CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205394Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	December 29, 2022
Application Type and Number:	NDA 205394
Product Name and Strength:	RizaFilm (rizatriptan) oral (b) (4) film, 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	IntelGenx Corp. (IntelGenx)
PNR ID #:	2022-1044724815
DMEPA 2 Safety Evaluator:	Beverly Weitzman, PharmD
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

IntelGenx previously submitted the proposed proprietary name, Rizaport*** on November 26, 2013, and amendment received on December 6, 2013, under NDA 205394. We found the proposed name Rizaport*** conditionally acceptable under NDA 205394 on January 22, 2014.[a] However, NDA 205394 received a complete response (CR) letter on January 31, 2014.

On September 29, 2018, IntelGenx submitted a Class 2 Resubmission to NDA 205394 to address the deficiencies identified in the CR letter.

Thus, IntelGenx resubmitted the name, Rizaport*** for review on November 6, 2018, as part of the Class 2 Resubmission for NDA 205394. However, we found the proposed proprietary name Rizaport*** unacceptable due to (b) (4) with another proposed proprietary name, (b) (4)** under NDA 205394 on December 10, 2018.[b]

Subsequently, IntelGenx submitted the proposed proprietary name, RizaFilm for review under NDA 205394 on March 13, 2018. However, the proprietary name review was terminated due to the NDA 205394 receiving a CR letter on March 28, 2019.

On September 26, 2019, IntelGenx submitted a Class 2 Resubmission to NDA 205394 to address the deficiencies identify in the CR letter.

Thus, IntelGenx resubmitted the name, RizaFilm for review on November 4, 2019. We found the proposed name, RizaFilm conditionally acceptable under NDA 205394 on January 27, 2020.[c] However, NDA 205394 received a CR letter on March 24, 2020.

As part of the Class 2 resubmission in response to the CR, IntelGenx resubmitted the name, RizaFilm, for review on October 17, 2022.

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[a] Sheppard, J. Proprietary Name Review for Rizaport*** (NDA 205394). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 JAN 22. Panorama No. 2013-16616.

[b] Rider, B. Proprietary Name Review for Rizaport*** (NDA 205394). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 DEC 10. Panorama No. 2018-27144489.

[c] Mena-Grillasca, C. Proprietary Name Review for Rizaport*** (NDA 205394). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 27. Panorama No. 2018-27144489.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 17, 2022.

- Intended Pronunciation: ri'-zah-film
- Active Ingredient: rizatriptan
- Indication of Use: Acute treatment of migraine with or without aura in adults and pediatric patients 12 to 17 years old.
- Route of Administration: oral
- Dosage Form: oral (b) (4) film
- Strength: 10 mg
- Dose and Frequency:
    - Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg
    - Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more
- How Supplied: Cartons of 6, 12, and 18 individually packaged in an aluminum laminate pouch.
- Storage: Store at room temperature, 59°F-77°F (15°C- 25°C)
- Reference Listed Drug/Reference Product: Maxalt-MLT (NDA 020865)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that RizaFilm would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for RizaFilm. The Division of Neurology 2 (DN 2) did not comment on the findings of OPDP's assessment for RizaFilm.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, RizaFilm.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

IntelGenx indicated in their submission that the proposed proprietary name, RizaFilm, is derived from rizatripan.

We note that the proposed name RizaFilm incorporates part of the proposed product's dosage form designation (i.e., 'film' for 'oral (b) (4) film'), which was evaluated in our previous review.[e] After considering the risk associated with this name strategy, we did not have any objections to the inclusion of the dosage form as part of the name and we maintain our previous decision.

2.2.3 Comments from Other Review Disciplines at Initial Review

The Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to RizaFilm at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-one practitioners participated in DMEPA's prescription studies for RizaFilm. The responses did not directly overlap with any currently marketed products or any products in the pipeline. However, one respondent in the voice study interpreted the proposed proprietary name as "Risivil", which demonstrates similarity to the approved product, Prinivil (lisinopril), and the over-the-counter product, Resinol (petrolatum and resorcinol). We evaluated the name pair, RizaFilm and Prinivil, further and find that there are sufficient orthographic and phonetic differences. We also evaluated the name pair, RizaFilm and Resinol, further and find that there are sufficient orthographic, phonetic, and product characteristic differences.

