestrogen prescriptions dispensed from U.S. outpatient retail pharmacies, from about (b) (4) prescriptions in 2013 to about (b) (4) prescriptions dispensed in 2017. In 2017 about (b) (4)% of the total estradiol valerate injection prescriptions dispensed from U.S. outpatient retail pharmacies were for Delestrogen.[e] Our evaluation of this data supports that retail pharmacies will serve as the primary dispensers for both Delstrigo and Delestrogen. The lower frequency of use for Delestrogen may reduce some of the risk for name confusion errors; however, wrong drug errors may still occur.

THRESHOLD BETWEEN MODERATELY SIMILAR AND HIGHLY SIMILAR NAME PAIR

The Applicant notes FDA's use of POCA version 4.2 and raised concerns that the revision that occurred with POCA version 4.2 places more emphasis on similarity that occurs at the beginning of a name pair. With a combined POCA score of 70%, the Applicant proposes that Delstrigo falls on the threshold between moderately similar and highly similar when compared with Delestrogen. The Applicant states that the high POCA score appears to be due solely to an increased sensitivity of the algorithm to the beginning of the name. Furthermore, the Applicant states that Delstrigo would have received a lower combined POCA score of 64% prior to implementation of FDA's revised POCA algorithm.

With a combined POCA score of 70%, FDA would characterize Delstrigo and Delestrogen as highly similar. We note that POCA scores are useful for characterizing similarity between name pairs; however, POCA scores do not serve as the single determining factor for acceptability of a proposed proprietary name. As stated in FDA's draft guidance *Best Practices in Developing Proprietary Names for Drugs*, the final determination on the acceptability of a proposed

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[c] Delestrogen [prescribing information]. Chestnut Ridge, NY: Par Pharmaceutical, Inc. August 2017. [cited 2018 MAY 25]. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e8f94df9-0692-4462-a7f0-fe019a0a3f07

[d] IQVIA SMART SOLUTIONS, Year 2017. Extracted May 28, 2018

[e] IQVIA National Prescription Audit. Years 2013-2017. Extracted May 17, 2018

proprietary name is based on FDA's review of all information and analyses described in the guidance.

We carefully considered each of the Applicant's points and supporting documentation, and we have determined that none of the mitigations presented by the Applicant are sufficient to prevent name confusion between Delstrigo and Delestrogen when considered independently. However, when all the mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.

4 CONCLUSION

We conclude that the proposed proprietary name, Delstrigo, is conditionally acceptable.

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

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the information submitted in support of your Request for Reconsideration of the proposed proprietary name, Delstrigo. We conclude that your proposed proprietary name, Delstrigo, is acceptable.

If any of the proposed product characteristics as stated in your March 27, 2018 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

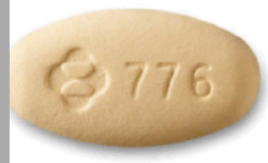
APPENDIX A. Comparison of product characteristics between Delstrigo and Delestrogen

Product Characteristic	Delstrigo	Delestrogen
Nonproprietary name	Doravirine, Lamivudine, and Tenofovir Disoproxil Fumarate Tablets	Estradiol valerate injection, USP
Indication	Treatment of HIV-1 infection in treatment naive patients	(1) Treatment of moderate to severe vasomotor symptoms associated with the menopause; (2) Treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with the menopause; (3) Treatment of hypoestrogenism due to hypogonadism, castration or primary ovarian failure; (4) Treatment of advanced androgen-dependent carcinoma of the prostate (for palliation only).
Dosage Form	Tablets	Injection
Dosage Strength	100 mg/300 mg/300 mg	50 mg/5 mL (10 mg/mL) 100 mg/5 mL (20 mg/mL) 200 mg/5 mL (40 mg/mL)
Frequency of Administration	Once Daily	Varies per Indication of Use – either every four weeks or every one to two weeks
Route	Oral	Intramuscular Injection
Usual Dose	One tablet daily	Varies per Indication: (1&2) 10 mg to 20 mg every four weeks (3) 10 mg to 20 mg every four weeks (4) 30 mg or more administered every one or two weeks
Class Type (Rx/OTC)	Rx	Rx
Strength Type	Single	Multiple

APPENDIX B. Comparison of product packaging and dosage form between Delstrigo and Delestrogen*

Delstrigo Packaging and Product Images: 30-Count Bottle (No Outer Carton) and Oval, Yellow Tablet Debossed with Merck's Logo and the Product Code

