

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

219249Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	September 12, 2024
Application Type and Number:	NDA 219249
Product Name, Dosage Form, and Strength:	Itovebi (inavolisib) tablets, 3 mg and 9 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genentech, Inc. (Genentech)
PNR ID #:	2024-1044725885-1
DMEPA 2 Safety Evaluator:	Ngoc-Linh Do, PharmD
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Itovebi, based on the revised pronunciation from “eye-TOH-veh-bee” to “eye-TOVE-bee”. The proposed proprietary name, Itovebi, was found conditionally acceptable under NDA 219249 on August 15, 2024.^a

Genentech notified us via email on August 28, 2024 that their commercial team intends to pronounce the proposed proprietary name, Itovebi, as eye-TOVE-bee.

2 DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Itovebi, we evaluated the previously identified names taking into account the change in pronunciation. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Itovebi.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The September 12, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Itovebi.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Itovebi, is conditionally acceptable.

^a Do, N. Proprietary Name Memorandum for Itovebi (NDA 219249). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Aug 15. PNR ID No. 2024-1044725885.

4 REFERENCE

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>.

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/s/

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PROPRIETARY NAME MEMORANDUM

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:	August 15, 2024
Application Type and Number:	NDA 219249
Product Name, Dosage Form, and Strength:	Itovebi (inavolisib) tablets, 3 mg and 9 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genentech, Inc. (Genentech)
PNR ID #:	2024- 1044725885
DMEPA 2 Safety Evaluator:	Ngoc-Linh Do, PharmD
DMEPA 2 Acting Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Itovebi, which was found unacceptable under NDA 219249 on May 1, 2024.^a The proposed proprietary name, Itovebi, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) *** , under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Itovebi, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 219249 is November 27, 2024, whereas the underlying application for (b) (4) *** remains in IND status. Therefore, if the proposed proprietary name, Itovebi, is granted approval under NDA 219249 on or before November 27, 2024, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) *** .

Thus, Genentech resubmitted the proposed proprietary name, Itovebi, for review on July 11, 2024 under NDA 219249.^b

2 DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Itovebi, DMEPA 2 evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA 2 searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The July 18, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA 2 evaluated the status of the underlying application of the conflicting name, (b) (4) *** , and determined that if NDA 219249 for Itovebi is approved on or before November 27, 2024, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) *** , given the underlying application for (b) (4) *** remains in IND status.

Based upon our safety assessment of the proposed proprietary name, Itovebi, the application goal date for NDA 219249, and the status of the underlying application for (b) (4) *** , we find Itovebi conditionally acceptable.

^a Jones, G. Proprietary Name Review for Itovebi (NDA 219249). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 MAY 1. PNR ID No. 2023-1044725492.

^b Request for Proprietary Name Review (Preferred Proprietary Name: Itovebi)/Request for Withdrawal of Proprietary Name Review (Alternative Proprietary Name: (b) (4)). South San Francisco (CA): Genentech, Inc.; 2024 JUL 11. Available from: <\\CDSESUB1\\EVSPROD\\nda219249\\0026\\m1\\us\\cover-letter.pdf>.

2.2 COMMUNICATION OF DMEPA'S DETERMINATION

On August 15, 2024, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

3 CONCLUSION

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

3.1 COMMENTS TO GENENTECH, INC.

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

If any of the proposed product characteristics as stated in your submission, received on July 11, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCE

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>.

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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)

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Date of This Review:	May 1, 2024
Application Type and Number:	IND 130909 NDA 219249
Product Name, Dosage Form, and Strength:	Itovebi (inavolisib) tablets, 3 mg and 9 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genentech Inc (Genentech)
PNR ID #:	2023-1044725492
DMEPA 2 Safety Evaluator:	Grace P. Jones, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Itovebi, 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. Genentech submitted an external name study, conducted by (b) (4), for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 30, 2023^b under IND 130909 and on March 27, 2024^c under NDA 219249; and in the proposed Prescribing Information received on March 27, 2024 under NDA 219249.

