CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219122Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	December 23, 2024
Application Type and Number:	NDA 219122
Product Name, Dosage Form, and Strength:	Brynovin (sitagliptin) oral solution, 25 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Azurity Pharmaceuticals (Azurity)
PNR ID #:	2024-1044726119
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Brynovin, which was found conditionally acceptable under NDA 219122 on April 2, 2024.[a] However, NDA 219122 received a Complete Response on November 04, 2024, due to issues with facility inspections. Thus, Azurity resubmitted the proposed proprietary name, Brynovin, under NDA 219122 for re-review on November 18, 2024.[b] We note that all product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Brynovin would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Brynovin. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Brynovin.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Brynovin, we 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. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The November 26, 2024, search of USAN stems did not find any USAN stems in the proposed proprietary name, Brynovin.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On December 23, 2024, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

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, Brynovin, is conditionally acceptable.

---

[a] Patel, V. Proprietary Name Review for Brynovin (NDA 219122). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Apr 02. PNR ID No. 2024-1044725551.

[b] Request for Proprietary Name Review Brynovin NDA 219122. Overland Park (KS): Azurity Pharmaceuticals; 2024 Nov 18. Available from: \\CDSESUB1\EVSPROD\nda219122\0002\m1\us\118-prop-name-rev-req-brynovin.pdf.

3.1 COMMENTS TO AZURITY PHARMACEUTICALS

We have completed our review of the proposed proprietary name, Brynovin, 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 18, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

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.

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

/s/

VRAJ K PATEL
12/23/2024 12:42:42 PM

DAMON A BIRKEMEIER
12/23/2024 01:01:13 PM

IDALIA E RYCHLIK
12/23/2024 01:05:05 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 2, 2024
Application Type and Number:	NDA 219122
Product Name, Dosage Form, and Strength:	Brynovin (sitagliptin hydrochloride) oral solution, 25 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Azurity Pharmaceuticals (Azurity)
PNR ID #:	2024-1044725551
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Brynovin, 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. Azurity did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 4, 2024[a] and the prescribing information received on January 4, 2024[b].

Table 1. Relevant Product Information for Brynovin	
Intended pronunciation:	Bri-know-vin
Active ingredient:	sitagliptin hydrochloride
Indication:	adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Dosage Form:	oral solution
Strength:	25 mg/mL
Route of administration:	oral
Usual dosage and frequency:	The recommended dose is 100 mg (4 mL) once daily. Can be taken with or without food. For patients with moderate renal impairment (eGFR greater than or equal to 30 mL/min/1.73 m^2 to less than 45 mL/min/1.73m^2), the recommended dose is 50 mg (2 mL) once daily. For patients with severe renal impairment (eGFR less than 30 mL/min/1.73m^2) or with end-stage renal disease (ESRD) requiring hemodialysis or peritoneal dialysis, the recommended dose is 25 mg (1 mL) once daily.
How Supplied:	25 mg/mL is supplied as a clear colorless, to nearly colorless aqueous solution in an amber glass bottle with a child resistant closure. 120 mL, NDC 24338-017-01
Storage:	Store refrigerated at 2°C to 8°C (36°F to 46°F); Protect from light. Avoid excessive heat and freezing. Discard unused portion 90 days after first opening.
Reference Listed Drug:	Januvia (sitagliptin hydrochloride) NDA 021995.

[a] Request for Proprietary Name Review NDA 219122 Brynovin. Woburn (MA): Azurity Pharmaceuticals; 2024 Jan 04. Available from: \\CDSESUB1\EVSPROD\nda219122\0002\m1\us\118-prop-name-rev-req-brynovin.pdf.

[b] Proposed prescribing information for Brynovin. Woburn (MA): Azurity Pharmaceuticals; 2024 Jan 04. Available from: \\CDSESUB1\EVSPROD\nda219122\0001\m1\us\1-14-1-3-prescribing-info-label.pdf.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Brynovin would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Brynovin. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Brynovin.

