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RESEARCH**

APPLICATION NUMBER:

206426Orig1s000

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
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: March 4, 2014

Reviewer: James Schlick, RPh, MBA
Division of Medication Error Prevention and Analysis

Team Leader: Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Rapivab (Peramivir) Injection
200 mg/20 mL (10 mg/mL)

Application Number: NDA 206426

Applicant: Biocryst Pharmaceuticals, Inc.

OSE RCM #: 2013-16754

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Rapivab, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

The proposed proprietary name, Rapivab, was reviewed in OSE Review# 2010-1951 under IND 069038, dated March 4, 2011, and was found acceptable. The frequency of administration for peramivir has changed since our previous review. See Section 1.2 for the changes in frequency.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 21, 2013 proprietary name submission.

- Active Ingredient: Peramivir
- Indication of Use: Treatment of acute uncomplicated influenza in patients 18 years and older
- Route of Administration: Intravenous Infusion
- Dosage Form: Solution for injection
- Strength: 200 mg/20 mL (10 mg/mL)
- Dose and Frequency: A single 600 mg intravenous infusion over a minimum of 15 minutes. No dose adjustments for hepatic or renal insufficiency are required.

Dose and frequency presented in OSE Review # 2010-1951, dated March 4, 2011	Dose and frequency presented in the current submission
600 mg intravenously over a minimum of 15 minutes once daily (b) (4)	A single 600 mg dose given intravenously over a minimum of 15 minutes

- How Supplied/Container and Closure Systems: Vials each containing 200 mg per vial; Carton containing 3 vials per carton
- Storage: 20°C to 25°C (68°F to 77°F).

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

During our review, the Division of Antiviral Products (DAVP) provided the following comment:

“Rapi” sounds promotional. DAVP also noticed with RAPIACTA (the trade name for peramivir in Japan), and now with RAPIVAB, the use of “RAPI” suggests “rapid”, which might imply “fast acting” or “rapid improvement”. It’s more blatant with RAPIACTA, which to me sounds like “rapid acting”.

DAVP’s comments were forwarded to the Office of Prescription Drug Promotion (OPDP) for consideration. OPDP maintained their non-objection to the name because they previously reviewed the name and did not object, and OPDP did not object to the proposed proprietary name (b) (4)***. Furthermore, OPDP stated that unlike the trade name in Japan, Rapiacta, this proposed name does not have a suffix in addition to “rapi-“ that would evoke the term “rapid acting”.

DMEPA concurs with OPDP’s rationale. DAAAP responded to OPDP’s comments on February 19, 2014 with no further objections to the name Rapivab.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.¹

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Rapivab, has no intended meaning. This proprietary name is comprised of a single word that does not contain a modifier, route of administration, or dosage form that is misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Sixty-six practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with any currently marketed products from the United States nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. One participant responded with the name, Rapivir, in the outpatient study which is a marketed product in Mexico. See Appendix D for more details.

Thirty-seven of sixty-six (56%) participants responded correctly. All participants in the inpatient prescription written study responded correctly. In the outpatient prescription written study, the letters ‘v’ and first ‘a’ were misinterpreted as the letters ‘r’ and ‘o’ respectively. In the voice prescription, the letters ‘v’, ‘i’, and ‘b’ were misinterpreted as the letters ‘b’, ‘a’, and ‘p’ respectively.

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¹ USAN stem list searched January 10, 2014.

We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 2, 2014 e-mail, the Division of Antiviral Products (DAVP) forwarded the following comment:

DAVP has not really begun the review of this new NDA, however I forwarded your email to the clinical team and our only concerns so far is that the proposed name sounds more like a biologic or vaccine (from the “ab” at the end of name). No concerns from a promotional or sound alike perspective.

DMEPA reviewed the FDA’s “Complete List of Vaccines Licensed for Immunization and Distribution in the US”², and did not find the suffix ‘-vab’ or ‘-ab’ at the end of any proper or proprietary names. We note that certain biologics contain the USAN stem – mab, such as the established name, Rituximab. However, we are not aware of any evidence to support that the suffix ‘-vab’ in RapiVab implies that the product is a biologic or vaccine. Therefore, DMEPA does not have any concerns with the use of ‘-vab’ in this proposed proprietary name.

DMEPA searched Drugs at FDA Database (See Reference Section 5 for a description of the database) on January 21, 2014 using the search term “mab”. We reviewed each name found for the potential to look or sound like the name RapiVab. See Appendix F for the list of names. DMEPA did not find any names that we determined could be confused with RapiVab.