Table 1. Relevant Product Information for Itovebi	
Intended pronunciation:	eye-TOH-veh-bee
Active ingredient:	inavolisib
Indication:	(b) (4)
Dosage Form:	tablets
Strength:	3 mg and 9 mg
Route of administration:	oral

^a Proprietary Name/Request for Review. South San Francisco (CA): Genentech Inc; 2023 NOV 30. Available from: <\\CDSESUB1\EVSPROD\ind130909\0175\m1\us\proprietary-names.pdf>.

^b Proprietary Name/Request for Review. South San Francisco (CA): Genentech Inc; 2023 NOV 30. Available from: <\\CDSESUB1\EVSPROD\ind130909\0175\m1\us\proprietary-names.pdf>.

^c Proprietary Name/Request for Review. South San Francisco (CA): Genentech Inc; 2024 MAR 27. Available from: <\\CDSESUB1\EVSPROD\nda219249\0001\m1\us\proprietary-name-review.pdf>.

Table 1. Relevant Product Information for Itovebi									
Usual dosage and frequency:	9 mg taken orally once daily with or without food <i>Dose Modifications for Adverse Reactions:</i> Table 1: Dose Reduction Guidelines for Adverse Reactions^d <table> <tr> <th>Dose Reduction Schedule</th><th>Dose Modified</th></tr> <tr> <td>Starting dose</td><td>9 mg daily</td></tr> <tr> <td>First dose reduction</td><td>6 mg daily</td></tr> <tr> <td>Second dose reduction</td><td>3 mg daily</td></tr> </table>	Dose Reduction Schedule	Dose Modified	Starting dose	9 mg daily	First dose reduction	6 mg daily	Second dose reduction	3 mg daily
Dose Reduction Schedule	Dose Modified								
Starting dose	9 mg daily								
First dose reduction	6 mg daily								
Second dose reduction	3 mg daily								
How Supplied:	Film-coated tablets packaged in 30-counts in a (b) (4) bottle								
Storage:	Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F) [see USP Controlled Room Temperature].								

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Itovebi 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 Itovebi. The Division of Oncology 1 (DO1) did not comment on the findings of OPDP's assessment for Itovebi.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.^e

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Genentech did not provide a derivation or intended meaning for the proposed proprietary name, Itovebi, in their submission. This proprietary name is comprised of a single word that

^d New/NDA for Inavolisib NDA 219249. South San Francisco (CA): Genentech Inc; 2024 MAR 27. Available from: <\\CDSESUB1\EVSPROD\nda219249\0001\m1\us\redlined-label-text.pdf>.

^e USAN stem search conducted on January 9, 2024.

does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On January 10, 2024, the Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Itovebi at the initial phase of the review.

2.2.4 FDA NAME SIMULATION STUDIES

Seventy-seven practitioners participated in DMEPA's prescription studies for Itovebi. 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 prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search^f identified 100 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 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 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
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	98
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

We determined that ninety-nine (99) of the one-hundred (100) names will not pose a risk for confusion with Itovebi as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4) ***. The rationale for the risk of confusion is described below:

(b) (4)

^f POCA search conducted on January 9, 2024 in version 5.5.

(b) (4)



(b) (4)



Therefore, based on the totality of the information above, we find the proposed proprietary name, Itovebi, vulnerable to medication errors due to name confusion with (b) (4) ***.

2.2.8 COMMUNICATION OF DMEPA 2'S DETERMINATION

On May 1, 2024, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

3 CONCLUSION

The proposed proprietary name, Itovebi, is not acceptable from a safety perspective. The proposed proprietary name, Itovebi, is vulnerable to name confusion with (b) (4) ***. Therefore, the decision to deny the name will be communicated to Genentech Inc via letter (See Section 3.1).

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796- 0942.

3.1 COMMENTS TO GENENTECH INC

We have completed our review of the proposed proprietary name, Itovebi, and have concluded that this proprietary name is unacceptable for the following reasons:

Itovebi vs. pending proprietary name

The proposed proprietary name, Itovebi, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Itovebi, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name Itovebi, you will be requested to submit another name.

We acknowledge that our conclusion differs from that of the (b) (4) external study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the (b) (4) external study.

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.^k

*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.

