CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219097Orig1s000

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:	April 25, 2024
Application Type and Number:	NDA 219097
Product Name, Dosage Form, and Strength:	Imkeldi (imatinib) oral solution, 400 mg/5 mL (80 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Shorla Pharma Ltd. (Shorla Pharma)
PNR ID #:	2024-1044725602
DMEPA 2 Safety Evaluator:	Rina Patel, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD
DMEPA 2 Associate Director for Nomenclature & Labeling:	Hina Mehta, PharmD

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Imkeldi, 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. Shorla Pharma submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission[b] and prescribing information[c] received on January 31, 2024.

Table 1. Relevant Product Information for Imkeldi	
Intended pronunciation:	Im kel' dee
Active ingredient:	imatinib
Indication:	• Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. • Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy. • Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). • Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy. • Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. • Adult patients with aggressive systemic mastocytosis (ASM) without the 0816V c-Kit mutation or with c-Kit mutational status unknown. • Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIPIII-PDGFRa fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIPIII-PDGFRa fusion kinase negative or unknown. • Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). • Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). • Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.
Dosage Form:	oral solution

[a] Proprietary Name Safety Summary for IMKELDI. [redacted] (b) (4) 2023 Dec 18. Available from: \\CDSESUB1\EVSPROD\nda219097\0001\m1\us\1-18-prop-name-safety-summ-imkeldi.pdf.

[b] Request for Proprietary Name Review (Imkeldi NDA 219097). Clonmel (Ireland): Shorla Pharma Ltd; 2024 Jan 31. Available from: \\CDSESUB1\EVSPROD\nda219097\0001\m1\us\1-18-imkeldi-cover-letter.pdf.

[c] Proposed prescribing information for Imkeldi. Clonmel (Ireland): Shorla Pharma Ltd; 2024 Jan 31. Available from: \\CDSESUB1\EVSPROD\nda219097\0001\m1\us\1-14-1-3-drft-label-txt.pdf.

Table 1. Relevant Product Information for Imkeldi	
Strength:	400 mg/5 mL (80 mg/mL)
Route of administration:	oral
Usual dosage and frequency:	• **Adults:** o With Ph+ CML CP: 400 mg/day o With Ph+ CML AP or BC: 600 mg/dayWith Ph+ ALL: 600 mg/day o With MDS/MPD: 400 mg/day o With ASM: 100 mg/day or 400 mg/day o With HES/CEL 100 mg/day or 400 mg/day o With DFSP: 800 mg/day o With GIST: 400 mg/day o Maximum daily dose: 800 mg • **Pediatrics:** o With Ph+ CML or Ph+ ALL: 340 mg/m^2/day • Maximum daily dose: 600 mg/day • **Hepatic impairment:** o Mild to moderate hepatic impairment: no dose adjustment o Severe hepatic impairment: 25% decrease in the recommended dose • **Renal impairment:** o CrCl 20-39 mL/min: 50% decrease in the recommended starting dose. Doses greater than 400 mg are not recommended. o CrCl 40-59 mL/min: Doses greater than 600 mg are not recommended. • **Dose adjustments for hepatotoxicity and non-hematologic adverse reactions:** o Adults: reduce 400 mg/day to 300 mg/day, 600 mg/day to 400 mg/day, or 800 mg/day to 600 mg/day o Pediatrics: 260 mg/m^2/day • **Dose adjustments for hematologic adverse reactions:** o Dose reductions are based on indication and starting dose. Dose reductions may be implemented after appropriate treatment interruption for severe neutropenia and thrombocytopenia. o Adults with a starting dose of 400 mg/day: reduce dose to 300 mg/day o Adults with a starting dose of 600 mg/day: reduce dose to 400 mg/day, then to 300 mg/day o Adults with a starting dose of 800 mg/day: reduce dose to 600 mg/day, then to 400 mg/day o Pediatrics: reduce dose to 260 mg/m^2/day • Doses should be administered once daily, but a dose of 800 mg/day should be administered as 400 mg twice daily.
How Supplied:	(b) (4) mL amber PET bottle (b) (4)
Storage:	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].
Reference Listed Drug:	GLEEVAC (imatinib mesylate) NDA 021588

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Imkeldi would not misbrand the proposed product. The Division of Hematologic Malignancies 1 (DHM 1) and The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Imkeldi.