2.2 SAFETY ASSESSMENT

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

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

Azurity did not provide a derivation or intended meaning for the proposed proprietary name, Brynovin, in their submission. This proprietary name is comprised of a single word that contains the letter string "IN", which is a medical abbreviation for the route of administration "intranasal". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the letter string "IN" is a common letter string in existing drug nomenclature (e.g., Agrylin, Avastin, Dilantin, Herceptin, etc.) and we are unaware of post-market reports of medication errors associated with this specific abbreviation through our routine surveillance. Due to the placement of this medical abbreviation within the proposed proprietary name, we evaluated the potential risk of misinterpreting the proposed proprietary name as "Brynov IN" and did not identify any concerns. In addition, the dosage form for Brynovin (oral solution) and packaging (amber glass bottle) may help mitigate potential for wrong site of application errors because medications intended for administration in the nose are typically packaged in spray bottles. Therefore, in this case we do not object to the proposed proprietary name based on the inclusion of this medical abbreviation. Brynovin does not contain any other 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 February 6, 2024, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Brynovin at the initial phase of the review.

[c] USAN stem search conducted on January 19, 2024.

2.2.4 FDA NAME SIMULATION STUDIES

Seventy-seven practitioners participated in DMEPA's prescription studies for Brynovin. We note that three participants in the FDA name simulation voice study interpreted the proposed name, Brynovin, to start with the letter 'r' (Renoven, n = 1; Renovin, n = 1; and Ronovin, n = 1). We considered these interpretations in our analysis. Additionally, we note that 'Renovin' and 'Renoven' are close variations to the marketed product 'Renova' identified in our POCA search. Orthographically, Brynovin and Renova have sufficient differences. Phonetically, the ending sound of the suffix ('-vin' vs. '-va') offers some phonetic difference. Additionally, the products differ in strength (25 mg/mL vs. 0.02% and 0.05%) and a prescription for Renova should include the strength. The dose is also different (100 mg (4 mL) vs. a pea sized amount or apply to acne lesions) and should be specified on the prescription. There is no overlap in the route of administration (oral vs. topical), dosage form (oral solution vs. cream), and indication (diabetes vs. acne), which provides additional differentiation if included on a prescription/order. Therefore, we determined that the risk for name confusion is adequately minimized (Appendix E).

Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[d] identified 202 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, and 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 ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	197
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 202 names contained in Table 2 determined none of the names will pose a risk for confusion with Brynovin as described in Appendices C through H.

[d] POCA search conducted on January 19, 2024 in version 5.5.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On April 2, 2024, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Brynovin, is conditionally acceptable.

If you have any questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO AZURITY PHARMACEUTICALS

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

A request for proprietary name review for Brynovin should be submitted once your marketing application is submitted.

If any of the proposed product characteristics as stated in your submission, received on January 4, 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.[e]

*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.

[e] 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[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 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-

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

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?		

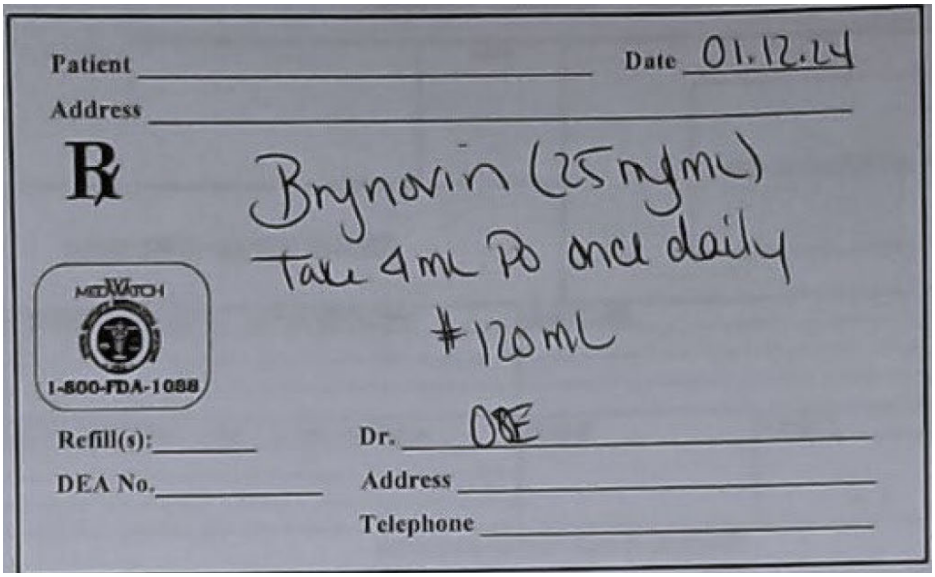
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)
• Do the names begin with different first letters?
• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
• *FDA considers the length of names different if the names differ by two or more letters.
• Considering variations in scripting of some letters (such as z and f), is there a different number or</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤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?	