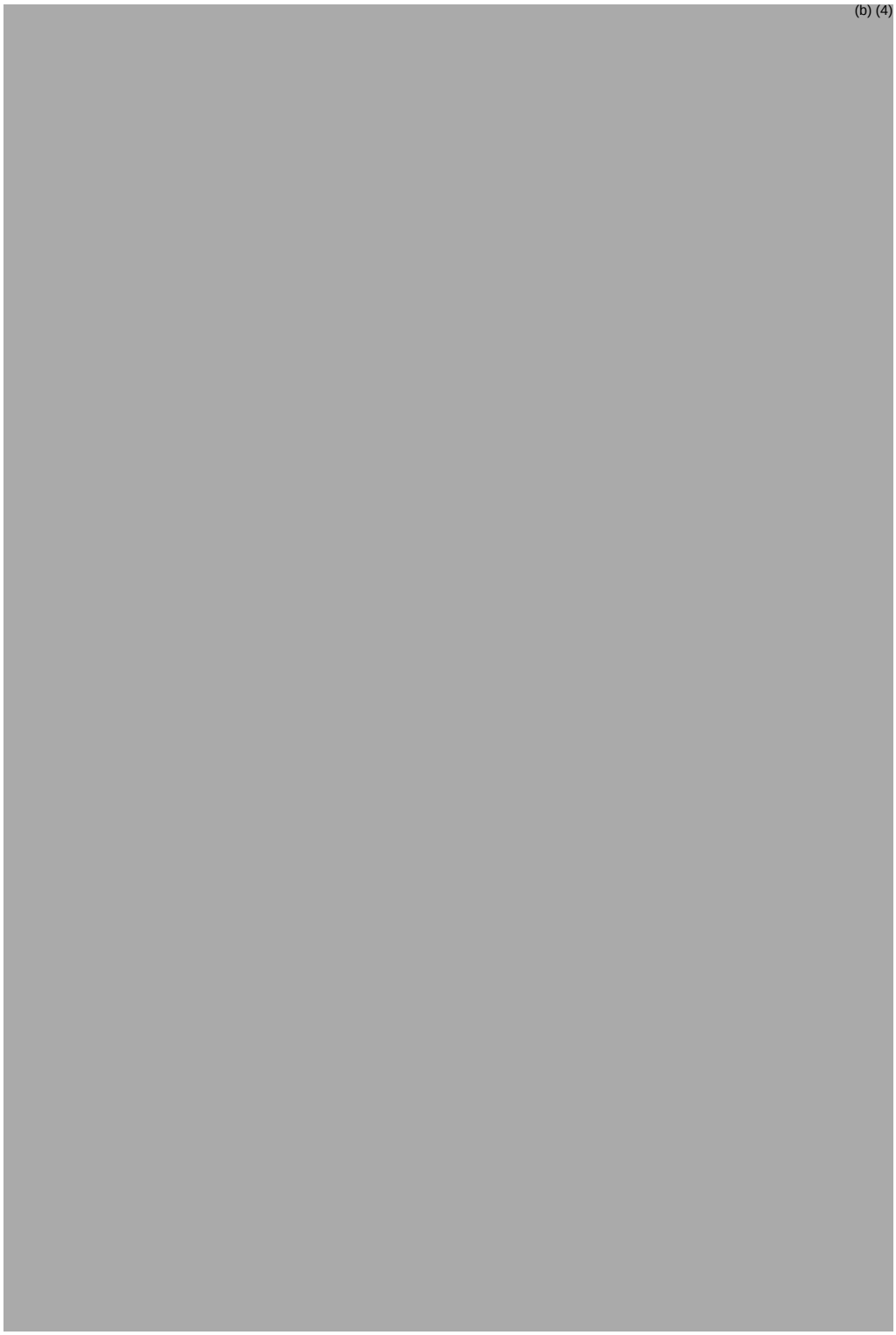
(b) (4)



Delestrogen Packaging and Product Images: Vial in Outer Carton, to be dispensed with Alcohol Swabs (not shown), Syringes and Needles

(b) (4)

***We note the image of Delestrogen provided by Merck (above) did not include the current in-use carton labeling for Delestrogen, thus we include images of the current-in use carton labeling below, which was used for additional evaluation of Delstrigo and Delestrogen product characteristics.**


(b) (4)


(b) (4)

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

/s/

VALERIE S WILSON
06/22/2018

OTTO L TOWNSEND
06/22/2018

IRENE Z CHAN
06/25/2018

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:	May 15, 2018
Application Type and Number:	NDA 210806
Product Name and Strength:	Pifeltro (doravirine) Tablets, 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck Sharp & Dohme Corp.
Panorama #:	2018-21573551
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Pifeltro, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) *** on November 16, 2017. However, we found the name, (b) (4) *** (b) (4)

Thus, the Applicant submitted the name, Pifeltro, for review on March 13, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 13, 2018.