2.2 SAFETY ASSESSMENT

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

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

Shorla Pharma did not provide a derivation or intended meaning for the proposed proprietary name, Imkeldi, in their submission. This proprietary name is comprised of a single word that contains the letter string 'im' at the beginning of the name, which is the abbreviation for the intramuscular route of administration that may be used on a prescription. We evaluated the potential risk of misinterpreting the proposed proprietary name Imkeldi as "im [name similar to Keldi]".[e] We acknowledge there is another name under review, (b) (4)***, which shares the same four letters with and could look similar to 'keldi'. Thus, we considered the risk if the name were to be misinterpreted as "IM (b) (4)***". However, since neither product is an injectable product that would be administered by the intramuscular route of administration (oral solution vs. capsule) the misinterpretation "IM (b) (4) would create a prescription that would need to be clarified as the administration would not be possible, thus risk of such confusion resulting in a medication error is minimized. Therefore, we do not object to the letters "Im" in this case. Additionally, the letter string 'im' at the beginning of a proprietary name is common in drug nomenclature for currently marketed drug products (e.g., Imbruvica, Imitrex, Imfinzi, Imodium, etc.). Thus, we do not object to the inclusion of the medical abbreviation 'im' in the proposed proprietary name in this case.

We also note that this proprietary name contains the letter string 'ld' in the middle of the name, which is an abbreviation for the modifier "low dose". Given the location of the letter string 'ld' in the middle of the name and its lack of prominence, it is unlikely to be separated from the surrounding letters in a manner that could lead to confusion.

Beyond these abbreviations, we note that Imkeldi does not contain any additional components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

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[d] USAN stem search conducted on February 2, 2024.

[e] POCA search conducted on February 14, 2024 in version 5.5.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On March 1, 2024, the Division of Hematologic Malignancies 1 (DHM 1) did not forward any comments or concerns relating to Imkeldi at the initial phase of the review.

2.2.4 FDA NAME SIMULATION STUDIES

Seventy-eight (78) practitioners participated in DMEPA's prescription studies for Imkeldi.

One voice study participant misinterpreted the proposed proprietary name as "(b) (4)***", which is a proprietary name under review. We evaluated the name pair Imkeldi and (b) (4)*** and find that there are sufficient orthographic, phonetic, and product characteristic differences.

Imkeldi vs. (b) (4)***

Orthographically, the infixes (-kel- vs. (b) (4)) and suffixes (-di vs. (b) (4) provide sufficient differences. Specifically, Imkeldi contains three upstroke letters (k, l, and d) while (b) (4)*** (b) (4) Further, (b) (4)*** contains the (b) (4) (b) (4) which is not seen in Imkeldi. These differences give the names different shapes when scripted.

Phonetically, the first and second syllables (im kel' vs. (b) (4) and the beginning sounds of the last syllable (dee vs (b) (4) sound different when spoken.

Although the strengths differ (400 mg/5 mL [80 mg/mL]) vs. (b) (4) and (b) (4) (b) (4), we acknowledge that Imkeldi is available as a single strength; therefore, this information may not be included in a prescription. The products also differ in frequency (once daily or twice daily vs. (b) (4)), dosage form (oral solution vs. (b) (4), and route of administration (oral vs. (b) (4)) which may provide additional differentiation if included. Therefore, we find there is minimal risk of name confusion with the name pair (see Appendix E).

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 35 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 lists the number of names retrieved from our POCA search, FDA Prescription Stimulation Study, and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

[f] POCA search conducted on February 2, 2024 in version 5.5.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	32
Low similarity name pair: combined match percentage score ≤54%	7

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

Our analysis of the 40 names contained in Table 2 determined none of the names will pose a risk for confusion with Imkeldi as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On April 25, 2024, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 1 (DHM 1).