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. Brynovin Study (Conducted on 1/12/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Brynovin 25 mg per milliliter. Take 4 milliliters by mouth once daily. Dispense 120 mililiters.
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Brynovin	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Brynovin People Received Study: 165 People Responded: 77					
Total	19	19	19	20	77
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
BRENOVEN	0	0	2	0	2
BRENOVIN	0	0	3	0	3
BREWNOVIN	0	0	1	0	1
BRINOVEN	0	0	3	0	3

BRINOVIN	0	0	4	0	4
BRUNOVIN	0	0	1	0	1
BRYNORIN	1	0	0	0	1
BRYNOVIA	1	0	0	0	1
BRYNOVIM	1	0	0	0	1
BRYNOVIN	13	19	0	20	52
BRYNOVIRA	1	0	0	0	1
BRYNOVRA	1	0	0	0	1
BRYNOVUN	1	0	0	0	1
GRINOVEN	0	0	1	0	1
RENOVEN	0	0	1	0	1
RENOVIN	0	0	1	0	1
RONOVIN	0	0	1	0	1
VRENOVEN	0	0	1	0	1

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

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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.	Brynovin	100	This name is the subject of this review.
2.	Bronitin	74	Brand discontinued with no generic equivalents available. NDA 016126 withdrawn FR effective 06/18/2009.
3.	Broncolin	71	Orthographically, Brynovin has a downstroke letter 'y' in the 3rd position whereas Broncolin has an upstroke letter 'l' in the 7th position providing some orthographic differences. Phonetically, the first syllable ('bry-' vs 'bron-') of this name pair sounds different. The first part of the second ('-no-' vs. '-co-') and third syllable ('-vin' vs. '-lin') also sound different providing some phonetic differences. Broncolin is a family name used for a variety of over-the-counter products. A dosage form (ointment, capsules, lozenge) would have to be specified for this product. The dose/frequency of these products (Broncolin Ointment [Rub on throat and chest up to three times daily], Broncolin Cold and Flu Relief [2 soft gels every 4 hours], Brocolin Herbal Extracts and Honey, Broncolin Honey Eucalyptus, Broncolin Honey Lemon [Dissolve 1 drop in the mouth, may repeat every hour as needed]) do not overlap with the recommended dosing for Brynovin, which further differentiates this family of products from Brynovin.

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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.
			When all the aforementioned mitigations are considered in totality, we find the risk of confusion adequately minimized in this case.

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.	Tritocin	66
2.	Prazosin	64
3.	Benzoin	62
4.	Oncovin	58
5.	Bleomycin	57
6.	(b) (4)	56
7.	Biotin	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: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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.	(b) (4)	66	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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.	Propoven	66	This name pair has sufficient orthographic and phonetic differences.
3.	Brovana	65	Orthographically, the infixes ('-no-' vs. '-va-') and suffixes ('vin' vs. '-na') look different. Brynovin has one downstroke letter ('y') in the third position while Brovana has no downstroke letters. Phonetically, this name pair has sufficient phonetic differences.
4.	Bridion	64	This name pair has sufficient orthographic and phonetic differences.
5.	Brenzavvy	62	This name pair has sufficient orthographic and phonetic differences.
6.	Breyanzi	62	Orthographically, the infixes ('-no-' vs. '-yan-') and suffixes ('vin' vs. '-zi') look different. Phonetically, this name pair has sufficient phonetic differences. The following product characteristics may provide additional differentiation if included: 1. There is no direct overlap in dose and frequency of administration (100 mg (4 mL) once daily vs. single dose containing a target of 100×10^6 CAR-positive viable T cells two to seven days after completion of lymphodepleting chemotherapy) or route of administration (oral vs. intravenous).