RizaFilm vs. Prinivil:

Orthographically, the name pair begins with different first letters (R vs. P) that look different. Additionally, RizaFilm (or Rizafilm if not written with the capital F) contains the uppercase letter "F" and/or cross-stroke lowercase letter 'f" or upstroke/downstroke lower case letter "f" in the 5th position (depending how scripted) which give the names different shapes when scripted. Furthermore, the last 3 letters string (ilm vs. vil) look sufficiently different.

Phonetically, all 3 syllables (Ri-zah-film vs. Pri-ni-vil) sound different when spoken.

RizaFilm vs. Resinol:

Orthographically, RizaFilm (or Rizafilm if not written with the capital F) contains the uppercase letter "F" and/or cross-stroke lowercase letter 'f" or upstroke/downstroke lower case letter "f" in the 5th position (depending how scripted) which give the names different

[d] USAN stem search conducted on December 13, 2022.

[e] Mena-Grillasca, C. Proprietary Name Review for Rizaport*** (NDA 205394). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 27. Panorama No. 2018-27144489.

shapes when scripted. Furthermore, the last 3 letters string (ilm vs. nol) look sufficiently different.

Phonetically, the third syllables (film vs. naal) sound different when spoken.

Additionally, the following product characteristics may provide additional differentiation if included: there is no direct overlap in strength (10 mg vs. 55%/2%), dosage form (b) (4) film tablet vs. ointment) or route of administration (oral vs. topical).

Furthermore, FDA's Phonetic and Orthographic Computer Analysis (POCA) program calculates a combined score of 46% for this name pair suggesting there is low similarity between the names.

When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion between both name pairs is mitigated to an acceptable level (See Appendices E and F).

Additionally, we note 7 respondents in the voice study misinterpreted the sound of the third letter "z" as a "s".

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified eighty-one names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified six names not previously analyzed. 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. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	8

[f] POCA search conducted on December 13, 2022 in version 5.1.

Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 8 names contained in Table 1 determined none of the names will pose a risk for confusion with RizaFilm as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On December 29, 2022, DMEPA 2 communicated our determination to the Division of Neurology 2 (DN 2).

3 CONCLUSION

The proposed proprietary name, RizaFilm, is conditionally acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240-402-0012.

3.1 COMMENTS TO INTELGENX CORP.

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

If any of the proposed product characteristics as stated in your submission, received on October 17, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

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. [g]

[g] National Coordinating Council for Medication Error Reporting and Prevention. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***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[h]. 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.

[h] 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.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

   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.

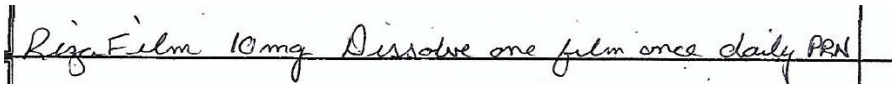
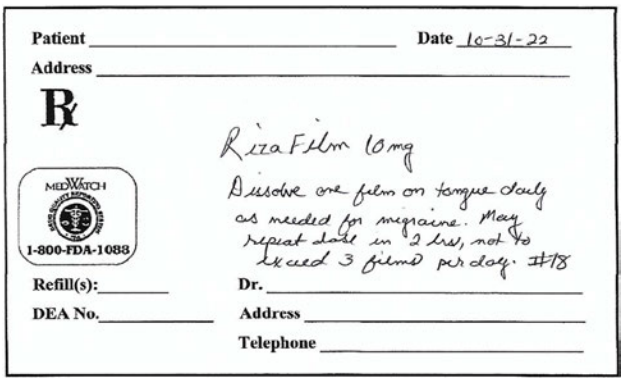
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. RizaFilm Study (Conducted on October 31, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  Patient _____ Date 10-31-22 Address _____ ℞ RizaFilm 10mg Dissolve one film on tongue daily as needed for migraine. May repeat dose in 2 hrs, not to exceed 3 films per day. #18 MEDWATCH 1-800-FDA-1088 Refill(s):_____ DEA No._____ Dr. _____ Address _____ Telephone _____	RizaFilm Dissolve 1 film on tongue daily as needed as needed for migraines. May repeat dose in 2 hours not to exceed 3 films per day. Dispense #18.
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
RizaFilm	

