

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

219840Orig1s000

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:	February 14, 2025
Application Type and Number:	NDA 219840
Product Name, Dosage Form, and Strength:	E-Z-DISK (barium sulfate) tablets, 700 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bracco Diagnostics Inc. (Bracco)
PNR ID #:	2024-1044726120
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
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1 INTRODUCTION

This review evaluates the proposed proprietary name, E-Z-DISK, 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. Bracco did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

E-Z-DISK has been marketed under the proposed proprietary name, E-Z-DISK, since September 2009. However, this product has never been approved by the FDA. Therefore, on November 21, 2024, Bracco submitted NDA 219840 and request for proprietary name review to seek FDA approval for E-Z-DISK.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission^a and the prescribing information^b received on November 21, 2024.

Table 1. Relevant Product Information for E-Z-DISK	
Intended pronunciation:	ē/zē/disk
Active ingredient:	barium sulfate
Indication:	E-Z-DISK is a (b) (4) contrast agent indicated for (b) (4) (b) (4).
Dosage Form:	tablets
Strength:	700 mg
Route of administration:	oral
Dose and frequency:	(b) (4)
How Supplied:	E-Z-DISK is supplied as a white to lightly colored tablet, ½ inch in diameter, with EZEM inscribed on one side and 778 on the other side, in a (b) (4) glass bottle containing 100 tablets.
Storage:	Store at USP controlled room temperature 20°C to 25°C (68°F to 77°F). Protect from moisture.
Reference Listed Drug:	E-Z-HD (barium sulfate) NDA 208036

^a Proprietary Names (NDA 219840 E-Z-DISK). Princeton (NJ): Bracco Diagnostics Inc.; 2024 NOV 21. Available from: <\\CDSESUB1\EVSPROD\nda219840\0001\m1\us\118-proprietary-name\118-proprietary-name.pdf>

^b Proposed prescribing information for E-Z-DISK. Princeton (NJ): Bracco Diagnostics Inc.; 2024 NOV 21. Available from: <\\CDSESUB1\EVSPROD\nda219840\0001\m1\us\114-labeling\1141-draft-labeling\11413-draft-label-text\11413-draft-labeling-text.pdf>

2 DISCUSSION

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, E-Z-DISK.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that E-Z-DISK 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 E-Z-DISK. The Division of Imaging and Radiation Medicine (DIRM) did not comment on the findings of OPDP's assessment for E-Z-DISK.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, E-Z-DISK.

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

In their submission, Bracco noted the proposed proprietary name, E-Z-DISK, “comes from the name of the company which originally marketed this product (E-Z-EM)” and that “‘Disk’ refers to a thin circular object”. Additionally, Bracco noted that “the current proprietary name has been used for the [unapproved] drug product in the US market since market introduction in September 2009”. Bracco also stated that “there are no current data indicating medication errors or name confusion with other named drugs”. Our routine post-market surveillance has not identified name confusion medication errors associated with E-Z-DISK.

The proposed proprietary name includes the term “disk”, which is defined as a thin circular object.^d Based on the proposed prescribing information, the proposed E-Z-DISK dosage form is a round tablet with a ½ inch diameter. Additionally, we confirmed with the Office of Pharmaceutical Quality (OPQ) via email communication on January 14, 2025, that the correct dosage form for this product is a “tablet” and that use of “disk” in the proprietary name does not conflict with the “tablet” dosage form. Further, “disk” is not listed as an FDA approved dosage form.^e Therefore, we do not object to the inclusion of the word “disk” in the proprietary name given the tablet shape aligns with the definition of “disk”. Outside of this, we note the

^c USAN stem search conducted on January 14, 2025.

^d “Disk”. Merriam-Webster.com Dictionary. Accessed on January 23, 2025. Available from: <https://www.merriam-webster.com/dictionary/disk>

^e Structured Product Labeling Resources – Dosage Forms. Accessed January 31, 2025. Available from: <https://www.fda.gov/industry/structured-product-labeling-resources/dosage-forms>

proposed name does not contain any other components that can contribute to medication errors.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Imaging and Radiation Medicine (DIRM) did not forward any comments or concerns relating to E-Z-DISK at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-four (84) practitioners participated in DMEPA's prescription simulation studies for E-Z-DISK.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name "E-Z Mix" from the static pick list. The participant entered the sequence "E-Z", and incorrectly selected "E-Z Mix" from the generated list after 11 seconds in order to proceed with the FDA prescription stimulation study. The CPOE simulation software generated a static pick list that included "E-Z Mix" as the fifteenth name in the list while "E-Z-DISK" was listed as the twenty-third name in the list. However, we were unable to find product characteristics for "E-Z Mix" in commonly used drug databases. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk (see Appendix G).

One respondent in the verbal study misinterpreted the name as "EZDISK" (no hyphens) which is a close variation of the product name Ezdose (barium sulfate) oral suspension. However, we identified Ezdose as an international product marketed in Canada. Thus, we determined the risk of confusion is adequately minimized (see Appendix G).

The remaining 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 prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search^f identified 18 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search and the FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1

^f POCA search conducted on December 10, 2024 in version 5.9.

Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	16
Low similarity name pair: combined match percentage score $\leq 54\%$	2

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 19 names contained in Table 2 determined none of the names will pose a risk for confusion with E-Z-DISK as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On February 14, 2025, DMEPA 2 communicated our determination to the Division of Imaging and Radiation Medicine (DIRM).

3 CONCLUSION

The proposed proprietary name, E-Z-DISK, is conditionally acceptable.

3.1 COMMENTS TO BRACCO DIAGNOSTICS INC.

We have completed our review of the proposed proprietary name, E-Z-DISK, and have concluded that this proprietary name is conditionally acceptable.

If any of the proposed product characteristics as stated in your submission, received on November 21, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>).

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>).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or>.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3. 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.⁹

Table 3. 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.

⁹ National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors>. Last accessed 10/05/2020.

Table 3. 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 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, Cerner RxNorm, Purple Book, 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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Tables 4-6) 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 that 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 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - o 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.

- o 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 5).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

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

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 OPQ 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 Safety Evaluator 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 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq$ 70%).			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 as 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?		
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Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
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	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 as vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

	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 names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	
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Table 6. Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. E-Z-DISK Study (Conducted on 1/8/2025)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> E-Z-disk 1 tab orally (b) (4) (b) (4)	E-Z-DISK Take 1 tablet orally (b) (4) #1
<u>Outpatient Prescription:</u> Patient _____ Date <u>1-8-25</u> Address _____  1-800-FDA-1088 E-Z-Disk Take 1 tablet orally (b) (4) #1 Refill(s): _____ Dr. <u>OSE</u> DEA No. _____ Address _____ Telephone _____	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
E-Z-DISK	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: E-Z-DISK					
People Received Study: 167					
People Responded: 84					
Total	24	22	17	21	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
E-3-DISK	1	0	0	0	1
E-Z -DISK	0	1	0	0	1
E-Z DISC	0	1	0	0	1
E-Z DISK	6	6	0	0	12
E-Z MIX	0	0	0	1	1
E-Z- DISK	1	1	0	0	2
E-Z- DISTA	0	1	0	0	1
E-Z-DISC	0	1	0	0	1
E-Z-DISK	16	10	0	20	46
EASY DISC	0	0	8	0	8
EASYDISC	0	0	1	0	1
EZ DISC	0	0	6	0	6
EZ DISK	0	1	1	0	2
EZDISK	0	0	1	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is ≥70%)

No.	Proposed name: E-Z-DISK Pronunciation: ē/zē/disk Established name: barium sulfate Dosage form: tablets Strength(s): 700 mg Dosage: 1 tablet (700 mg) once (b) (4)	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.	E-Z-DISK	100	This name is the subject of this review.

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4) ***	55

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: E-Z-DISK Pronunciation: ē/zē/disk Established name: barium sulfate Dosage form: tablets Strength(s): 700 mg Dosage: 1 tablet (700 mg) once (b) (4)	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.	Eze D.S.	65	Orthographically, the ending of the names (D.S. vs.-DISK) provide some difference. Specially, E-Z-DISK contains the dotted letter 'i' and upstroke letter 'k' which is absent from Eze D.S. Phonetically, Eze D.S. contains a two-syllable modifier (dee - ess) which sounds different than the ending syllable of E-Z-DISK ("disk"). Although the products differ in strength (700 mg vs. 500 mg), both products are single strength, so the strength may be omitted on a prescription order. The name pair also differs based on

No.	Proposed name: E-Z-DISK Pronunciation: ē/zē/disk Established name: barium sulfate Dosage form: tablets Strength(s): 700 mg Dosage: 1 tablet (700 mg) once (b) (4)	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
			frequency of administration (one-time dose (b) (4) vs. three to four times daily). Additionally, we note E-Z-DISK is proposed for use in radiography of the esophagus. Therefore, E-Z-DISK must be administered under the ordering physician's supervision (b) (4), whereas Eze D.S. may be self-administered by patients without supervision for the relief of discomfort associated with acute, painful musculoskeletal conditions. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
2.	Diskets	60	This name pair has sufficient orthographic and phonetic differences.
3.	End-Zit	57	This name pair has sufficient orthographic and phonetic differences.
4.	End-Itch	56	This name pair has sufficient orthographic and phonetic differences.
5.	Evamist	56	This name pair has sufficient orthographic and phonetic differences.
6.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
7.	Ed A-Hist	55	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Amvisc	54
2.	Medisilke	53

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.	(b) (4) ***	68	Proposed proprietary name for IND (b) (4) found unacceptable by CBER's Advertising and Promotional Labeling Branch (APLB) on (b) (4). No alternate name submitted for review.
2.	Ezdose	68	International product marketed in Canada. See Section 2.2.4.
3.	E-Z Mix	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. See Section 2.2.4.
4.	Ed-Tuss Hc	58	Name identified in RxNorm database. Per Redbook, product is deactivated and no generic equivalents are available.
5.	Evovist	56	Name identified in RxNorm 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 confusionⁱ.

No.	Name	POCA Score (%)
1.	Meditest	56
2.	Zgesic	56
3.	Med-Hist	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

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