2.2.5 Failure Mode and Effects Analysis of Similar Names

The potential letter and letter string variations listed in Appendix B were used to search for names with possible orthographic and phonetic similarity to the proposed proprietary name, RapiVab. Table 1 lists the names with orthographic or spelling similarity to the proposed proprietary name, RapiVab, identified by the primary reviewer (PR) and the Expert Panel Discussion (EPD), which were not previously identified and evaluated in OSE Review # 2010-1951.

Because the frequency of administration has changed, we evaluated the previously identified names of potential concern (see OSE Review # 2010-1951) and considered any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our review determined the change in frequency does not alter our previous conclusion.

² <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833>. Accessed on February 25, 2014

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and Other Disciplines)					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Bayrab	FDA	(b) (4)***	FDA	Ravicti	FDA
Pavabid	FDA	Rifamate	FDA	Pipracil	FDA
Kapvay	FDA	Repliva	FDA	Rapivir	FDA
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)***	FDA	Rabavert	FDA		
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Rapivab***	FDA				

Our analysis of the 12 names contained in Table 1 determined all 12 names will not pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Analgesia, Anesthesia, and Addiction Products (DAAAP) via e-mail on February 7, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on February 7, 2014, they provided the following concerns:

- *As noted below, “vab” sounds like mab, therefore making it appear to be a monoclonal Ab.*
- *“Rapi” sounds promotional. DAVP also noticed with RAPIACTA (the trade name for peramivir in Japan), and now with RAPIVAB, the use of “RAPI” suggests “rapid”, which might imply “fast acting” or “rapid improvement”. It’s more blatant with RAPIACTA, which to me sounds like “rapid acting”.*

We want to convey our concerns, but let OSE make the decision based on applying standards you use across other divisions and products.

See section 2.2.4 for the consideration of the suffix ‘-vab’ in our safety assessment. See section 2.1 for the promotional assessment of the proposed proprietary name.

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3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Danyal Chaudhry, OSE project manager, at 301-796-3813.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 21, 2013 submission are altered, the name must be resubmitted for review.

4 REFERENCES

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

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

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. 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.

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

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the 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. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. *Natural Medicines Comprehensive Databases* (www.naturaldatabase.com)

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

10. *Access Medicine* (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

11. *USAN Stems* (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

12. *Red Book* (www.thomsonhc.com/home/dispatch)

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

13. *Lexi-Comp* (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

14. *Medical Abbreviations* (www.medilexicon.com)

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

15. *CVS/Pharmacy* (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

16. *Walgreens* (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. *Rx List* (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

18. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

19. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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.³

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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 reviewer 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because 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.

³ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, 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. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. 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.⁴

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

⁴ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
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/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary 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. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches 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 the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic 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, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of 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 record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with 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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment 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 proprietary name to be confused with another drug name because of name confusion and, thereby, 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 orthographically or phonetically similar 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 primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

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

characteristics listed in Section 1.2 of this review. 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 Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the 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, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes 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 not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name 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 the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’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 PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. 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)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, 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 but involve a naming characteristic that when incorporated into a proprietary name may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, 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, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, 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.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in proposed name, Rapivab	Scripted may appear as	Spoken may be interpreted as
Capital 'R'	B, K,D,P	
Lower case 'r'	s,n,v	
lower case 'a'	c, -ci-, -ce-, el,o	Any vowel
lower case 'p'	x, q,	
lower case 'i'	e, l,	Any vowel
lower case 'v'	r, n	f, b
Lower case 'a'	See above	Any vowel
Lower case 'b'	l, li, ls, h, k, f, te, lo	Silent (may not be heard), d, p
Letter String for 'Rapivab'		
iv	w, m	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Rapivab Study (Conducted on January 23, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <hr/> <p>Rapivab 600mg IV over 15 min</p>	<p>Rapivab #3 Bring to Clinic</p>
<p>Rapivab #3 bring to clinic</p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study				
66 People Responded				
Study Name: Rapivab				
Total	22	18	26	66
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
RAPABAB	0	5	0	5
RAPAVAB	0	5	0	5
RAPAVAB #3	0	2	0	2
RAPAVAP	0	1	0	1
RAPINAB	1	0	0	1
RAPIRAB	8	0	0	8
RAPIVAB	8	2	25	35
RAPIVAB # 3 BRING TO CLINIC	1	0	0	1
RAPIVAB INTRAVENOUSLY OVER 15 MINUTES	0	0	1	1
RAPIVAP	0	1	0	1
RAPIVIR	1	0	0	1
RAPPABAPP	0	1	0	1
REPABAB	0	1	0	1
RIPIVAB	1	0	0	1
ROPIRAB	1	0	0	1
ROPIVAB	1	0	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Rapivab	Failure preventions
1.	Ravicti	Glycerol Phenylbutyrate	Look alike	The name pair has sufficient orthographic differences
2.	Pavabid	Papaverine	Look-alike	The name pair has sufficient orthographic differences
3.	(b) (4)		Sound alike	The name pair has sufficient phonetic differences
4.	Rapivab***	Peramivir	Look and sound alike	Name that is the subject of this review
5.	Rapivir	Valacyclovir	Look alike	International product marketed in Mexico