FDA Prescription Simulation Responses (Aggregate Report)

263 People Received Study
91 People Responded

Study Name: RizaFilm

Total	26	22	20	23	91
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
RESOFILM 10MG	0	0	1	0	1
RISAFILM	0	0	3	0	3
RISFILM	0	0	1	0	1
RISG FILM	1	0	0	0	1
RISIVIL	0	0	1	0	1
RISOFILM	0	0	1	0	1

RIZA FILM	12	0	1	5	18
RIZAFIBM	0	0	0	1	1
RIZAFILM	12	22	10	13	57
RIZAFILM 10MG	1	0	0	0	1
RIZOFILM	0	0	1	0	1
RIZZA FILM	0	0	0	1	1
RIZZAFILM	0	0	0	3	3
RYZAFILM	0	0	1	0	1

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

No.	**Proposed name:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral (b) (4) film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	**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.**
	N/A		

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 (%)
	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:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral (b) (4) film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Risdiplam	62	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
3.	Prinivil	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral (b) (4) film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	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**
			Orthographically, the name pair begins with different first letters (R vs. P) that look different. Additionally, RizaFilm (or Rizafilm if not written with the capital F) contains the uppercase letter "F" and/or cross-stroke lowercase letter 'f" or upstroke/downstroke lower case letter "f" in the 5th position (depending how scripted) which give the names different shapes when scripted. Furthermore, the last 3 letters string (ilm vs. vil) look sufficiently different. Phonetically, all 3 syllables (Ri-zah-film vs. Pri-ni-vil) sound different when spoken.
4.	Remimazolam	56	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 (%)
1.	Resinol	46

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

No.	Name	POCA Score (%)	Failure preventions
1.	Ribavarin	56	Name identified in Drugs at FDA database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Hemofil M	56
2.	Trilaciclib	55

[i] 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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

BEVERLY WEITZMAN
12/29/2022 05:26:42 PM

STEPHANIE L DEGRAW
12/29/2022 06:15:11 PM

DANIELLE M HARRIS
12/29/2022 07:51:30 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	January 27, 2020
Application Type and Number:	NDA 205394
Product Name and Strength:	RizaFilm (rizatriptan) oral film, 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	IntelGenx Corp. (IntelGenx)
Panorama #:	2019-35585742
DMEPA Safety Evaluator:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

IntelGenx previously submitted the proposed proprietary name, Rizaport*** on November 26, 2013, amended on December 6, 2013. The proposed name Rizaport*** was found conditionally acceptable under NDA 205394 on January 22, 2014[a]. However, NDA 205394 received a Complete Response letter on January 31, 2014. The application was resubmitted (resubmission/class 2) on September 29, 2018. The proposed proprietary name Rizaport*** was resubmitted on November 6, 2018 and found unacceptable due to (b) (4) (b) (4)***, under NDA 205394 on December 10, 2018[b]. RizaFilm was submitted on March 13, 2018; however, the proprietary name review was terminated due to the NDA 205394 receiving a Complete Response letter on March 28, 2019. The application was resubmitted (resubmission/class 2) on September 26, 2019.

Thus, IntelGenx submitted the name, RizaFilm, for review on November 4, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 4, 2019.

- Intended Pronunciation: ri'-zah-film
- Active Ingredient: rizatriptan
- Indication of Use: Acute treatment of migraine with or without aura in adults and pediatric patients 12 to 17 years old.
- Route of Administration: oral
- Dosage Form: oral film
- Strength: 10 mg
- Dose and Frequency:
    - Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg
    - Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more
- How Supplied: cartons of 6, 12, and 18 individually packaged films
- Storage: Room temperature, 59-86F (15-30°C).
- Reference Listed Drug/Reference Product: Maxalt-MLT NDA 020865

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[a] Sheppard, J. Proprietary Name Review for Rizaport*** (NDA 205394). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 Jan 22. Panorama No. 2013-16616.