- Intended Pronunciation: pih-FEL-tro
- Active Ingredient: doravirine
- Indication of Use: In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 100 mg
- Dose and Frequency: 1 tablet once daily
- How Supplied: Bottles of 30 tablets
- Storage: Store TRADEMARK at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis

(b) (4)

(DMEPA) and the Division of Antiviral Products (DAVP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Pifeltro, is a coined term with no intrinsic meaning. 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, March 29, 2018 e-mail, the Division of Antiviral Products (DAVP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 76 names 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.

2.2.6 Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. 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%	1

[b] USAN stem search conducted on March 19, 2018.

[c] POCA search conducted on March 19, 2018 in version 4.2.

Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	68
Low similarity name pair: combined match percentage score ≤54%	7

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

Our analysis of the 76 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antiviral Products (DAVP) via e-mail on May 10, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAVP on May 15, 2018, they stated no additional concerns with the proposed proprietary name, Pifeltro.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any 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 name, Pifeltro, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on March 13, 2018, 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 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., 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.

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

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
Step 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 **with** overlapping or similar strengths or doses.

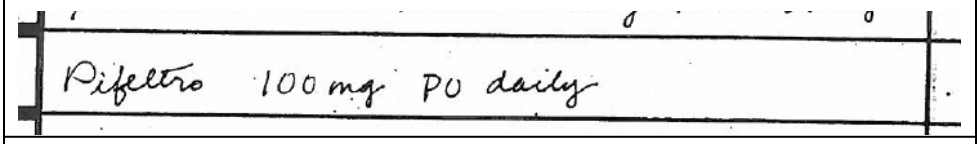
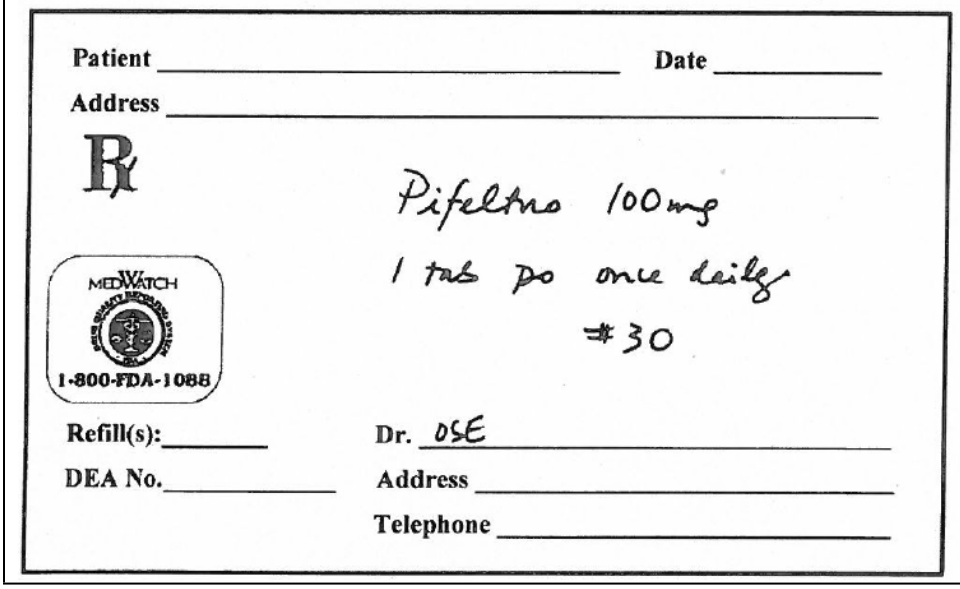
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Figure 1. Pifeltro Study (Conducted on March 30, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Pifeltro 100 mg Take 1 tablet by mouth once daily Dispense #30

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

302 People Received Study
52 People Responded

Study Name: Pifeltro

Total	14	18	20	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DEFELTRO	0	2	0	2
DESELTRO	0	3	0	3
DIFELTRO	0	2	0	2
DIFFELTRO	0	1	0	1
DISELTRO	0	2	0	2
DISELTROW	0	1	0	1
DISXYLTRO	0	1	0	1
DYSELTRO	0	1	0	1
PIFELRTRO	0	0	0	1
PIFELTHRO	1	0	0	1
PIFELTNO	5	0	0	5
PIFELTRO	7	0	20	27
PIFLTRO	1	0	0	1
PISCELTRO	0	1	0	1
TERCELTRO	0	1	0	1
TESELTRO	0	2	0	2
TIFELTRO	0	1	0	1

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

No.	**Proposed name: Pifeltro** **Established name: doravirine** **Dosage form: Tablet** **Strength(s): 100 mg** **Usual Dose: 1 tablet by mouth once daily**	**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.	Pifeltro	100	Subject of review.