3 CONCLUSION

The proposed proprietary name, Imkeldi, is conditionally acceptable.

If you have any questions or need clarifications, please contact Candido Alicea, OSE project manager, at 240-402-8310.

3.1 COMMENTS TO SHORLA PHARMA LTD.

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

If any of the proposed product characteristics as stated in your submission, received on January 31, 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.[g]

*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.

[g] 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 ≥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 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 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.
    - 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 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, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[h] Shah, M, Merchant, L, 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 ≥ 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?		

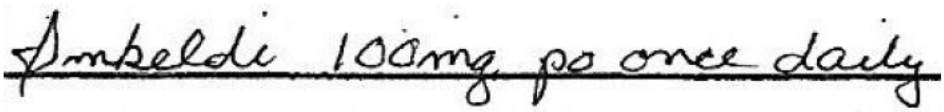
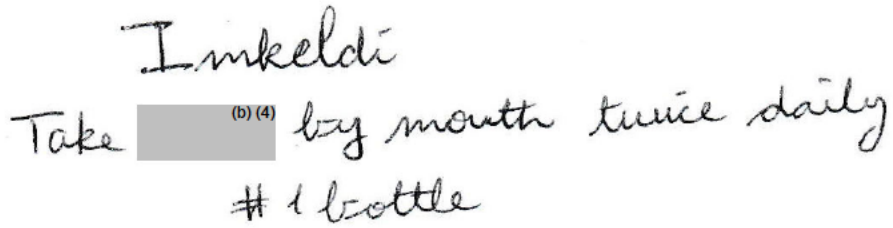
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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	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: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤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 name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. 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. Imkeldi Study (Conducted on 2/16/2024)

<table>
<tr><th>Handwritten Medication Order Prescription</th><th>Verbal Prescription</th></tr>
<tr><td><u>Medication Order:</u>
  </td><td rowspan="4">Imkeldi
Take (b) (4)
by mouth twice daily. Dispense one bottle.</td></tr>
<tr><td><u>Outpatient Prescription:</u>
  </td></tr>
<tr><td>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</td></tr>
<tr><td>Imkeldi</td></tr>
</table>

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Imkeldi People Received Study: 164 People Responded: 78					
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
Total	20	20	20	18	78
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
EMCALDI	0	0	1	0	1
EMKELDI	0	0	1	0	1
EMKELDY	0	0	1	0	1
EMKELLDEE	0	0	1	0	1
HIMKELDI	0	0	1	0	1
(b) (4)	0	0	1	0	1
IMBELDI	10	0	0	0	10
IMCALDE	0	0	1	0	1
IMCALDI	0	0	2	0	2
IMCELDY	0	0	1	0	1
IMKALDI	0	0	1	0	1
IMKELCLI	0	1	0	0	1
IMKELDE	0	0	1	0	1
IMKELDI	9	19	4	18	50
IMKELDY	0	0	2	0	2
IMKELVY	0	0	1	0	1
INKELDI	0	0	1	0	1
SMKELDI	1	0	0	0	1

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

No.	Proposed name: Imkeldi Established name: imatinib Dosage form: oral solution Strength(s): 400 mg/5 mL (80 mg/mL) Usual dose: Adults: 100 mg, 300 mg, 400 mg, or 600 mg once daily or 400 mg BID Pediatrics: 260 mg/m2/day or 340 mg/m2/day	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.	Imkeldi	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: Imkeldi Established name: imatinib Dosage form: oral solution Strength(s): 400 mg/5 mL (80 mg/mL) Usual dose: Adults: 100 mg, 300 mg, 400 mg, or 600 mg once daily or 400 mg BID Pediatrics: 260 mg/m2/day or 340 mg/m2/day	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.	Imdelltra***	64	Orthographically, the lengths of the names (7 letters vs. 9 letters) differ making the name pair appear dissimilar when scripted. Imkeldi contains the letter 'k' in the third position while Imdelltra*** contains the rounded letter 'd' in the third position providing some difference. Also, the suffixes of the name pair differ.

