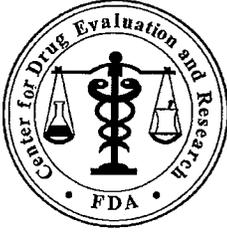


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-911

PROPRIETARY NAME REVIEW(S)



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: October 16, 2008

To: Russell Katz, MD, Director
Division of Neurology Drug Products

Thru: Kellie Taylor, PharmD, MPH, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis

From: Jinhee J. Lee, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name: Banzel (Rufinamide) Tablets
100 mg, 200 mg, 400 mg

Application Type/Number: NDA 21-911

Applicant: Eisai Medical Research Inc.

OSE RCM #: 2008-1320

This document contains proprietary and confidential information that should not be released to the public.

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EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found that the proposed name, Banzel, is vulnerable to name confusion that could lead to medication errors with the name _____ is currently an investigation new drug application in the Agency. At this time, the acceptability of the proprietary name, Banzel, is dependent upon which application is approved first. If Banzel is approved first, we will recommend that the second product, _____, seek an alternate name. b(4)

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, we rescind this Risk Assessment finding, and recommend that the name be resubmitted for review. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

1 BACKGROUND

1.1 INTRODUCTION

This consult was written in response to a request from the Division of Neurology Drug Products for assessment of the proprietary name "Banzel" regarding potential name confusion with other proprietary or established drug names.

Additionally, revised container labels, carton, and insert labeling were not provided for evaluation at the time of this review. Refer to OSE Review 2008-485, dated September 2, 2008 for label and labeling recommendations. Please submit revised labels and labeling when available.

1.2 REGULATORY HISTORY

1.3 PRODUCT INFORMATION

Banzel is the proposed name for Rufinamide. Banzel is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and in adults. Banzel is available in 100 mg, 200 mg, and 400 mg tablets. b(4)

Children: Treatment should be initiated at a daily dose of approximately 10 mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10 mg/kg increments every other day to a target dose of 45 mg/kg/day or 3200 mg per day, whichever is less, administered in two equally divided doses.

Adults: Treatment should be initiated at a daily dose of 400 mg to 800 mg per day administered in two equally divided doses. The dose should be increased by 400 mg to 800 mg per day every 2 days until a maximum of 3200 mg per day in two equally divided doses is reached.

*** Name pending approval. Not FOI releasable.

2 METHODS AND MATERIALS

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Banzel, and the proprietary and established names of drug products existing in the marketplace and those pending IND, BLA, NDA, and ANDA products currently under review by CDER.

For the proprietary name, Banzel, the medication error staff of DMEPA search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). DMEPA also conducts internal CDER prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see detail 2.1.3).

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see detail 2.1.3). The overall risk assessment is based on the findings of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.¹ FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap, or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. As such, the Staff considers the product characteristics associated with the proposed drug throughout the risk assessment, since the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed drug name include, but are not limited to established name of the proposed product, the proposed indication, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

2.1.1 Search Criteria

The medication error staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

¹ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

For this review, particular consideration was given to drug names beginning with the letter 'B' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.³⁴

To identify drug names that may look similar to Banzel, the Staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (6 letters), upstrokes (2, capital letter 'B', 'l'), down-strokes (one, if "z" is scripted), cross-strokes (one, 'z'), and dotted letters (none). Additionally, several letters in Banzel may be vulnerable to ambiguity when scripted, including the letter 'B' may appear as 'D', 'P', 'R', 'V', or 'Z'; lower case 'a' appear as a lower case 'u'. As such, the Staff should also consider these alternate appearances when identifying drug names that may look similar to Banzel.

When searching to identify potential names that may sound similar to Banzel, the medication error staff search for names with similar number of syllables (2), stresses (BAN-zel or ban-ZEL), consonant sound pronunciation ("Ban" versus "Bohn" or "zel" versus "zul"), and placement of vowel and consonant sounds. In addition, several letters in Banzel may be subject to interpretation when spoken, including the letter 'B' which may be misinterpreted as 'D', 'V', or 'P'; the letter 'z' may be misinterpreted as 'c' or 's'; and 'm' may be misinterpreted as 'n'. As such, the staff also consider these alternate pronunciations when identifying drug names that may sound similar to Banzel. The Applicant's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the medication error staff were provided with the following information about the proposed product: the proposed proprietary name (Banzel), the established name (Rufinamide), proposed indication (treatment of seizures associated with Lennox-Gastaut Syndrome), strength (100 mg, 200 mg, 400 mg), dose (400 mg to 3200 mg in divided doses), frequency of administration (twice daily), route (oral) and dosage form of the product (tablet). Appendix A provides a more detailed listing of the product characteristics the medication error staff general take into consideration.