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	POCA Score (%)
2.	Goprelto	62
3.	Trilitron	60
4.	Pegintron	58
5.	Pine Tar	58

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: Pifeltro** **Established name: doravirine** **Dosage form: Tablet** **Strength(s): 100 mg** **Usual Dose: 1 tablet by mouth once 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**
6.	Pedi-Pro	64	This name pair has sufficient orthographic and phonetic differences.
7.	Teflaro	64	This name pair has sufficient orthographic and phonetic differences
8.	Paxil CR	63	This name pair has sufficient orthographic and phonetic differences.
9.	Sivextro	62	This name pair has sufficient orthographic and phonetic differences.
10.	Testro	62	This name pair has sufficient orthographic and phonetic differences.
11.	Perflutren	61	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Pifeltro Established name: doravirine Dosage form: Tablet Strength(s): 100 mg Usual Dose: 1 tablet by mouth once 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
12.	(b) (4) ***	61	(b) (4)
13.	Epiflur	60	This name pair has sufficient orthographic and phonetic differences.
14.	Fematrol	60	This name pair has sufficient orthographic and phonetic differences.
15.	Steglatro	60	This name pair has sufficient orthographic and phonetic differences.
16.	Vivitrol	59	This name pair has sufficient orthographic and phonetic differences.
17.	Phenetron	58	This name pair has sufficient orthographic and phonetic differences.
18.	Caltro	58	This name pair has sufficient orthographic and phonetic differences.
19.	Kovaltry	58	This name pair has sufficient orthographic and phonetic differences.
20.	Procentra	57	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Pifeltro Established name: doravirine Dosage form: Tablet Strength(s): 100 mg Usual Dose: 1 tablet by mouth once 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
21.	Difil G Forte	56	This name pair has sufficient orthographic and phonetic differences.
22.	Paser D/R	56	This name pair has sufficient orthographic and phonetic differences.
23.	Polycitra	56	This name pair has sufficient orthographic and phonetic differences.
24.	Polytrim	56	This name pair has sufficient orthographic and phonetic differences.
25.	Prefest	56	This name pair has sufficient orthographic and phonetic differences.
26.	Pri-Dextra	56	This name pair has sufficient orthographic and phonetic differences.
27.	Testro-L.A.	56	This name pair has sufficient orthographic and phonetic differences.
28.	Cebatrol	55	This name pair has sufficient orthographic and phonetic differences.
29.	Defitelio	55	This name pair has sufficient orthographic differences. The 2nd and 3rd syllables of this name pair sound different. Difitelio contains an additional syllable.

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

No.	Name	POCA Score (%)
30.	Herpetrol	54
31.	Oleptro	54
32.	Polifeprosan 20	53
33.	Lipitor	53
34.	Piketoprofen	52
35.	Epitol	52
36.	Perlite	50

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
37.	Pacitron	66	International product formerly marketed in United Kingdom.
38.	Capitrol	64	Discontinued product with no generic equivalents. Withdrawn Pending FR Notice 7/20/2007 (NDA 17594).
39.	Femintrol	60	Name discontinued per Redbook with no generic equivalents available.
40.	Fosfestrol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
41.	Teferrol	60	Name identified in RxNorm database, but unable to find product characteristics in commonly used drug databases.
42.	Ferriseltz	58	International product formerly marketed in Italy, Netherlands, Greece, Japan, and Spain.
43.	tropisetron	57	International product marketed in Europe, Australia, New Zealand, Japan, South Korea, Philippines, and Asia.
44.	Petrola	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Pre Folic	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	Pse-Gg Tr	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Stilphostrol	55	Discontinued product with no generic equivalents. Withdrawn Pending FR Notice 9/13/2000 (NDA 10010).
48.	Fenoterol	55	International product marketed or formerly marketed in Germany, Japan, Canada, Australia, Belgium, Chile, Denmark, Finland, France, Greece, Hong Kong, Hungary, Ireland, Netherlands, Norway, New Zealand, Philippines, Mexico, Spain, Sweden, Thailand, United Kingdom, Venezuela, Portugal, Austria, Brazil, Czech Republic, Indonesia, Malaysia, Poland, South Africa, Singapore, Switzerland, and Ukraine.