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Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	Proposed name: <i>Rapivab</i> Dosage Form: <i>Injection</i> Strength: <i>200 mg/20 mL</i> <i>(10 mg/mL)</i> Usual Dose: <i>Single 600 mg intravenous infusion over at least 15 minutes</i>	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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.	<p>BayRab (Rabies Immune Globulin)</p> <p>Solution for Injection</p> <p>150 International Units/mL</p> <p>Usual Dose: A single 20 IU/kg (20 IU to 4,000 IU) intramuscular dose. Administer concurrently with the rabies vaccine.</p>	<p>Orthographic: The letter strings ‘Ba’ and ‘rab’ can look similar to the letter strings ‘Ra’ and ‘vab’ if the letter ‘R’ in BayRab is not capitalized. Both names contain a downstroke letter in the third position.</p> <p>Dose: Possible overlap in dose (600 vs. 600 based on weight for BayRab)</p> <p>Frequency of Administration: Both products are given as a single dose.</p> <p>Strength: Both products are single strength; therefore, the strength may be omitted from the prescription.</p> <p>Dosage Form: Both products are a solution for injection</p>	<p>Orthographic: The additional letter ‘i’ in Rapivab provides a different shape to the name between the downstroke ‘p’ and letter ‘v’ when compared to the downstroke letter ‘y’ and the letter ‘r’ in BayRab. Because of the particular letters the letter ‘i’ is in between in Rapivab, it provides distinction between the name pair. The letter ‘i’ is more prominent due to the scripting after the loop in the letter ‘p’ and before the upstroke to start the letter ‘v’.</p> <p>The letter ‘R’ in BayRab provides differentiation when it is scripted in upper case.</p>

No.	Proposed name: <i>Rapivab</i> Dosage Form: <i>Injection</i> Strength: <i>200 mg/20 mL</i> <i>(10 mg/mL)</i> Usual Dose: <i>Single 600 mg intravenous</i> <i>infusion over at least 15</i> <i>minutes</i>	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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.	(b) (4)		
3.	Rifamate (Isoniazid and Rifampin) Capsules 150 mg/300 mg Usual Dose: 2 capsules orally once daily	Orthographic: Both names begin with the letter 'R' and both names have an upstroke letter in the suffix. The letter 'b' can look similar to the letter string 'te'. Strength: Both products are single strength; therefore, the strength may be omitted from the prescription.	Orthographic: The letter 'm' in Rifamate does not look similar to the letter 'v' when scripted. The letter 'f' does not look similar the letter 'p' when scripted. Frequency of Administration: Once daily vs. a single dose

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No.	Proposed name: <i>Rapivab</i> Dosage Form: <i>Injection</i> Strength: <i>200 mg/20 mL</i> <i>(10 mg/mL)</i> Usual Dose: <i>Single 600 mg intravenous infusion over at least 15 minutes</i>	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
4.	Pipracil (Piperacillin) Powder for Injection 2 gm, 3 gm, 4 gm vial Usual Dose: 200 mg to 4 grams every 6 to 12 hours intramuscularly or via intravenous infusion.	Orthographic: The letter string ‘Pip’ and ‘Rap’ can look similar when scripted. The letter string ‘il’ and ‘ab’ can look similar when scripted. Route of Administration: Both products can be given intravenously Dose: There can be an overlap in dose based on weight with Pipracil	Orthographic: The letter string ‘ra’ in Pipracil does not look similar to the letter ‘i’ when scripted. Strength: Pipracil has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity in strength Frequency of Administration: Every 6 to 12 hours vs. a single dose
5.	Kapvay (Clonidine) Extended-release Tablets 0.1 mg and 0.2 mg Usual Dose: 0.1 mg orally once daily; 0.1 mg or 0.2 mg twice daily, or 0.1 mg in the AM and 0.2 mg in the PM.	Orthographic: The letter strings ‘Kap’ and ‘Rap’ can look similar when scripted. Both names have the letter string ‘va’ in similar positions.	Orthographic: Rapivab has an upstroke letter ‘b’ at the end of the name where Kapvay has the downstroke letter ‘y’ at the end of the name. Thus, the ends of the names have a different shape. Strength: Kapvay has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity in strength Dose: There is no overlap or numerical similarity in dose Frequency of Administration: Once daily or twice daily vs. a single dose

