CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208844Orig1s000

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:	March 1, 2016
Application Type and Number:	NDA 208844
Product Name and Strength:	Varibar Pudding (barium sulfate) paste, (b)(4)% (w/v)
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Bracco Diagnostics Inc.
Panorama #:	2015-2251565
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Varibar Pudding, 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

Varibar Pudding has been in the US market since 2000. However, this product has never been approved by the FDA. As a result, on December 14, 2015, Bracco submitted an NDA for Varibar Pudding (barium sulfate) paste ((b) (4) % w/v) and proposed proprietary name review for the product.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 14, 2015 proprietary name submission.

- Intended Pronunciation: ˈver- ə - \ˈbär \ \ˈpu̇-diŋg
- Active Ingredient: barium sulfate
- Indication of Use: for use in adult and pediatric patients for modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology
- Route of Administration: Oral
- Dosage Form: Paste
- Strength: (b) (4) % w/v
- Dose and Frequency: The typical dose is 5 mL in adults (b) (4) patients. During a single modified barium swallow examination, multiple doses of Varibar Pudding may be administered
- How Supplied: Multiple-unit LDPE tube containing 230 mL
- Storage: Store at USP Controlled Room Temperature 20 to 25°C (68 to 77° F). Protect from freezing.

  Once opened, VARIBAR PUDDING may be used for up to 21 days when stored at USP Controlled Room Temperature, 20 to 25°C (68 to 77° 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. DMEPA and the Division of Medical Imaging

Products (DMIP) 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[1].

2.2.2 Components of the Proposed Proprietary Name

The applicant provided a rationale for Varibar Pudding as follows:

- VARI (for "VARIous viscosities") – The VARIBAR series of products are formulated to span the range of consistencies and textures (thin liquid, nectar, honey, spoon-thick) and food textures (purees, pastes) as defined by NDD guidelines.
- BAR (refers to "BARium") - VARIBAR series of products include barium sulfate as the active ingredient in the formulation (same concentration) which is opaque to X-rays and acts as the positive radiographic contrast agent in VARIBAR formulations.
- PUDDING (refers to "PUDDING"-like consistency/texture) VARIBAR *PUDDING i*s one of the VARIBAR products that is formulated to a defined apparent viscosity similar to pudding-like preparations commonly prepared and used for VFSS/ MBS use, as aligned the NDD food texture (puree/ pastes) category. armor

This proposed proprietary name is comprised of two words, Varibar and Pudding. The Applicant notes that they use the modifier 'pudding' to distinguish the consistency/texture of this product from other Varibar products that are marketed. We note that the dosage form of this product is paste and although we discourage the use of dosage form as modifiers or modifiers that make reference to the dosage form, we note that this product has been on the market for over 15 years as Varibar Pudding. As noted in section 2.2.8., we have not identified any post-marketing cases or signals related to name confusion with this. Furthermore, this product is used by a specific healthcare practitioner specialty who are already familiar with the product's name as "Varibar Pudding". Changing the proprietary name of the product at this point may introduce confusion among the medical community given the recognition of this product among health care professionals of this community with the barium products and their ability to distinguish among various Varibar products based on this modifier. Moreover, in the meeting that occurred between DMEPA and DMIP in early 2014, DMIP also noted that they prefer to keep the current names for all the barium products.

[1]USAN stem search conducted on January 21, 2016.

2.2.3 FDA Name Simulation Studies

Fifty-three 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.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 28, 2016 e-mail, the Division of Medical Imaging (DMIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	14
Low similarity name pair: combined match percentage score ≤49%	0

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Varibar Pudding will be available in strength of (b)(4)% w/v. Since this is not a typical strength that is not commonly marketed strength, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Varibar Pudding that were not identified in POCA, and found to have an overlap in strength with Varibar Pudding.

Table 1A. eDRLS Search Results	**POCA score**
N/A	

[2] POCA search conducted on January 13, 2016.