^k 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 (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.
 - 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 names¹. 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, 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

¹ Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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%).			
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? <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 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 $\geq 55\%$ 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 there a different number or	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 $\geq 55\%$ to $\leq 69\%$).

	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?	
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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. Itovebi Study (Conducted on 12/21/2023)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Itovebi 9mg po q24 hours</i>	Itovebi Take 1 tablet by mouth every 24 hours Dispense 30
<u>Outpatient Prescription:</u> <i>Itovebi 9mg</i> <i>Take 1 tablet po every 24 hours</i> <i>#30</i>	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Itovebi	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Itovebi					
People Received Study: 166					
People Responded: 77					
Total	14	25	16	22	77
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
EYTOVABY	0	0	1	0	1
EYTOVEBY	0	0	1	0	1
IFOVEBI	0	1	0	0	1
IOTAVEE	0	0	1	0	1
ISOVEBI	0	1	0	0	1
ITOVABE	0	0	4	0	4
ITOVABEE	0	0	3	0	3
ITOVABI	0	0	2	0	2
ITOVABY	0	0	3	0	3
ITOVBI	0	1	0	0	1
ITOVEBI	3	21	0	22	46
ITOVEBIC	0	1	0	0	1
ITOVYABYE	0	0	1	0	1
STOVEBI	11	0	0	0	11

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

No.	Proposed name: Itovebi Established name: inavolisib Dosage form: tablets Strength(s): 3 mg and 9 mg Usual dose: 9 mg by mouth once daily; dose reductions: 3 mg or 6 mg by mouth once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Itovebi	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Pitocin	58
2.	(b) (4) ***	58
3.	toviaz	58
4.	Cytovene	56
5.	Mektovi	56
6.	Ritonavir	56
7.	Ibu-Tab	55
8.	Ibutab	55

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Itovebi Established name: inavolisib Dosage form: tablets Strength(s): 3 mg and 9 mg Usual dose: 9 mg by mouth once daily; dose reductions: 3 mg or 6 mg by mouth once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	tovet	66	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Itovebi Established name: inavolisib Dosage form: tablets Strength(s): 3 mg and 9 mg Usual dose: 9 mg by mouth once daily; dose reductions: 3 mg or 6 mg by mouth once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Isovue-M 200	64	This name pair has sufficient orthographic and phonetic differences.
3.	Isovue-M 300	64	This name pair has sufficient orthographic and phonetic differences.
4.	Isovue-M-200	64	This name pair has sufficient orthographic and phonetic differences.
5.	Isovue-M-300	64	This name pair has sufficient orthographic and phonetic differences.
6.	Isovue-200	62	This name pair has sufficient orthographic and phonetic differences.
7.	Isovue-370	62	This name pair has sufficient orthographic and phonetic differences.
8.	Isovue-128	62	This name pair has sufficient orthographic and phonetic differences.
9.	Isovue-250	62	This name pair has sufficient orthographic and phonetic differences.
10.	Isovue-300	62	This name pair has sufficient orthographic and phonetic differences.
11.	Isovue 370	62	This name pair has sufficient orthographic and phonetic differences.
12.	Isocet	60	This name pair has sufficient orthographic and phonetic differences.
13.	Otovel	60	This name pair has sufficient orthographic and phonetic differences.
14.	Tobi	60	This name pair has sufficient orthographic and phonetic differences.
15.	Idose Tr	59	This name pair has sufficient orthographic and phonetic differences.
16.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Itovebi Established name: inavolisib Dosage form: tablets Strength(s): 3 mg and 9 mg Usual dose: 9 mg by mouth once daily; dose reductions: 3 mg or 6 mg by mouth once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
17.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
18.	Otobione	56	This name pair has sufficient orthographic and phonetic differences.
19.	Ibu-Tab 200	55	This name pair has sufficient orthographic and phonetic differences.
20.	Impavido	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.	Accuzyme	43

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.	Isovate	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Inoven	64	International product marketed in the United Kingdom.
3.	Isovex	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	(b) (4) ***	62	Proposed proprietary name found unacceptable by DMEPA under BLA 761232; (b) (4) IND 135699; (b) (4) Subsequently, the proposed proprietary name