No.	Proposed name: <i>Rapivab</i> Dosage Form: <i>Injection</i> Strength: <i>200 mg/20 mL</i> <i>(10 mg/mL)</i> Usual Dose: <i>Single 600 mg intravenous infusion over at least 15 minutes</i>	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
6.	<p>Repliva 21/7 Multivitamin with Iron and Succinic Acid</p> <p>Tablets 21 multivitamin with iron tablets 7 succinic acid tablets; each with 150 mg</p> <p>Usual Dose: One tablet orally once daily</p>	<p>Orthographic: The letter strings ‘Rep’ and ‘Rap’ can look similar when scripted. Both names have the letter string ‘va’ in similar positions.</p> <p>Strength: Both products are single strength; therefore, the strength may be omitted from the prescription.</p>	<p>Orthographic: Repliva has an upstroke letter ‘l’ in the fourth position where Rapivab does not. Rapivab has an upstroke letter ‘b’ at the end of the name where Repliva does not. Thus, giving the names a different shape.</p> <p>Dose: There is no overlap or numerical similarity in dose</p> <p>Frequency of Administration: Once daily vs. a single dose</p>
7.	<p>Rabavert (Rabies vaccine) for injection</p> <p>2.5 units of rabies antigen per mL</p> <p>Usual Dose: (for prophylaxis post exposure in immunocompetent patients): One milliliter intramuscularly on days 0, 3, 7, 14 and 28.</p>	<p>Phonetic: Both names share the letter string (‘Ra’) and the letter ‘v’ in the fifth position.</p> <p>Overlapping product characteristics include dosage form (injection), route of administration (parenteral) and frequency of administration in 24 hours (once).</p>	<p>Phonetic: The letter string ‘ba’ does not sound similar to the letter string ‘pi’ when spoken. The letter string ‘ert’ does not sound similar to the letter string ‘ab’ when spoken.</p> <p>Differing product characteristics Dose: (1 mL vs. 600 mg)</p>

Appendix F: Search of the *Drugs at FDA* Database using the Search Term “mab”. Search done on 1/21/2014

<u>Drug Name</u>	<u>Active Ingredients</u>
<u>ACTEMRA</u>	<u>TOCILIZUMAB</u>
<u>ADCETRIS</u>	<u>BRENTUXIMAB VEDOTIN</u>
<u>ARZERRA</u>	<u>OFATUMUMAB</u>
<u>AVASTIN</u>	<u>BEVACIZUMAB</u>
<u>BENLYSTA</u>	<u>BELIMUMAB</u>
<u>BEXXAR</u>	<u>TOSITUMOMAB; IODINE I 131 TOSITUMOMAB</u>
<u>CAMPATH</u>	<u>ALEMTUZUMAB</u>
<u>CEA-SCAN</u>	<u>ARCITUMOMAB</u>
<u>CIMZIA</u>	<u>CERTOLIZUMAB PEGOL</u>
<u>DERMABET</u>	<u>BETAMETHASONE VALERATE</u>
<u>ERBITUX</u>	<u>CETUXIMAB</u>
<u>GAZYVA</u>	<u>OBINUTUZUMAB</u>
<u>HEMABATE</u>	<u>CARBOPROST TROMETHAMINE</u>
<u>HERCEPTIN</u>	<u>TRASTUZUMAB</u>
<u>HUMIRA</u>	<u>ADALIMUMAB</u>
<u>ILARIS</u>	<u>CANAKINUMAB</u>
<u>KADCYLA</u>	<u>ADO-TRASTUZUMAB EMTANSINE</u>
<u>LUCENTIS</u>	<u>RANIBIZUMAB</u>
<u>MYLOTARG</u>	<u>GEMTUZUMAB OZOGAMICIN</u>