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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. Breyanzi is unlikely to be dispensed from a pharmacy as it is patient-specific Chimeric Antigen Receptor (CAR) T cell product that consists of two individually formulated CD4+CAR+ and CD8+CAR+ frozen T cell suspensions prepared in patient-specific 5 mL infusion vials stored frozen (-130˚ C). 3. It is shipped in liquid nitrogen to be administered by trained qualified personal. A patient's name and identifier will be on each dose because patients receiving Breyanzi undergo leukapheresis to enable patient-specific product generation. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
7.	Synovacin	62	This name pair has sufficient orthographic and phonetic differences.
8.	Vytorin	62	This name pair has sufficient orthographic and phonetic differences.
9.	Premarin	62	This name pair has sufficient orthographic and phonetic differences.
10.	Prandin	62	This name pair has sufficient orthographic and phonetic differences.
11.	Trimo San	62	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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
12.	Braftovi	61	This name pair has sufficient orthographic and phonetic differences.
13.	Benoquin	60	This name pair has sufficient orthographic and phonetic differences.
14.	Briellyn	60	This name pair has sufficient orthographic and phonetic differences.
15.	Byooviz	60	Orthographically, the location of the downstroke letter 'y' (third position vs. second position) offers some difference in shape. Additionally, the infixes ('-nov-' vs. '-oo-') look different offering some orthographic difference. Phonetically, this name pair has sufficient phonetic differences. The following product characteristics may provide additional differentiation if included: 1. There is no overlap in the dose and frequency of administration (100 mg (4 mL) once daily vs. 0.5 mg once monthly) or route of administration (oral vs. intravitreal). 2. In this case, the practice settings for each product would further mitigate the potential for confusion between the products. Brynovin is an oral solution primarily used in the outpatient setting for chronic daily use whereas Byooviz must be administered by intravitreal

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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
			injection under aseptic conditions by a qualified retinal specialist in a healthcare setting. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
16.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
17.	Banophen	59	This name pair has sufficient orthographic and phonetic differences.
18.	Dromoran	59	This name pair has sufficient orthographic and phonetic differences.
19.	Brineura	58	This name pair has sufficient orthographic and phonetic differences.
20.	Briumvi	58	This name pair has sufficient orthographic and phonetic differences.
21.	Broncotron	58	This name pair has sufficient orthographic and phonetic differences.
22.	Bronkaid	58	This name pair has sufficient orthographic and phonetic differences.
23.	Bronkids	58	This name pair has sufficient orthographic and phonetic differences.
24.	Bydureon	58	This name pair has sufficient orthographic and phonetic differences.
25.	Tru-Micin	58	This name pair has sufficient orthographic and phonetic differences.
26.	Brimonidine	57	This name pair has sufficient orthographic and phonetic differences.
27.	Berinert	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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
28.	Biotussin	56	This name pair has sufficient orthographic and phonetic differences.
29.	Novolin	56	This name pair has sufficient orthographic and phonetic differences.
30.	Novolin 70/30	56	This name pair has sufficient orthographic and phonetic differences.
31.	Renova	56	Orthographically, this name pair has sufficient orthographic differences. Phonetically, the ending sound of the suffix ('-vin' vs. '-va') offers some phonetic differences. The following differences in product characteristics may also help to minimize the risk of errors: 1. The products differ in strength (25 mg/mL vs. 0.02% and 0.05%) and a prescription for Renova should include the strength. 2. The dose is also different (100 mg (4 mL) vs. a pea sized amount or apply to acne lesions) and should be specified on the prescription. 3. There is no overlap in the route of administration (oral vs topical), dosage form (oral solution vs cream), and indication (diabetes vs acne) which provides additional differentiation if included on a prescription/order. When all of the aforementioned mitigations are considered in totality, we