[b] Rider, B. Proprietary Name Review for Rizaport*** (NDA 205394). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Dec 10. Panorama No. 2018-27144489.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that RizaFilm would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for RizaFilm.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, RizaFilm.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

IntelGenx indicated in their submission that the proposed proprietary name, RizaFilm, is derived from 'rizatriptan'. We note that the proposed name RizaFilm incorporates part of the dosage form designation (i.e. 'film' for 'oral film') in the name. Although we typically discourage the inclusion of the dosage form in proprietary names, we note that the use of the word 'film' could not lead to confusion in this case. Beyond this dosage form, we note that RizaFilm does not contain any additional components (i.e. a modifier, medical abbreviation, etc.) that could be misleading or contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, November 18, 2019 e-mail, the Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to RizaFilm at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-four (n=74) practitioners participated in DMEPA's prescription studies for RizaFilm. 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[d] identified 70 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. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

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[c] USAN stem search conducted on November 27, 2019.

[d] POCA search conducted on November 27, 2019 in version 4.3.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
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%	66
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 70 names contained in Table 1 determined none of the names will pose a risk for confusion with RizaFilm as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology 2 (DN 2) via e-mail on January 16, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology 2 (DN 2) on January 22, 2020, they stated no additional concerns with the proposed proprietary name, RizaFilm.

3 CONCLUSION

The proposed proprietary name, RizaFilm, is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO INTELGENX CORP.

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

If any of the proposed product characteristics as stated in your submission, received on November 4, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

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.[e]

***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%.

[e] National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

- 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 names7F[f]. 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.

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.

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

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 *t*), 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:

<table>
<tr><td></td><td colspan="2">

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

</td></tr>
<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?

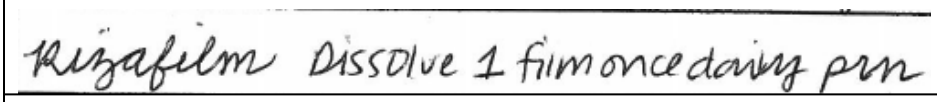
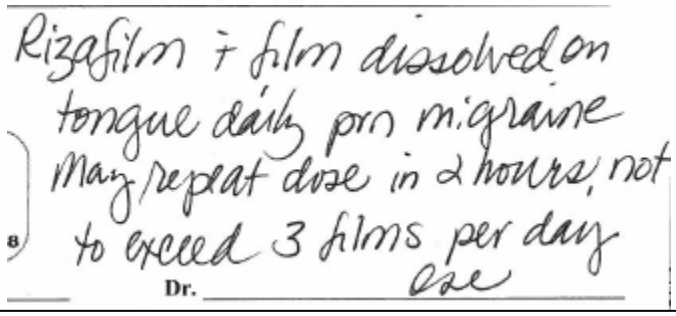
</td></tr>
</table>

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

Figure 1. RizaFilm Study (Conducted on November 7, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	RizaFilm Dissolve one film on tongue daily as need for migraine. May repeat dose in 2 hours, not exceed 3 films per day. Dispense #18

FDA Prescription Simulation Responses (Aggregate Report)

As of Date 11/29/2019

212 People Received Study

74 People Responded

Study Name: RizaFilm

Total	40	13	21	74
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
KIZAFILM	0	0	1	1
RESAFILM	0	1	0	1
RESOFILM	0	1	0	1
REZAFILM	0	1	0	1
RISAFILM	1	2	0	3
RIZAFIL	1	0	0	1
RIZAFILIM	1	0	0	1
RIZAFILLM	0	0	1	1
RIZAFILM	37	4	18	59
RIZIFILM	0	3	0	3
RIZIFIM	0	1	0	1
RIZZAFILM	0	0	1	1

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

No.	**Proposed name:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	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.	RizaFilm	100	Name subject of this review.
2.	Drizalma	70	This name pair has sufficient orthographic and phonetic differences. Orthographic: The first letters in the names are different ('R' vs. 'D'). Additionally, the letter 'f' in the infix of RizaFilm/Rizafilm (either with a capitalized letter 'F' or an upstroke lowercase letter 'f') gives the names different shapes when scripted. And, RizaFilm has a dotted letter 'i' in the suffix, whereas Drizalma does not contain any dotted letters in the suffix. Finally, the ending of the suffixes are different ('m' vs. 'a'). Phonetic: RizaFilm is stressed in the first syllable (Ri' zah film) vs. Drizalma is stressed in the second syllable (Dri zal' mah). 1st syllables (ri vs. dri) – Drizalma has an extra consonant sound 'd' at the beginning of the first syllable. 2nd syllables (za vs. zal) – Drizalma has an extra consonant sound 'l' at the end of the second syllable. 3rd syllables (film vs. ma) – The third syllables sound different. In addition to the above orthographic and phonetic differences, the following differences in product characteristics may help differentiate the products, if included: The strength would be needed on a prescription for Drizalma (20 mg, 30 mg, 40 mg, 50 mg) and the strengths don't overlap with that of RizaFilm (10 mg).