<u>Drug Name</u>	<u>Active Ingredients</u>
<u>MYOSCINT</u>	<u>IMCIROMAB PENTETATE</u>
<u>PERJETA</u>	<u>PERTUZUMAB</u>
<u>PROLIA</u>	<u>DENOSUMAB</u>
<u>PROTASCINT</u>	<u>CAPROMAB PENDETIDE</u>
<u>RAPTIVA</u>	<u>EFALIZUMAB</u>
<u>RAXIBACUMAB</u>	<u>RAXIBACUMAB</u>
<u>REMICADE</u>	<u>INFLIXIMAB</u>
<u>REOPRO</u>	<u>ABCIXIMAB</u>
<u>RITUXAN</u>	<u>RITUXIMAB</u>
<u>SIMPONI</u>	<u>GOLIMUMAB</u>
<u>SIMPONI ARIA</u>	<u>GOLIMUMAB</u>
<u>SIMULECT</u>	<u>BASILIXIMAB</u>
<u>SOLIRIS</u>	<u>ECULIZUMAB</u>
<u>STELARA</u>	<u>USTEKINUMAB</u>
<u>SYNAGIS</u>	<u>PALIVIZUMAB</u>
<u>TECHNETIUM (99m Tc) FANOLESOMAB; NEUTROSPEC</u>	<u>TECHNETIUM (99m Tc) FANOLESOMAB; NEUTROSPEC</u>
<u>TYSABRI</u>	<u>NATALIZUMAB</u>
<u>VECTIBIX</u>	<u>PANITUMUMAB</u>
<u>VERLUMA</u>	<u>NOFETUMOMAB</u>
<u>XGEVA</u>	<u>DENOSUMAB</u>

<u><i>Drug Name</i></u>	<u><i>Active Ingredients</i></u>
<u><i>XOLAIR</i></u>	<u><i>OMALIZUMAB</i></u>
<u><i>YERVOY</i></u>	<u><i>IPILIMUMAB</i></u>
<u><i>ZENAPAX</i></u>	<u><i>DACLIZUMAB</i></u>
<u><i>ZEVALIN</i></u>	<u><i>IBRITUMOMAB TIUXETAN</i></u>

Appendix G: Complete List of Vaccines Licensed for Immunization and Distribution in the US

Product Name	Trade Name	Sponsor
Adenovirus Type 4 and Type 7 Vaccine, Live, Oral ¹	No Trade Name	Barr Labs, Inc.
Anthrax Vaccine Adsorbed ²	Biothrax	Emergent BioDefense Operations Lansing Inc.
BCG Live ³	BCG Vaccine	Organon Teknika Corp LLC
BCG Live ⁴	TICE BCG	Organon Teknika Corp LLC
Diphtheria & Tetanus Toxoids Adsorbed ⁵	No Trade Name	Sanofi Pasteur, Inc
Diphtheria & Tetanus Toxoids Adsorbed	No Trade Name	Sanofi Pasteur, Ltd
Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Tripedia	Sanofi Pasteur, Inc (not available)
Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed ⁶	Infanrix	GlaxoSmithKline Biologicals
Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed ⁷	DAPTACEL	Sanofi Pasteur, Ltd
Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed, Hepatitis B (recombinant) and Inactivated Poliovirus Vaccine Combined ⁸	Pediarix	GlaxoSmithKline Biologicals
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine ⁹	KINRIX	GlaxoSmithKline Biologicals
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine ¹⁰	Pentacel	Sanofi Pasteur Limited
Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) ¹¹	PedvaxHIB	Merck & Co, Inc
Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) ¹²	ActHIB	Sanofi Pasteur, SA
Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) ¹³	Hiberix	GlaxoSmithKline Biologicals, S.A.

Product Name	Trade Name	Sponsor
Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B Vaccine (Recombinant) ¹⁴	Comvax	Merck & Co, Inc
Hepatitis A Vaccine, Inactivated ¹⁵	Havrix	GlaxoSmithKline Biologicals
Hepatitis A Vaccine, Inactivated ¹⁶	VAQTA	Merck & Co, Inc
Hepatitis A Inactivated and Hepatitis B (Recombinant) Vaccine ¹⁷	Twinrix	GlaxoSmithKline Biologicals
Hepatitis B Vaccine (Recombinant) ¹⁸	Recombivax HB	Merck & Co, Inc
Hepatitis B Vaccine (Recombinant) ¹⁹	Engerix-B	GlaxoSmithKline Biologicals
Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant ²⁰	Gardasil	Merck and Co, Inc.
Human Papillomavirus Bivalent (Types 16, 18) Vaccine, Recombinant ²¹	Cervarix	GlaxoSmithKline Biologicals
Influenza A (H1N1) 2009 Monovalent Vaccine ²²	No Trade Name	CSL Limited
Influenza A (H1N1) 2009 Monovalent Vaccine ²³	No Trade Name	MedImmune LLC
Influenza A (H1N1) 2009 Monovalent Vaccine ²⁴	No Trade Name	ID Biomedical Corporation of Quebec
Influenza A (H1N1) 2009 Monovalent Vaccine ²⁵	No Trade Name	Novartis Vaccines and Diagnostics Limited
Influenza A (H1N1) 2009 Monovalent Vaccine ²⁶	No Trade Name	Sanofi Pasteur, Inc.
Influenza Virus Vaccine, H5N1 ²⁷ (for National Stockpile)	No Trade Name	Sanofi Pasteur, Inc.
Influenza A (H1N1) Virus Monovalent Vaccine, Adjuvanted ²⁸	No Trade Name	ID Biomedical Corporation of Quebec
Influenza Virus Vaccine (Trivalent, Types A and B) ²⁹	Afluria	CSL Limited