No.	Proposed name: Brynovin Established name: sitagliptin hydrochloride Dosage form: oral solution Strength(s): 25 mg/mL Usual dose: 100 mg (4 mL) 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
			find the risk of confusion is adequately minimized in this case.
32.	Novolin N	56	This name pair has sufficient orthographic and phonetic differences.
33.	Riboflavin	56	This name pair has sufficient orthographic and phonetic differences.
34.	Novolin R	55	This name pair has sufficient orthographic and phonetic differences.
35.	(b) (4)	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.	Granumed	49
2.	Norvir	48

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 NDA (b) (4) found to be acceptable (OSE# (b) (4)); however, the entire application was withdrawn by the Applicant on (b) (4)
2.	Breonesin	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Brevicon	66	Brand discontinued with no generic equivalents available. NDA 017566 and NDA 017743 withdrawn FR effective 11/19/2018 and 01/22/2021, respectively.
4.	Bromine	66	Product is not a drug. It is a chemical compound.

No.	Name	POCA Score (%)	Failure preventions
5.	Primycin	66	International product marketed in the Philippines.
6.	Bromaphen	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Propovan	64	International product marketed in Argentina, Brazil, Philippines, Argentina, and Venezuela.
8.	Renovist	64	Brand discontinued with no generic equivalents available.
9.	Trinalin	64	Brand discontinued with no generic equivalents available. NDA 018506 withdrawn FR effective 04/04/2005.
10.	Varenzin	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Brivudine	63	International product marketed in numerous countries
12.	Bromatan	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	B-12 Resin	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Fibro-Vein	62	International product marketed in United Kingdom.
15.	(b) (4)	62	Proposed proprietary name for IND 137856 found unacceptable by DMEPA (OSE# 2020-1043779388). NDA 216264 approved under the proprietary name Bludigo.
16.	Ortho-Novin	61	International product formerly marketed in Ireland.
17.	Bio-Mycin	60	Veterinary Product
18.	Bromaline	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	Bromide Ion	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Brondil	60	International product marketed in Thailand and the Philippines.
21.	Finevin	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
22.	Inoven	60	International product formerly marketed in the UK.

No.	Name	POCA Score (%)	Failure preventions
23.	Otrivin	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
24.	Phrenilin	60 (P 70)	Brand discontinued with no generic equivalents available. ANDA 087811 withdrawn FR effective 01/02/2020.
25.	Benylin	58	Brand discontinued with no generic equivalents available. NDA 006514 withdrawn FR effective 09/25/1997 & NDA 019014 withdrawn FR effective 12/29/1997.
26.	Bisolvon	58	International product marketed in Japan, India, Australia, Mexico, and Germany.
27.	Branchamin	58	Brand discontinued with no generic equivalents available. NDA 018678 withdrawn FR effective 11/15/1990.
28.	Branchamin 4%	58	Brand discontinued with no generic equivalents available. NDA 018678 withdrawn FR effective 11/15/1990.
29.	Bronopol	58	Veterinary Product
30.	Privine	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
31.	(b) (4)	57	Proposed proprietary name for IND 126779 found unacceptable by DMEPA (OSE #2017-13946987). NDA 209355 was approved under the proprietary name Bryhali.
32.	Bio-Tropin	56	Brand discontinued with no therapeutic equivalence (TE) codes provided per Drugs@FDA database, and off the market per Clinical Pharmacology database with no 4.8 mg powder for injection somatropin generic equivalents available. Also identified as an international product marketed in Israel and Mexico per Micromedex Tox and Drug Product Results database.
33.	Barmine	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Barophen	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
35.	Bovadine	56	Veterinary Product