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

No.	Name	POCA Score (%)
49.	Bitolterol	64
50.	Optil SR	64
51.	(b) (4)***	61
52.	Teril CR	60
53.	Zipeprol	60
54.	Foltrin	60
55.	Fer-In-Sol TR	60
56.	Trital SR	59
57.	Xelpros***	58
58.	(b) (4)***	58
59.	Veletri	58
60.	Foltrate	58
61.	Topilar	58
62.	(b) (4)***	56
63.	Theophyl-SR	56
64.	Metylperon	56
65.	(b) (4)***	56
66.	(b) (4)***	56
67.	Velphoro	56
68.	Tafluprost	56
69.	Fleet EZ-Prep	56
70.	Febuprol	56
71.	S-T Febrol	56
72.	(b) (4)***	56
73.	Eprizero	56
74.	Bicitra	55
75.	Lipidro	55
76.	Vital E- Repro	55

[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/

VALERIE S WILSON
05/15/2018

OTTO L TOWNSEND
05/15/2018

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*****

****This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.****

Date of This Review:	February 06, 2018
Application Type and Number:	NDA 210807
Product Name and Strength:	Delstrigo (doravirine, lamivudine, and tenofovir disoproxil fumarate) Tablets, 100 mg/300 mg/300 mg
Product Type:	Multi-ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck Sharp and Dohme Corp
Panorama #:	2017-19081976
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD
DMEPA Deputy Division Director:	Irene Z. Chan, PharmD, BCPS
DMEPA Division Director:	Todd Bridges, RPh

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Delstrigo, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the November 16, 2017 proprietary name submission.

- Intended Pronunciation: del-STREE-go
- Active Ingredient: doravirine, lamivudine, and tenofovir disoproxil fumarate
- Indication of Use: A complete regimen for the treatment of HIV-1 infection in (b) (4) patients
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 100 mg/300 mg/300 mg
- Dose and Frequency: 1 tablet by mouth once daily
- How Supplied: Bottles of 30 tablets
- Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Antiviral Products (DAVP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[a] USAN stem search conducted on November 28, 2017.

2.2.2 Components of the Proposed Proprietary Name

The Applicant stated in their submission that the proposed name, Delstrigo, is a coined term with no intrinsic meaning. 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 7, 2017 e-mail, the Division of Antiviral Products (DAVP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-four practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. However, one participant from the verbal prescription study commented that Delstrigo looks like and sounds like Delsym. We determined there is low similarity for confusion between this name pair as outlined in Appendix F. 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 122 names 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.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and FDA Prescription Simulation 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%	118
Low similarity name pair: combined match percentage score ≤54%	3

[b] POCA search conducted on November 28, 2017 in version 4.2.

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

We determined 122 of the 123 names will not pose a risk for confusion as described in Appendices C through H. However, the proposed name could be confused with Delestrogen. The rationale for the risk of confusion is described in Section 3.1

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antiviral Products (DAVP) via e-mail on January 31, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAVP on February 2, 2018, they stated no additional concerns with the proposed proprietary name, Delstrigo.

3 CONCLUSIONS

The proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with Delestrogen. Therefore, the decision to deny the name will be communicated to the Applicant via letter (See Section 3.1).

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 name, Delstrigo, and have concluded that this name is unacceptable for the following reasons:

The proposed proprietary name, Delstrigo, may be confused with the marketed product, Delestrogen, due to orthographic similarities and overlapping product characteristics. Delestrogen is indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause, moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause, treatment of hypoestrogenism due to hypogonadism, castration, or primary ovarian failure, and treatment of advanced androgen-dependent carcinoma of the prostate.

The orthographic similarities between Delstrigo and Delestrogen stem from both names beginning with the same first three letters, D-e-l. The infixes of this name pair share similar letter strings (-strig- vs -strog-) and can look similar when scripted. Additionally, the suffixes of this name pair (-go vs -gen) can look similar when scripted if the letters "o" and "en" are written with a trailing tail.

The similarities between this name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) which calculates a combined orthographic and phonetic score of 70% and an individual orthographic score of 80%, indicating high similarity between this name pair.[c]

We acknowledge that the additional letter "e" in the infix of Delestrogen offers some orthographic difference; however, this difference may be overlooked due to the overwhelming similarity of the rest of the name pair.