Product Name	Trade Name	Sponsor
Influenza Virus Vaccine (Trivalent, Types A and B) ³⁰	FluLaval	ID Biomedical Corp of Quebec
Influenza Vaccine, Live, Intranasal (Trivalent, Types A and B) ³¹	FluMist	MedImmune, LLC
Influenza Virus Vaccine (Trivalent, Types A and B) ³²	Fluarix	GlaxoSmithKline Biologicals
Influenza Virus Vaccine (Trivalent, Types A and B) ³³	Fluvirin	Novartis Vaccines and Diagnostics Ltd
Influenza Virus Vaccine (Trivalent, Types A and B) ³⁴	Agriflu	Novartis Vaccines and Diagnostics S.r.l.
Influenza Virus Vaccine (Trivalent, Types A and B) ³⁵	Fluzone, Fluzone High-Dose and Fluzone Intradermal	Sanofi Pasteur, Inc
Influenza Virus Vaccine (Trivalent, Types A and B) ³⁶	Flucelvax	Novartis Vaccines and Diagnostics, Inc.
Influenza Vaccine (Trivalent) ³⁷	Flublok	Protein Sciences Corporation
Influenza Vaccine, Live, Intranasal (Quadrivalent, Types A and Types B) ³⁸	FluMist Quadrivalent	MedImmune, LLC
Influenza Virus Vaccine (Quadrivalent, Types A and Types B) ³⁹	Fluarix Quadrivalent	GlaxoSmithKline Biologicals
Influenza Virus Vaccine (Quadrivalent, Types A and Types B) ⁴⁰	Fluzone Quadrivalent	Sanofi Pasteur, Inc
Influenza Virus Vaccine (Quadrivalent, Types A and Types B) ⁴¹	FluLaval Quadrivalent	ID Biomedical Corporation
Japanese Encephalitis Virus Vaccine, Inactivated, Adsorbed ⁴²	Ixiaro	Intercell Biomedical

Product Name	Trade Name	Sponsor
Japanese Encephalitis Virus Vaccine Inactivated ⁴³	JE-Vax	Research Foundation for Microbial Diseases of Osaka University
Measles and Mumps Virus Vaccine, Live	M-M-Vax	Merck & Co, Inc (not available)
Measles, Mumps, and Rubella Virus Vaccine, Live ⁴⁴	M-M-R II	Merck & Co, Inc
Measles, Mumps, Rubella and Varicella Virus Vaccine Live ⁴⁵	ProQuad	Merck & Co, Inc
Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine ⁴⁶	Menveo	Novartis Vaccines and Diagnostics, Inc.
Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine ⁴⁷	MenHibrix	GlaxoSmithKline Biologicals
Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine ⁴⁸	Menactra	Sanofi Pasteur, Inc
Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined ⁴⁹	Menomune-A/C/Y/W-135	Sanofi Pasteur, Inc
Plague Vaccine	No trade name	Greer Laboratories Inc. (not available)
Pneumococcal Vaccine, Polyvalent ⁵⁰	Pneumovax 23	Merck & Co, Inc
Pneumococcal 7-valent Conjugate Vaccine ⁵¹ (Diphtheria CRM ₁₉₇ Protein)	Prevnar	Wyeth Pharmaceuticals Inc
Pneumococcal 13-valent Conjugate Vaccine ⁵² (Diphtheria CRM ₁₉₇ Protein)	Prevnar 13	Wyeth Pharmaceuticals Inc
Poliovirus Vaccine Inactivated (Human Diploid Cell)	Poliovax	Sanofi Pasteur, Ltd (not available)
Poliovirus Vaccine Inactivated (Monkey Kidney Cell) ⁵³	IPOL	Sanofi Pasteur, SA
Rabies Vaccine ⁵⁴	Imovax	Sanofi Pasteur, SA