No.	Name	POCA Score (%)	Failure preventions
36.	Brevidil	56	International product formally marketed in the UK.
37.	Brevidil M	56	International product formally marketed in the UK.
38.	Bromanyl	56	Brand discontinued with no generic equivalents available. ANDA 088343 withdrawn FR effective 5/13/2002.
39.	Bromuphed	56 (P 78)	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Bronchodil	56	International product marketed in India.
41.	Bronkodyl	56	Brand discontinued with no generic equivalents available. ANDA 085264 withdrawn FR effective 08/31/2000.
42.	Brucine	56	Product is not a drug. It is a type of seed.
43.	Enovid	56	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 010976 withdrawn FR effective 06/18/2009.
44.	Ergonovine	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
45.	Otrivine	56	International product marketed in the United Kingdom.
46.	Progynova	56	International drug product marketed in various countries including Ukraine, Argentina, Australia, Austria, Belgium, Chile, China, Finland, and France.
47.	(b) (4)	56	(b) (4)
48.	Rynatan	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
49.	Brolene	55	International Product marketed in the UK, Australia, Greece, and Ireland.
50.	Bromelains	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	Bunazosin	55	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 confusion[g]

No.	Name	POCA Score (%)
1.	Prinivil	64
2.	Romozin	64
3.	Trobicin	64
4.	Fibrinogen	62
5.	Minocin	62
6.	Roymicin	61
7.	Vibramycin	61
8.	Crinone	60
9.	Dynacin	60
10.	Prodrin	60
11.	Thrombin	60
12.	Tobramycin	60
13.	Tri-Nefrin	60
14.	Trioxin	60
15.	Trypsin	60
16.	Noromycin	59
17.	Privigen	59
18.	Prudoxin	59
19.	Rimoxyn	59
20.	Romycin	59
21.	Trovan	59
22.	Durabolin	58
23.	Durabolin 50	58
24.	Lanozin	58
25.	Merbromin	58
26.	Naringin	58
27.	Normison	58

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

No.	Name	POCA Score (%)
28.	Obredon	58
29.	Paromycin	58
30.	Paroven	58
31.	Pro-Vent	58
32.	Reno-Dip	58
33.	Ribavirin	58
34.	Travogyn	58
35.	Tretinoin	58
36.	Vanobid	58
37.	Agrimycin	57
38.	Cromolyn	57
39.	Dronabinol	57
40.	Drotaverin	57
41.	Dynaxin	57
42.	Fibrinogen,I-125	57
43.	Neurontin	57
44.	Principen	57
45.	Principen '125'	57
46.	Principen '250'	57
47.	Principen '500'	57
48.	Prozinc	57
49.	Renamin	57
50.	Renamin 6.5	57
51.	(b) (4)	57
52.	Zarontin	57
53.	Adrenalin	56
54.	Auranofin	56
55.	Chibroxin	56
56.	Chymosin	56
57.	Corydine	56
58.	Crocin	56
59.	Droncit	56

No.	Name	POCA Score (%)
60.	Duramycin	56
61.	Green-Tussin	56
62.	Klonopin	56
63.	Noroxin	56
64.	Pricortin	56
65.	Pri-Cortin 50	56
66.	Primaxin	56
67.	Proferrin	56
68.	Promazine	56
69.	Protropin	56
70.	Razoxin	56
71.	Remedy 4-In-1	56
72.	Remeven	56
73.	Rimifon	56
74.	Robaxin	56
75.	Robaxin-750	56
76.	Sprayzoin	56
77.	Triolein	56
78.	Tronolane	56
79.	Vancocin	56
80.	Ventolin	56
81.	Viroxyn	56
82.	(b) (4)	56
83.	Aminosyn	55
84.	Aminosyn 10	55
85.	Aminosyn 10%	55
86.	Aminosyn 3.5	55
87.	Aminosyn 3.5%	55
88.	Aminosyn 5	55
89.	Aminosyn 5%	55
90.	Aminosyn 7	55
91.	Aminosyn 7%	55

No.	Name	POCA Score (%)
92.	Aminosyn 8.5	55
93.	Aminosyn 8.5%	55
94.	Cybolin-12	55
95.	Dermabon	55
96.	Fortolin	55
97.	Orbivan	55
98.	Primidone	55
99.	Probuphine	55
100.	Rebinyn	55
101.	Robimycin	55
102.	Tenormin	55
103.	Trovan Iv	55
104.	Tryptophan	55

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

/s/

VRAJ K PATEL
04/02/2024 11:13:45 AM

DAMON A BIRKEMEIER
04/02/2024 11:24:46 AM

MISHALE P MISTRY
04/02/2024 12:14:42 PM