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 (%)
3.	Rifaximin	58
4.	Relafen Note: Discontinued nabumetone product with generic equivalents available.	56

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:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	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
5.	Gordofilm	64	This name pair has sufficient orthographic and phonetic differences.
6.	Triazolam	62	This name pair has sufficient orthographic and phonetic differences.
7.	Ridafed Note: Discontinued pseudoephedrine product with branded and generic equivalents available.	62	This name pair has sufficient orthographic and phonetic differences. Orthographic: Ridafed has an additional upstroke letter 'd' in the 3rd position that is not present in RizaFilm. Rizafilm may have a downstroke letter in the 3rd position, if the 'z' is scripted with a downstroke, which gives the names different shapes when scripted. Phonetic: The third syllables ('film' vs. 'fed') of this name pair sound different.
8.	Ryplazim*** Note: Proposed name for CBER BLA 125659, which received a CR letter on 4/9/2018.	62	This name pair has sufficient orthographic and phonetic differences. Orthographic: RizaFilm has a dotted letter 'i' in the 2nd position, whereas Ryplazim*** has a downstroke letter 'y' in the 2nd position. Additionally, RizaFilm has an upstroke letter 'l' in the suffix, whereas Ryplazim*** does not contain any upstroke letters in the suffix.

No.	**Proposed name:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	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**
			These differences give the names different shapes when scripted. Phonetic: The second syllables 'za' vs. 'pla' begin with different consonant sounds ('z' vs. 'pl'). The third syllables 'film' vs. 'zim' has different consonant sounds 'f' and 'l' vs 'z'.
9.	Rifampin	61	This name pair has sufficient orthographic and phonetic differences.
10.	Rezamid	60	This name pair has sufficient orthographic and phonetic differences. Orthographic: The suffixes ('film' vs. 'mid') of this name pair look different. Phonetic: The third syllables ('film' vs. 'mid') of this name pair have sufficient phonetic differences.
11.	Rifadin	60	This name pair has sufficient orthographic and phonetic differences. Orthographic: The upstroke letter 'f' appears in the suffix (5th position) of RizaFilm vs. in the infix (3rd position) of Rifadin. Additionally, the upstroke letter 'l' in the suffix of RizaFilm makes the suffixes ('film' vs 'din') look different when scripted.
12.	Tricalm	60	This name pair has sufficient orthographic and phonetic differences.
13.	Uricalm	60	This name pair has sufficient orthographic and phonetic differences.
14.	Rid-A-Pain	59	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	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
15.	Ruby-fill	59	This name pair has sufficient orthographic and phonetic differences.
16.	Derifil	58	This name pair has sufficient orthographic and phonetic differences.
17.	Krintafel	58	This name pair has sufficient orthographic and phonetic differences.
18.	Ramipril	58	This name pair has sufficient orthographic and phonetic differences.
19.	Ribavirin	58	This name pair has sufficient orthographic and phonetic differences.
20.	Seizalam	58	This name pair has sufficient orthographic and phonetic differences.
21.	Vizamyl	57	This name pair has sufficient orthographic and phonetic differences.
22.	Duofilm	56	This name pair has sufficient orthographic and phonetic differences.
23.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.
24.	Ridramin Note: Discontinued chlorpheniramine maleate product with branded and generic equivalents available.	56	This name pair has sufficient orthographic and phonetic differences.
25.	Rifamate	56	This name pair has sufficient orthographic and phonetic differences.
26.	Risamine	56	This name pair has sufficient orthographic and phonetic differences. Orthographic: The suffixes (‘film’ vs. ‘mine’) of this name pair look different when scripted. Phonetic: The third syllables (‘film’ vs. ‘mine’) of this name pair sound different.