Lastly, the medication error staff also consider the potential for the proposed name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. As such, these broader safety implications of the name are considered and evaluated throughout this assessment and the medication error staff provide additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

2.1.1.1 Databases and Information Sources

The proposed proprietary name, Banzel, was provided to the medication error staff of DMEPA to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to Banzel using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 6. To complement the process, the medication error staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic

³ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

⁴ Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the medication error staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

2.1.1.2 CDER Expert Panel Discussion

An Expert Panel Discussion is held by DMEPA to gather CDER professional opinions on the safety of the product and the proprietary name, Banzel. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of the DMEPA staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

The pooled results of the medication error staff were presented to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

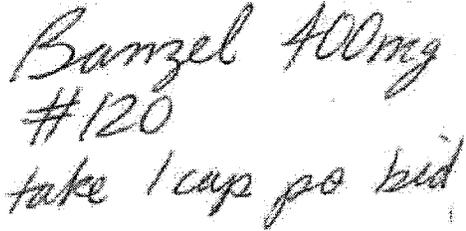
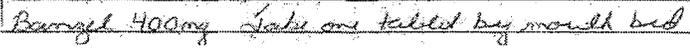
2.1.2 FDA Prescription Analysis Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Banzel with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ a total of 123 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The results are used by the Safety Evaluator to identify any orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Banzel in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These prescriptions are optically scanned and one prescription is delivered to a random sample of 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to the medication error staff.

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Figure 1. Banzel Study (conducted on September 23, 2008)

| HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER | VERBAL PRESCRIPTION |
|---|---|
| <p><u>Outpatient Prescription:</u></p>  | <p>Banzel 400 mg Dispense # 120 1 capsule by mouth twice daily.</p> |
| <p><u>Inpatient Medication Order :</u></p>  | |

2.1.3 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Modes and Effects Analysis and provide an overall risk of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁵ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix A. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, expert panel evaluation, and studies, and identifies potential failure modes by asking: "Is the name Banzel convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?" An affirmative answer indicates a failure mode and represents a potential for Banzel to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the

⁵ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated to determine the likely *effect* of the drug name confusion, by asking “Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?” The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would ultimately not be a source of medication errors in the usual practice setting, the name is eliminated from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

DMEPA will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator’s Risk Assessment:

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council’s definition.
5. Medication error staff identify a potential source of medication error within the proposed proprietary name. The proprietary name may be misleading, or inadvertently introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval: whichever product is awarded approval first has the right to the use the name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

If none of these conditions are met, then DMEPA will not object to the use of the proprietary name. If any of these conditions are met, then DMEPA will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Applicant; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the IOM, WHO, JCAHO, and ISMP, have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken in the past; but at great financial cost to the Applicant, and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval (see limitations of the process).

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the FMEA process is used to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name, and so DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 *Databases and information sources*

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DMEPA's searches identified 23 names as having some similarity to the name Banzel.

Eleven of the 23 names were thought to look like Banzel, which include: Banalg, Banjil, Danazol, Panafil, Pandel, Ranzil, Renagel, Renax, and Zenapax. Two names, Paxil, were thought to sound like Banzel. Ten names (Banflex, Bannal, Bensal HP, Bentyt, Benzac, Benzagel, Benzoin, Benzoyl peroxide, Benzyl benzoate, and Vansil) were thought to look and sound similar to Banzel.

A search of the United States Adopted Name (USAN) stem list on September 16, 2008 identified no USAN stems within the proposed name, Banzel.

3.1.2 *CDER Expert Panel Discussion*

The Expert Panel reviewed the pool of names identified by the DMEPA staff (see section 3.1.1. above) and noted no additional names.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.1.3 *FDA Prescription analysis studies*

A total of 32 practitioners responded. None of the responses overlap with any existing or proposed drug names. About eighty-one percent of the participants (n=26) interpreted the name correctly as "Banzel".

5 CONCLUSIONS AND RECOMMENDATIONS

The results of the Proprietary Name Risk Assessment found that the proposed name, Banzel, is vulnerable to name confusion in the usual practice setting that could lead to medication errors because of its orthographic similarity and overlapping product characteristics to _____ . At this time, the acceptability of the proprietary name, Banzel, is dependent upon which application is approved first. _____ is currently an investigational new drug application in the Agency. If Banzel is approved first, we will recommend that the second product, _____ , seek an alternate name.

b(4)

If **any** of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. If the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

5.1 COMMENTS TO THE DIVISION

DMEPA would appreciate feedback of the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy DMEPA on any communication to the sponsor with regard to this review. If you have further questions or need clarifications, please contact Daniel Brounstein, OSE project manager, at 301-796-0674.