Product Name	Trade Name	Sponsor
Rabies Vaccine ⁵⁵	RabAvert	Novartis Vaccines and Diagnostics
Rabies Vaccine Adsorbed	No Trade Name	BioPort Corp(not available)
Rotavirus Vaccine, Live, Oral ⁵⁶	ROTARIX	GlaxoSmithKline Biologicals
Rotavirus Vaccine, Live, Oral, Pentavalent ⁵⁷	RotaTeq	Merck & Co., Inc.
Smallpox (Vaccinia) Vaccine, Live ⁵⁸	ACAM2000	Sanofi Pasteur Biologics Co.
Tetanus & Diphtheria Toxoids Adsorbed for Adult Use ⁵⁹	No Trade Name	MassBiologics
Tetanus & Diphtheria Toxoids Adsorbed for Adult Use ⁶⁰	DECAVAC	Sanofi Pasteur, Inc
Tetanus & Diphtheria Toxoids Adsorbed for Adult Use ⁶¹	TENIVAC	Sanofi Pasteur, Ltd
Tetanus Toxoid ⁶²	No Trade Name	Sanofi Pasteur, Inc
Tetanus Toxoid Adsorbed ⁶³	No Trade Name	Sanofi Pasteur, Inc
Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed ⁶⁴	Adacel	Sanofi Pasteur, Ltd
Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed ⁶⁵	Boostrix	GlaxoSmithKline Biologicals
Typhoid Vaccine Live Oral Ty21a ⁶⁶	Vivotif	Berna Biotech, Ltd
Typhoid Vi Polysaccharide Vaccine ⁶⁷	TYPHIM Vi	Sanofi Pasteur, SA
Varicella Virus Vaccine Live ⁶⁸	Varivax	Merck & Co, Inc
Yellow Fever Vaccine ⁶⁹	YF-Vax	Sanofi Pasteur, Inc
Zoster Vaccine, Live, (Oka/Merck) ⁷⁰	Zostavax	Merck & Co., Inc.

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/s/

JAMES H SCHLICK
03/04/2014

IRENE Z CHAN
03/04/2014



**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: March 4, 2011

Application Type/Number: IND# 069038

Through: Todd Bridges, R. Ph., Team Leader
Carol Holquist, R. Ph., Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Denise V. Baugh, Pharm.D., BCPS, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Rapivab (Peramivir) Injection
200 mg/20 mL (10 mg/mL)

Sponsor: Biocryst Pharmaceuticals, Inc.

OSE RCM #: 2010-1951

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

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EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name Rapivab for Biocryst Pharmaceuticals Inc.'s Peramivir Injection. Our evaluation determined the proposed name, Rapivab, is acceptable for this product. The proposed proprietary name must be re-reviewed upon submission of the NDA. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change. DMEPA will notify the Sponsor of these findings via letter.

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a request from Biocryst Pharmaceuticals, Inc., September 8, 2010, to evaluate the proposed proprietary name, Rapivab, from a promotional and safety perspective.

1.2 PRODUCT INFORMATION

Rapivab is an influenza neuramidase inhibitor for the treatment of influenza. The recommended dose is 600 mg given intravenously over 15 to 30 minutes once daily. Adult patients with known or suspected renal insufficiency must have creatinine clearance determined and the dose adjusted. Peramivir should be diluted in 0.9% or 0.45% Sodium Chloride Injection, USP that does not contain dextrose or other electrolytes. Once prepared, it should be administered immediately or stored under refrigerated conditions (2°C – 8°C or 36°F – 46°F). If refrigerated, the refrigerated diluted solution should be allowed to reach room temperature prior to administration. The diluted solution should be administered within 24 hours following preparation. Any unused diluted solution must be discarded after 24 hours. Rapivab will be available in cartons of (b) (4) x 20 mL vials. Vials of peramivir injection should be stored at ambient temperatures (15°C – 30°C or 59°F – 86°F). However, temperature extremes encountered during shipment and storage (including freezing) would likely not adversely affect the quality of this product.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Rapivab.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'R' 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.^{1,2}

To identify drug names that may look similar to 'Rapivab', the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (two, upper case 'R' and lower case 'b'), down-strokes (one, lower case 'p'), cross-strokes (none) and dotted letters (one, lower case 'i'). Additionally, several letters in Rapivab

¹ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

² Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

may be vulnerable to ambiguity when scripted (see Appendix B). As such, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Rapivab.