No.	**Proposed name:** RizaFilm **Established name:** rizatriptan **Dosage form:** oral film **Strength(s):** 10 mg **Usual Dose:** Adults: 10 mg single dose; separate repeat doses by at least two hours; maximum dose in a 24-hour period: 30 mg. Pediatric patients 12 to 17 years: 10 mg single dose in patients 40 kg (88 lb) or more	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
			In addition to the above orthographic and phonetic differences, the following differences in product characteristics may help differentiate the products if included: • The dose of RizaFilm is 1 film (10 mg) on top of the tongue with separate repeat doses at least 2 hours for a maximum of 30 mg in 24-hour period, whereas the dose of Risamine is to apply a thin film over the affected area. Therefore, there is no overlap in dose.
27.	Ritalin	56	This name pair has sufficient orthographic and phonetic differences.
28.	Trizivir	56	This name pair has sufficient orthographic and phonetic differences.
29.	Lariam	50	This name pair has sufficient orthographic and phonetic differences.
30.	Ridifed Note: Discontinued pse/triprolidine hcl product with branded and generic equivalents available.	55	This name pair has sufficient orthographic and phonetic differences.

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

N/A

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
31.	Rimacillin	68	International ampicillin product marketed in the UK.
32.	Rimafen	64	International ibuprofen product marketed in the UK.
33.	Rizaport***	64	First proposed proprietary name for NDA 205394, subject of this review. Rizaport*** was found unacceptable by DMEPA on December 10, 2018 (Panorama # 2018-27144489).
34.	Rimapam	61	International diazepam product marketed in the UK.
35.	Respiram	60	Veterinary doxapram hcl product voluntarily withdrawn.
36.	Rimacid	60	Discontinued international indomethacin product previously marketed in the UK.

No.	Name	POCA Score (%)	Failure preventions
37.	Revanil	59	International lisuride maleate product marketed in the UK.
38.	Rimadyl	59	Discontinued caprofen product with no generic equivalents available. NDA 018550 withdrawn FR effective 04/26/1996. Veterinary product.
39.	Rivotril	58	International clonazepam product marketed in various countries outside the U.S.
40.	Respillin	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	Razoxin	56	International razoxane product marketed in the UK.
42.	Rideril	56	Discontinued international thioridazine product previously marketed in the UK.
43.	Rimoxallin	56	Discontinued international amoxicillin trihydrate product previously marketed in the UK and Ireland.
44.	Rosanil	56	Discontinued sulfacetamide sodium/sulfur product with no generic equivalents available.
45.	Relaxin	55	International suxamethonium chloride product marketed in Japan.
46.	Reviparin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	A-fil	49	Discontinued methyl anthranilate/titanium dioxide product with no generic equivalents available.

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

No.	Name	POCA Score (%)
48.	Brevidil M	64
49.	Triphasil-21	63
50.	a0lQ6x6QIsN2NZn 90DD9C95 Triphasil-28	63
51.	Arumacil	60
52.	Previfem	60
53.	Britiazim	58
54.	Triavil (2-10, 2-25, 4-10, 4-25, 4-50)	58
55.	Trilafon	58
56.	Tri-Nasal	58
57.	Piroflam	57
58.	Azficel-T	56

[g] 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	POCA Score (%)
59.	Brevital	56
60.	Brotizolam	56
61.	Difflam	56
62.	Dritail	56
63.	Laratrim	56
64.	Midazolam	56
65.	Prazepam	56
66.	Primabalt	56
67.	Prinivil	56
68.	Tri-Vi-Sol	56
69.	Verticalm	56
70.	Niva-Fol	55

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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:	December 10, 2018
Application Type and Number:	NDA 205394
Product Name and Strength:	Rizaport (rizatriptan benzoate) oral (b) (4) film, 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	IntelGex Corp. (IntelGex)
Panorama #:	2018-27144489
DMEPA Safety Evaluator:	Briana Rider, PharmD
DMEPA Team Leader:	Lolita White, PharmD
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

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BRIANA B RIDER
12/10/2018

LOLITA G WHITE
12/10/2018

DANIELLE M HARRIS
12/10/2018

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	January 22, 2014
Reviewer:	Jacqueline Sheppard, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	Julie Neshiewat, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Rizaport (Rizatriptan) Oral (b) (4) Film 5 mg and 10 mg
Application Type/Number:	NDA 205394
Applicant/Sponsor:	RedHill Biopharma
OSE RCM #:	2013-16616

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JACQUELINE E SHEPPARD
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01/23/2014