No.	Proposed name: Imkeldi Established name: imatinib Dosage form: oral solution Strength(s): 400 mg/5 mL (80 mg/mL) Usual dose: Adults: 100 mg, 300 mg, 400 mg, or 600 mg once daily or 400 mg BID Pediatrics: 260 mg/m2/day or 340 mg/m2/day	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
			Specifically, Imdelltra*** contains the cross-stroke letter 't' in the 7th position while Imkeldi contains no cross-stroke letters. Phonetically, the beginning of the second syllables (kel' vs. del') and the third syllables (dee vs. trah) sound different when spoken. While there is numerical similarity in dose (100 mg vs. 10 mg), there is no direct overlap in strength (400 mg/5 mL [80 mg/mL] vs. 1 mg or 10 mg). Since Imdelltra*** is available in multiple strengths, a strength must be provided on a prescription. The products also differ in dosage form (oral solution vs. for injection), route of administration (oral vs. intravenous), and frequency of administration (once or twice daily vs. every 2 weeks) which may provide additional differentiation if included on a prescription. Additionally, Imdelltra*** is an injectable oncology drug. Because injectable oncology drugs administered by healthcare professionals are not communicated by verbal order and typically undergo independent double checks by two pharmacists in the usual

No.	Proposed name: Imkeldi Established name: imatinib Dosage form: oral solution Strength(s): 400 mg/5 mL (80 mg/mL) Usual dose: Adults: 100 mg, 300 mg, 400 mg, or 600 mg once daily or 400 mg BID Pediatrics: 260 mg/m2/day or 340 mg/m2/day	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
			clinical setting, the likelihood of phonetic name confusion and the risk of both pharmacists overlooking the differences in dose, route of administration, dosage form, and frequency is minimized. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
2.	Impeklo	62	Orthographically, the infixes differ as Impeklo contains the downstroke letter 'p' in the 3rd position while Imkeldi contains the upstroke letter 'k' in the same position and has no downstroke letters. This gives the names different shapes when scripted. Phonetically, the second and third syllables (kel' dee vs. pek' loe) sound different when spoken. Although Imkeldi and Impeklo are single strength products (400 mg/5 mL [80 mg/mL] vs. 0.05%), where the strength may be omitted on an order, the name pair differ in dose (100 mg, 300 mg, 400 mg, 600 mg once daily, 400 mg BID, 260 mg/m2/day or 340 mg/m2/day vs. apply topically), route of administration (oral vs. topical) and dosage form (oral solution vs. lotion) which may provide additional

No.	**Proposed name:** Imkeldi **Established name:** imatinib **Dosage form:** oral solution **Strength(s):** 400 mg/5 mL (80 mg/mL) **Usual dose:** Adults: 100 mg, 300 mg, 400 mg, or 600 mg once daily or 400 mg BID Pediatrics: 260 mg/m2/day or 340 mg/m2/day	**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**
			differentiation if included on a prescription. Thus, the risk of name confusion between the name pair is minimized.
3.	(b) (4)***	60	Orthographically, the lengths of the names (7 letters vs. (b) (4) differ making the name pair appear dissimilar when scripted. The name pair starts with different letters (I vs. (b) (4). Also, the infixes of the names (-kel- vs. (b) (4) provide the name pair with sufficient differences. Phonetically, the name pair have a different number of syllables (3 vs. (b) (4) (b) (4) The first two syllables (im kel' vs sound different when spoken.
4.	Beldin	58	This name pair has sufficient orthographic and phonetic differences.
5.	Emgality	58	This name pair has sufficient orthographic and phonetic differences.
6.	(b) (4)***	58	Orthographically, the ending of the names (-ldi vs. - (b) (4) differ. Specifically, Imkeldi contains two upstroke letters 'ld' in the 5th and 6th position and dotted letter 'i' in the 7th position while (b) (4)*** only contains (b) (4) (b) (4) These differences give the name different shapes when scripted.