5.2 COMMENTS TO THE APPLICANT

5.2.1 *Proprietary Name Assessment*

DMEPA has determined that the name Banzel is vulnerable to confusion with a product that is currently undergoing review by the Agency. In the event that the other application is awarded approval prior to your application, DMEPA will object to your name and recommend that you seek an alternate name for your product.

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6 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

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

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO*** (<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. ***AMF Decision Support System [DSS]***

DSS is a government database used to track individual submissions and assignments in review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***Electronic online version of the FDA Orange Book*** (<http://www.fda.gov/cder/ob/default.htm>)

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

Provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

10. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

12. Stat!Ref (www.statref.com)

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)

List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

Contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

15. Lexi-Comp (www.lexi.com)

A web-based searchable version of the Drug Information Handbook.

16. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

The medication error staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The medication error staff also examine the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly *and* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has lead to medication errors. The medication error staff apply their expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (i.e. “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the medication error staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, because the Applicant has little control over how the name will be spoken in practice, DMEPA also considers a variety of pronunciations that could occur in the English language.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name

| Type of similarity | Considerations when searching the databases | | |
|--------------------|---|--|---|
| | Potential causes of drug name similarity | Attributes examined to identify similar drug names | Potential Effects |
| Look-alike | Similar spelling | Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics | <ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication |
| | Orthographic similarity | Similar spelling Length of the name Upstrokes Downstrokes Cross-strokes | <ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication |

| | | |
|--------|--|--|
| Banzel | | |
| Benzel | | |
| Banzel | | |
| Banzel | | |

Appendix C: Names that lack convincing orthographic and/or phonetic similarities

| Name | Similarity to Banzel |
|---|----------------------|
|  | Look |
| Panafil | Look |
| Pandel | Look |
| Renax | Look |
| Zenapax | Look |
|  | Sound |
| Paxil | Sound |
| Banflex | Look and Sound |

Appendix D: Products with information not available.

| Name | Similarity to Banzel | |
|--------|----------------------|---|
| Bannal | Look and Sound | Herbal Product |
| Banji | Look and Sound | This is an unofficial term for marijuana. |

Appendix E: Products which have either been discontinued and no longer available in generic form or products whose proposed proprietary names were found unacceptable or withdrawn.

| Product name with potential for confusion | Similarity to Banzel | Status |
|---|----------------------|--|
| Vansil (Oxamniquine) | Look and Sound | This product has been discontinued and is not available in generic form. |
| Benzyl Benzoate | Look and Sound | This application was withdrawn by COMMISSIONER on April 6, 1971. |
| _____ | Look and Sound | This application was withdrawn by _____ |
| _____ | Look and Sound | This application was withdrawn by _____ |

b(4)

Appendix F: Proprietary names used only in Foreign Countries

| Proprietary Name | Similarity to Toviaz | Country |
|------------------|----------------------|--|
| Banjil | Look | Korea – active ingredient is urea. |
| Ranzil | Look | Mexico – active ingredient is ranitidine, however, this product is no longer actively marketed here. |
| Bonzol | Look and sound | Mexico – active ingredient is lansoprazole. |

*** This document contains proprietary and confidential information that should not be released to the public.***

Appendix G: Products with no numerical overlap in strength and dose.

| Product name with potential for confusion | Similarity to Banzel | Strength | Usual Dose (if applicable) |
|---|----------------------|---|---|
| Banzel (Rufinamide) | | 100 mg, 200 mg, 400 mg | Usual dose: 400 mg to 3200 mg in divided doses twice daily. |
| Banal (camphor, menthol, methyl salicylate) | Look | 2%/1%/4.9% topical lotion | Apply fast vanishing lotion with gentle massage to affected area not more than 3 to 4 times daily. |
| Bensal HP (benzoic acid/salicylic acid) | Look and Sound | 60 mg/gm and 30 mg/gm topical ointment | Spread a generous quantity evenly over the desired area to yield a thin continuous layer of approximately 1/8 of an inch of thickness. |
| Benzac (Benzoyl peroxide/clindamycin phosphate) | Look and Sound | 5%/1% gel | Apply twice daily, morning and evening, or as directed by MD, to affected areas after skin is gently washed, rinsed with warm water and patted dry. |
| Benzagel-5 Benzagel-10 (Benzoyl peroxide) | Look and Sound | 5%, 10% Topical Gel | Apply once or twice daily. |
| Benzoyl peroxide 2 ½ (Rx) Benzoyl Peroxide 5% Wash (Rx) Benzoyl Peroxide 10% Wash (Rx) Benzoyl Peroxide (Rx) | Look and Sound | 2.5% Topical Liquid 5% Topical Liquid 10% Topical Liquid 5%, 10% Topical Lotion 2.5%, 5%, 10% Topical Gel | Apply once or twice daily. |