No.	Name	POCA Score (%)	Failure preventions
			Tevimbra*** was found conditionally acceptable for (b) (4) BLA 761232.
5.	Bilovet	60	Veterinary product.
6.	(b) (4) ***	60	Proposed proprietary name for IND 120651 found unacceptable by DMEPA (OSE# 2020-41433839, dated 10/13/2020). Subsequently, for IND 120651, the proposed proprietary name Lunsumio*** was found conditionally acceptable by DMEPA (OSE# 2021-1044723993, dated 8/18/2021). This name was withdrawn on 12/23/2021 under IND 120651, but was later submitted under BLA 761263 and was found acceptable (OSE# 2022-1044724511 dated 6/7/2022).
7.	Isolyte E	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	(b) (4) ***	58	Proposed proprietary name for pre-submission (b) (4) submitted for review (b) (4) No alternate name has been proposed for review.
9.	(b) (4) ***	58	Proposed proprietary name for BLA 761240 withdrawn by the Applicant. BLA 761240 approved under the proprietary name, Loqtorzi.
10.	Iodide I-125	57	Product is not a drug. It is a radioisotope of iodine which has uses in biological assays, nuclear medicine imaging, and in radiation therapy as brachytherapy.
11.	(b) (4) ***	57	Proposed proprietary name for IND 121904 found unacceptable by DMEPA (OSE# 2019-34747367, dated 3/18/2020). NDA 214998 approved under the proprietary name Camzyos.
12.	Firovet	56	Veterinary product.
13.	Ipodate	56	Name identified in RxNorm database. Ipodate is the active moiety for the salt forms, ipodate sodium and ipodate calcium, which are discontinued and no generic equivalents are available.
14.	Isodettes	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
15.	Ketovail	56	International product marketed in the United Kingdom.
16.	(b) (4) ***	56	(b) (4)

No.	Name	POCA Score (%)	Failure preventions
			(b) (4)
17.	(b) (4) ***	56	(b) (4)
18.	(b) (4) ***	56	Proposed proprietary name for IND 137856 found unacceptable by DMEPA (OSE# 2020-1043779388, dated 10/1/2021). NDA 216264 approved under the proprietary name Bludigo.
19.	(b) (4) ***	56	The root name of the proposed proprietary name, (b) (4) *** Aerosphere for IND 118313 found unacceptable by DMEPA (OSE #2018-22563733 dated 10/18/2018). NDA 212122 approved under proprietary name, Breztri Aerosphere.

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion^m.

No.	Name	POCA Score (%)
1.	Enovid	62
2.	Cevi-Bid	61
3.	Nitro-Bid	60
4.	Zituvimet	60
5.	Zituvio	60
6.	Betavet	59
7.	Ketocid	59
8.	Lithobid	59
9.	Otozin	59
10.	Sitavig	59
11.	Atosiban	58

^m 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 (%)
12.	Estivin	58
13.	Evovist	58
14.	Lytgobi	58
15.	Nitro-Bid Iv	58
16.	Onivyde	58
17.	Ricobid	58
18.	Tavegil	58
19.	Temovate E	58
20.	Teveten	58
21.	(b) (4) ***	58
22.	Vosevi	58
23.	Bevespi	57
24.	Otobiotic	57
25.	Otocidin	57
26.	Tussi-Bid	57
27.	(b) (4) ***	56
28.	Enovid-E	56
29.	Enovid-E 21	56
30.	Eticovo	56
31.	Etogesic	56
32.	Ketaved	56
33.	Opuviz***	56
34.	Ricobid D	56
35.	Ritifed	56
36.	Sedivet	56
37.	Solvadi	56
38.	Sovaldi	56
39.	Tegsedi	56
40.	Theobid	56
41.	Tresiba	56
42.	Trovan Iv	56
43.	(b) (4) ***	56

No.	Name	POCA Score (%)
44.	Vitabee 12	56
45.	Cefobid	55
46.	Citravet	55
47.	Estrovis	55
48.	(b) (4) ***	55
49.	Tevimbra***	55
50.	Vitaped	55

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/s/

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