No.	Proposed name: Imkeldi Established name: imatinib Dosage form: oral solution Strength(s): 400 mg/5 mL (80 mg/mL) Usual dose: Adults: 100 mg, 300 mg, 400 mg, or 600 mg once daily or 400 mg BID Pediatrics: 260 mg/m2/day or 340 mg/m2/day	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
			Phonetically, the second and third syllables (kel' dee vs. (b) (4) sound different when spoken. We acknowledge the name pair are single strength products which may be omitted on a prescription (400 mg/5 mL [80 mg/mL] vs. (b) (4)) and overlap in dose (100 mg). However, the products differ in route of administration (oral vs. (b) (4) (b) (4)), frequency of administration (once daily or twice daily vs. (b) (4)), and dosage form (oral solution vs. (b) (4) which may provide additional differentiation if included on a prescription. Thus, the risk of name confusion between the name pair is minimized.
7.	Medisilke	57	This name pair has sufficient orthographic and phonetic differences.
8.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.
9.	Cimerli	56	This name pair has sufficient orthographic and phonetic differences.
10.	Igalmi	56	This name pair has sufficient orthographic and phonetic differences.
11.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Imkeldi Established name: imatinib Dosage form: oral solution Strength(s): 400 mg/5 mL (80 mg/mL) Usual dose: Adults: 100 mg, 300 mg, 400 mg, or 600 mg once daily or 400 mg BID Pediatrics: 260 mg/m2/day or 340 mg/m2/day	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
12.	(b) (4)***	36	See FMEA in Section 2.2.4.

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

No.	Name	POCA Score (%)
1.	Imfinzi	52
2.	Medidiol 10	50
3.	Amikacin	44
4.	Indocin	42
5.	Inbrija	33

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)***	66	Proposed proprietary name for IND (b) (4) found unacceptable by CBER on 04/19/2022. Subsequently, the Applicant submitted a reconsideration of this proposed proprietary name, (b) (4)***, that was again found unacceptable by CBER on 07/21/2022. The application was approved with the name Lenmeldy (BLA 125758) on March 18, 2024.
2.	(b) (4) **	62	Proposed proprietary name for ANDA 211699 found unacceptable by DMEPA (OSE# 2018-24210374). ANDA 211699 approved under the proprietary name Breyna.
3.	Skelid	60	Brand is discontinued with no generic equivalents available. NDA 020707 withdrawn FR effective 1/5/2015.

No.	Name	POCA Score (%)	Failure preventions
			International product currently marketed in Australia and formerly marketed in various other countries.
4.	Ismelin	58	Brand is discontinued with no generic equivalents available. NDA 012329 withdrawn FR effective 6/18/2009. International product currently marketed in Great Britain and formerly marketed in various other countries.
5.	(b) (4) **	58	Proposed proprietary name for NDA 214835 found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE# 2021-1044723871 dated 6/7/2021). NDA 214835 was approved under the proprietary name Risvan.
6.	Tildiem	58	International product currently marketed and formerly marketed in various countries.
7.	Immukin	56	International product currently marketed in the UK and Hong Kong and formerly marketed in Ireland.
8.	(b) (4) ***	56	Proposed proprietary name for (b) (4) found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE# (b) (4) dated (b) (4) (b) (4) (b) (4) and no new names have been submitted.
9.	(b) (4)		
10.			

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.	Embeline E	63
2.	Embelin	62
3.	Livdelzi***	60

[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

No.	Name	POCA Score (%)
4.	Medi-Lyte	58
5.	(b) (4)***	56
6.	Embeline	56
7.	(b) (4)***	56
8.	(b) (4)***	56
9.	Jinteli	56
10.	(b) (4)***	56
11.	Dical-D	55

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/s/

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