[c] POCA search conducted on November 28, 2017 in version 4.2.

In addition to orthographic similarities, Delstrigo and Delestrogen have numerical overlap between the 100 mg/300 mg/300 mg strength of Delstrigo and the 100 mg/5 mL strength of Delestrogen.

We acknowledge the difference in dosage form (tablet vs injection), dose (1 tablet or 100 mg/300 mg/300 mg vs 10 mg to 40 mg), and route of administration (oral vs intramuscular); however, because these products are only available in a single dosage form for a single route of administration, the dosage form and route of administration may be omitted from a prescription and would not serve as a differentiating factor in that case. Additionally, postmarketing reports have shown that when names are similar, differences in dosage form, dose, and route of administration may not prevent wrong drug errors from occurring. For example, name confusion has been reported between [(b) (4)] and Voluven despite their difference in dosage form ([(b) (4)] vs injection), dose ([(b) (4)] vs 50mL/kg (adults) 16 mL/kg or 36 mL/kg (pediatrics)), and routes of administration [(b) (4)] vs intravenous).[d] Additionally, name confusion has been reported between Inspra and Spiriva, despite differences in their dosage form (tablet vs capsule for inhalation), dose (25 mg or 50 mg or 1 tablet vs 18 mg or 2 inhalations or 1 capsule), and routes of administration (oral vs inhalation).[e]

Based on the totality of the information considered above, we find the proposed proprietary name, Delstrigo, vulnerable to medication errors due to name confusion with the currently marketed product, Delestrogen.

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

[d] Institute for Safe Medication Practices. Safety briefs: Look-alike name pair—VoLumen and Voluven. ISMP Med Saf Alert Acute Care. 2017; 22(25):2-3.

[e] Institute for Safe Medication Practices. Safety briefs: Confusion over newly marketed medications. ISMP Med Saf Alert Community/Ambulatory Care. 2005;4(8):1-2.

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. [f]

[f] 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[g]. 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.,

[g] 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

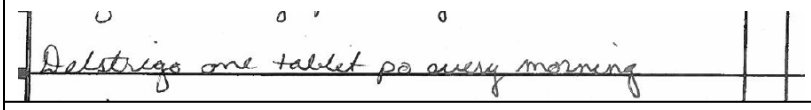
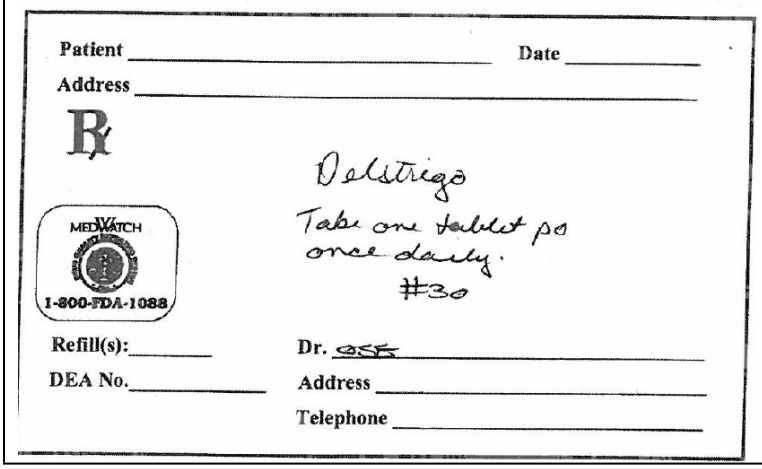
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic 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 ≤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

Figure 1. Delstrigo Study (Conducted on December 8, 2017)

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

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

294 People Received Study
94 People Responded

Study Name: Delstrigo

Total	29	26	39	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DELSTIGO	1	0	0	1
DELSTREEGO	0	1	0	1
DELSTREGO	0	6	0	6
DELSTRIEGO	0	1	0	1

DELSTRIGO	27	18	38	83
DELSTRIGS	0	0	1	1
DESTRIGO	1	0	0	1

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

No.	Proposed name: Delstrigo Established name: doravirine, lamivudine, tenofovir disoproxil fumarate Dosage form: Tablet Strength(s): 100 mg/300 mg/300 mg Usual Dose: 1 tablet by mouth once daily	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.	(b) (4) ***	76	(b) (4)

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	POCA Score (%)
2.	Menstridol	68
3.	(b) (4) ***	64
4.	Estring	63
5.	(b) (4) ***	63
6.	delta tritex	61
7.	Dextrose 25%	60
8.	Dextrose 50%	60
9.	Dextrose 60%	60
10.	delatestryl	59
11.	Depo-Estradiol	58
12.	Relistor	58