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

Our analysis of the 15 names contained in Table 1 and determined 15 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Varibar Pudding that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	January 22, 2016
Drug Name (Active Ingredient)	Barium sulfate
Event (MedDRA Terms)	**DMEPA Official Proprietary Name Review Search Terms Event List:** Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
Date Limits	- January 22, 2016

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, none of the reports identified noted any cases of name confusion with Varibar Pudding and thus were not relevant to this review.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Medical Imaging (DMIP) (via e-mail on February 17, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMIP on February 26, 2016, they stated no additional concerns with the proposed proprietary name, Varibar Pudding.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 14, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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. [3]

[3] 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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. 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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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 ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths 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 ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Varibar Pudding Study (Conducted on January 15, 2016)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Varibas Pudding 5 mL po now. Repeat as needed during exam Outpatient Prescription: Varibar Pudding Use as directed #1	Varibar Pudding Use as directed #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

239 People Received Study
53 People Responded

Study Name: Varibar Pudding

Total	17	14	22	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
VARIBAR	1	0	1	2
VARIBAR PUDDING	15	3	18	36
VARIBAS PUDDING	0	0	1	1
VARILBAS PUDDING	0	0	1	1
VARILEAR PUDDING	0	0	1	1

VARIVAR PUDDING	1	0	0	1
VERABAR PUDDING	0	4	0	4
VERAPAR PUDDING	0	1	0	1
VERIBAR PUDDING	0	5	0	5
VIRABAR PUDDING	0	1	0	1

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

No.	**Proposed name:** Varibar Pudding **Established name:** Barium sulfate **Dosage form:** Paste **Strength(s):** (b)(4)% w/v **Usual Dose:** The typical dose is 5 mL in adults (b)(4) patients. During a single modified barium swallow examination, multiple doses of Varibar Pudding may be administered.	**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.	Varibar Pudding	100	Subject of this review

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

No.	Name	POCA Score (%)
1.	N/A	

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

No.	**Proposed name:** Varibar Pudding **Established name:** Barium sulfate **Dosage form:** Paste **Strength(s):** (b) (4)% w/v **Usual Dose:** The typical dose is 5 mL in adults (b) (4) patients. During a single modified barium swallow examination, multiple doses of Varibar Pudding may be administered.	**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.	Verteporfin (Note: The Brand name is Visudyne.)	54	The infixes of this name pair have sufficient orthographic differences. The Varibar Pudding name contains an extra syllable. Additionally, none of the syllables sound similar.
2.	(b) (4)***	53	The infixes of this name pair have sufficient orthographic differences. The Varibar Pudding name contains an extra syllable. The (b) (4) syllable of the root name Varibar and (b) (4)*** sound different.
3.	Bivalirudin	52	The suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
4.	Vagi-Gard Douche	52	The suffixes of this name pair have sufficient orthographic differences. The Varibar Pudding name contains an extra syllable.
5.	Duraganidin	50	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
6.	Veripred	50	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.

No.	**Proposed name:** Varibar Pudding **Established name:** Barium sulfate **Dosage form:** Paste **Strength(s):** (b)(4)% w/v **Usual Dose:** The typical dose is 5 mL in adults (b)(4) patients. During a single modified barium swallow examination, multiple doses of Varibar Pudding may be administered.	**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**
7.	Vildagliptin	50	The infixes of this name pair have sufficient orthographic differences. The Varibar Pudding name contains an extra syllable. Additionally, none of the syllables sound similar between the two names.

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

No.	Name	POCA Score (%)
1.	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
1.	Vagisil Satin	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
2.	Va Disclosing	53	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
3.	Triarachidin	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
4.	Vascardin	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Parasal Sodium	51
2.	Frovatriptan	50
3.	Probampacin	50

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

No.	Name
1.	Invega Sustenna
2.	Aluvea

No.	Name
3.	Perfecting Mineral Beauty Balm with SPF 9
4.	Urea

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/s/

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