Appendix H: Potential confusing name with numerical overlap in strength or dose

| Banzel (Rufinamide) | 100 mg, 200 mg, 400 mg | Usual dose: 400 mg to 3200 mg in divided doses twice daily. |
|------------------------------|---|--|
| Failure Mode: Name confusion | Causes (could be multiple) | Effects |
| Danazol (Danazol) | <p>Orthographic similarity - Both names begin with letters that resemble each other when scripted ('Dan-' vs. 'Ban-') and have similar looking endings ('-zol' versus '-zel').</p> <p>Both have overlapping strengths (100 mg and 200 mg), usual dose (100 mg to 800 mg in divided doses vs. 400 mg to 3600 mg in divided doses), route of administration (oral), dosage form (capsule/tablet), and frequency of administration (twice daily) .</p> | <p>Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>When written, the names appear similar, however, the addition of another letter in the name Danazol, helps to distinguish this name from the proposed name, Banzel, because it lengthens the appearance of the name. Thus, despite some orthographic similarities and an overlap in strength, dosage form, route of administration, dosage, and frequency, we believe the risk for medication error is minimized by the orthographic differences in the names.</p> |
| Renagel (Sevelamer HCl) | <p>Orthographic similarity - Both names begin with letters that resemble each other when scripted ('Dan-' vs. 'Ban-') and have similar looking endings ('-gel' versus '-zel').</p> <p>Both have overlapping strengths (400 mg and 800 mg), dosage ranges (2400 mg to 4800 mg vs. 400 mg to 3600 mg), route of administration (oral), and dosage form (tablet).</p> | <p>Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic differences in the names. The placement of an additional letter in the middle of the name, Renagel, helps to differentiate the two names from each other.</p> <p>Despite some overlapping product and orthographic characteristics, we believe the risk for medication error to be minimal given the additional letter in Renagel.</p> |
| Benzoin (Benzoin) - OTC | <p>Orthographic and phonetic similarity -Both names begin with letters that resemble each other when scripted ('Benz-' vs. 'Banz-') and spoken. They both have two syllables and a similar number of letters (seven versus six).</p> <p>Both have a numerical similarity</p> | <p>Orthographic and phonetic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic and phonetic differences in the names. Although the names both begin with letters that resemble each other in script and speech ('Benz-'</p> |

| | | |
|---------------------------------|---|--|
| | <p>in strength (100 gm, 20 gm, and 40 gm versus 100 mg, 200 mg, and 400 mg).</p> | <p>versus 'Banz-') the upstroke letter in Banzel helps to differentiate the two names from each other. Furthermore, the remaining letters in Benzoin are distinct in sound from Banzel.</p> <p>The two products have a numerical similarity in strength, however, they do not share any other product characteristics, further differentiating the two products from each other. Thus, despite some overlapping product, phonetic and orthographic characteristics, we believe the risk for medication error to be minimal given the differences in their suffixes and product characteristics.</p> |
| <p>Bentyl (Dicyclomine HCl)</p> | <p>Orthographic and phonetic similarity - Both names begin with letters that resemble each other when scripted and pronounced ('Ben-' vs. 'Ban-') and the last two letters also sound-alike ('-yl' versus '-el'). Both have two syllables and are six letters in length</p> <p>Both have a numerical similarity in strength (10 mg and 20 mg versus 100 mg and 200 mg), route of administration (oral), and dosage form (tablet/capsule).</p> | <p>Orthographic and phonetic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p>Rationale:</p> <p>The risk for medication error is minimized by the orthographic and phonetic differences in the names. Although the names both begin with letters that resemble each other in script and speech ('Ben-' versus 'Ban-') and have a downstroke and upstroke letter placed in similar positions, the upstroke letter in the middle of the name Bentyl ("t") helps to differentiate the two names from each other. Furthermore, the remaining letters in Benzoin are distinct in sound from Banzel.</p> <p>The two products have a numerical similarity in strength, however, they do not share an overlapping dose (160 mg versus 400 mg to 3200 mg), and frequency of administration (four times daily versus twice daily), further differentiating the two products from each other. Thus, despite some overlapping product, phonetic and orthographic characteristics, we believe the risk for medication error to be minimal given the placement of the upstroke letter, "t", in Bentyl, and differences in product characteristics.</p> |

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