No.	Name	POCA Score (%)
13.	Calcitriol	58
14.	delzicol	58
15.	Trelstar	58
16.	Trelstar Depot	58
17.	Restoril	57
18.	Trelstar La	57
19.	Defitelio	57
20.	Dill Seed Oil	57
21.	Gadoteridol	56
22.	Sulfatrim	56
23.	Boostrix	56
24.	Zostrix	56
25.	Nostrilla	56
26.	Biltricide	56
27.	Gilotrif	56
28.	Telotristat	56
29.	Veletri	56
30.	Megestrol	56
31.	Stilbestrol	56
32.	Dalfopristin	56
33.	Dilatrate	56
34.	(b) (4) ***	55
35.	Dextran	55
36.	Dextran 1	55
37.	Dextran 110	55
38.	Dextran 40	55
39.	Dextran 70	55
40.	Dextran 75	55
41.	Distigmine	55
42.	Detrol	54

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: Delstrigo Established name: doravirine, lamivudine, and tenofovir disoproxil fumarate Dosage form: Tablet Strength(s): 100 mg/300 mg/300 mg Usual Dose: 1 tablet by mouth once 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**
43.	Elestrin	68	This name pair has sufficient orthographic and phonetic differences.
44.	(b) (4) ***	66	This name pair has sufficient orthographic differences. (b) (4)
45.	Dolasetron	65	This name pair has sufficient orthographic and phonetic differences.
46.	Estradiol	64	This name pair has sufficient orthographic and phonetic differences.
47.	Norlestrin 21 1/50	63	This name pair has sufficient orthographic and phonetic differences.
48.	Norlestrin 21 2.5/50	63	This name pair has sufficient orthographic and phonetic differences.
49.	Norlestrin 28 1/50	63	This name pair has sufficient orthographic and phonetic differences.
50.	Testred	63	This name pair has sufficient orthographic and phonetic differences.
51.	Testro-L.A.	61	This name pair has sufficient orthographic and phonetic differences.
52.	Zestril	61	This name pair has sufficient orthographic and phonetic differences.
53.	Estrogel	60	This name pair has sufficient orthographic and phonetic differences.
54.	Loestrin	60	This name pair has sufficient orthographic and phonetic differences.
55.	Loestrin 21 1.5/30	60	This name pair has sufficient orthographic and phonetic differences.
56.	Loestrin 21 1/20	60	This name pair has sufficient orthographic and phonetic differences.
57.	Testro Aq	60	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Delstrigo Established name: doravirine, lamivudine, and tenofovir disoproxil fumarate Dosage form: Tablet Strength(s): 100 mg/300 mg/300 mg Usual Dose: 1 tablet by mouth once 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
58.	Dalteparin	59	This name pair has sufficient orthographic and phonetic differences.
59.	Ogestrel	58	This name pair has sufficient orthographic and phonetic differences.
60.	Ogestrel 0.5/50-21	58	This name pair has sufficient orthographic and phonetic differences.
61.	Ogestrel 0.5/50-28	58	This name pair has sufficient orthographic and phonetic differences.
62.	Decalcitrol	58	This name pair has sufficient orthographic and phonetic differences.
63.	Deltalin	57	This name pair has sufficient orthographic and phonetic differences.
64.	deltasone	56	This name pair has sufficient orthographic and phonetic differences.
65.	Loestrin 24 Fe	56	This name pair has sufficient orthographic and phonetic differences.
66.	Loestrin Fe	56	This name pair has sufficient orthographic and phonetic differences.
67.	Loestrin Fe 1.5/30	56	This name pair has sufficient orthographic and phonetic differences.
68.	Loestrin Fe 1/20	56	This name pair has sufficient orthographic and phonetic differences.
69.	Lo Loestrin Fe	55	This name pair has sufficient orthographic and phonetic differences.
70.	Dilt-Xr	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
71.	Delsym	51

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
72.	Testradiol	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Gestrin	65	International product marketed in Taiwan.
74.	(b) (4) ***	64	Name entered by Safety Evaluator but unable to find any information
75.	Dermestril 100	63	International product marketed in Israel, Austria, Australia, Hong Kong, Finland, Ireland, Spain, Switzerland, United Kingdom, Belgium, Portugal, Germany, Czech Republic, Hungary, Greece, China, France, Italy
76.	Dermestril 25	63	International product marketed in Israel, Austria, Australia, Hong Kong, Finland, Ireland, Spain, Switzerland, United Kingdom, Belgium, Portugal, Germany, Czech Republic, Hungary, Greece, China, France, Italy
77.	Dermestril 50	63	International product marketed in Israel, Austria, Australia, Hong Kong, Finland, Ireland, Spain, Switzerland, United Kingdom, Belgium, Portugal, Germany, Czech Republic, Hungary, Greece, China, France, Italy
78.	Destolit	63	International product marketed in France, Portugal, and United Kingdom.
79.	Estriol	62	Veterinary product
80.	Gestronol	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
81.	Mestranol	61	Product characteristics not found in external databases.
82.	Testro	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
83.	Gestrinone	60	International product marketed in United Kingdom, Ireland, Malaysia, New Zealand, Portugal, Thailand, Australia, Singapore, Czech Republic, Spain, Netherlands, Switzerland, Mexico, China, and South Africa
84.	Dura-Estrin	60	Product discontinued and no generic products available.
85.	Dienestrol	58	Product discontinued with no generics equivalents available, withdrawn FR Effective 6/4/2004.

No.	Name	POCA Score (%)	Failure preventions
86.	Dexatrim	58	Discontinued. Product contained phenylpropanolamine (PPA) which was withdrawn from the market due to safety concerns.
87.	Delhistine D	58	Discontinued. Product contained phenylpropanolamine (PPA) which was withdrawn from the market due to safety concerns.
88.	Dolgesic	57	Discontinued product per Redbook with no generic equivalents available.
89.	Hydeltrasol	57	Product discontinued with no generics available, withdrawn FR Effective 9/22/1999 for NDA 010639 and withdrawn FR Effective 6/10/99 for NDA 011583.
90.	Polyestradiol	57	Product discontinued with no generic equivalents available, withdrawn FR Effective 9/17/2003.
91.	delatestadiol	56	Product discontinued per Redbook with no generic equivalents available.
92.	Dextrates	56	A pharmaceutical binder used in various tablet dosage forms.
93.	Oestrogel	56	International product marketed or formerly marketed in Hungary, Belgium, Italy, France, Hong Kong, Israel, Malaysia, Singapore, Thailand, United Kingdom, Mexico, Brazil, Indonesia Switzerland
94.	Kestrone 5	56	Product discontinued with no generic equivalents, withdrawn FR effective 12/09/1983.
95.	Norlestrin Fe 1/50	56	Product discontinued with no generic equivalents available, withdrawn FR Effective 6/17/1986.
96.	Norlestrin Fe 2.5/50	56	Product discontinued with no generic equivalents available, withdrawn FR Effective 6/17/1986.
97.	Depestrate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
98.	Adult strength	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
99.	Duratestrin	56	Product discontinued per Redbook with no generic equivalents available.
100.	ethylestrenol	56	Formerly marketed under the brand name Maxibolin, product discontinued. Withdrawn FR Effective 11/3/2016 for NDA 014005 and 7/21/2017 for NDA 014006.
101.	desogestrel	55	Not marketed as a single agent but one ingredient of several multi-ingredient oral contraceptive tablets.

No.	Name	POCA Score (%)	Failure preventions
102.	Nilstim	55	International product formerly marketed in United Kingdom.
103.	Dietrim Es	55	Discontinued. Product contained phenylpropanolamine (PPA) which was withdrawn from the market due to safety concerns.
104.	Estrovis	55	Product withdrawn from the market due to safety concerns. FR effective 12/17/1998.
105.	tridesilon	46	Discontinued with no generics available. Withdrawn FR effective 6/25/1997.

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

No.	Name	POCA Score (%)
106.	Calteridol	60
107.	Teldrin	60
108.	Colestid	59
109.	Alosetron	57
110.	Zestoretic	57
111.	Bel-Phen-Ergot	56
112.	Esoterica	56
113.	Gesterone	56
114.	Polistirex	56
115.	Sultopride	56
116.	Zentrudo	56
117.	Altreno	55
118.	Colestipol	55
119.	Glister	55
120.	Polyester-5 (Tg-38)	55
121.	Tensopril	55
122.	Testolin	55

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

No.	Name

[h] 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

No.	Name
1.	N/A

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	January 31, 2018
Application Type and Number:	NDA 210806
Product Name and Strength:	(b) (4) (doravirine) Tablet, 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck Sharp & Dohme Corp
Panorama #:	2017-19081900
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD
DMEPA Deputy Division Director:	Irene Z. Chan, PharmD, BCPS
DMEPA Division Director:	Todd Bridges, RPh

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