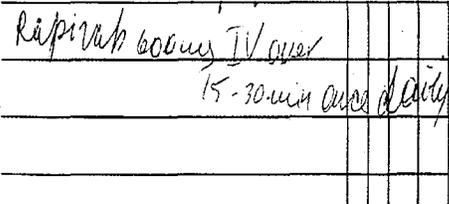
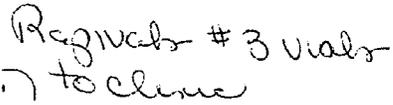
When searching to identify potential names that may sound similar to Rapivab, the DMEPA staff searches for names with similar number of syllables (three), stresses (RA-pi-vab, ra-PI-vab, or ra-pi-VAB), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary, such as the letters 'pi-' which may be interpreted as 'pe' or 'pih' and the letters '-vab' may be interpreted as '-vad'.

The Sponsor's intended pronunciation (ra' pi vab) was also taken into consideration, as it was included in the Proprietary Name Review Request. However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescriptions were communicated during the FDA prescription studies.

Figure 1. Indavo Prescription Study (conducted October 13, 2010)

HANDWRITTEN PRESCRIPTION and MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Prescription:</u></p>  <p>Rapivab 600mg IV over 15-30 min once daily</p>	<p>"Rapivab 600 mg IV over 15 to 30 minutes once daily"</p>
<p><u>Outpatient Prescription:</u></p>  <p>Rapivab #3 vials to clinic</p>	

3 RESULTS

The following sections describe DMEPA's findings from the database searches, CDER Expert Panel Discussion, and FDA prescription analysis studies.

3.1 DATABASE AND INFORMATION SOURCES

The DMEPA safety evaluator searches yielded a total of 22 names as having some similarity to the proposed proprietary name Rapivab.

Fifteen of the 22 names (Bepreve, Rapamune, Ropinerole, Bepridil, Buprenex, Kapidex, Kogenate, Vaprisol, Vepesid, Vaprisol in 5% Dextrose in plastic container, Rovicid, Rabavert, Pepcid, RapidVue, and (b) (4) (***) were thought to look like Rapivab. Two names, Ribavirin and Prevacid, were thought to sound like Rapivab and five names, Rapaflo, Rlalptiva, RibaTab, Rapivab, and Naprelan were thought to look and sound like Rapivab.

A search of the United States Adopted Name stem list on February 16, 2011, did not identify any United States Adopted Names (USAN) stem within the proposed name, Rapivab.

3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA safety evaluators (See Section 3.1 above) and did not identify additional names which were thought to have phonetic or orthographic similarity to Rapivab.

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 42 practitioners responded but none of the responses overlapped with any existing or proposed drug names. Ten (n=10) of the participants interpreted the name correctly as 'Rapivab' with correct interpretation occurring in the inpatient (n = 4) and outpatient (n = 6) written studies. The remainder of the responses misinterpreted the drug name. Common misinterpretations included mistaking the letter 'b' for the letters 'ls', 'k', 'h', or 'd'. The primary misinterpretations in the verbal responses included mistaking the letter 'i' for an 'a'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 COMMENTS FROM THE DIVISION OF ANTIVIRAL PRODUCTS (DAVP)

3.4.1 Initial Phase of Review

In response to the OSE September 20, 2010, e-mail, the Division of Antiviral Products (DAVP) had 'no comment' regarding the proposed proprietary name, Rapivab.

3.4.2 Midpoint of Review

DMEPA notified the Division of Antiviral Products via e-mail on February 28, 2011, that we find the proposed proprietary name, Rapivab acceptable. Per e-mail correspondence from DAVP on March 1, 2011, they indicated they had no additional comments and do not object to the name, Rapivab.

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

3.5 SAFETY EVALUATOR INDEPENDENT SEARCH

Independent searches by the primary Safety Evaluator found no additional names thought to look or sound similar to Rapivab and represent a potential source of confusion. Thus, we identified a total of twenty-two names as having some similarity to Rapivab.

4 DISCUSSION

The proposed name, Rapivab, was evaluated from a promotional and safety perspective based on the product characteristics provided by the Sponsor. Furthermore, we sought input from pertinent disciplines involved with the review of this application and considered it accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC did not have promotional concerns with the proposed name, Rapivab. DMEPA and the Division of Antiviral Products (DAVP) concurred with DDMAC's assessment.

4.2 SAFETY ASSESSMENT

DMEPA identified 22 names for their potential similarity to the proposed name, Rapivab. No other aspect of the name was identified as a potential source of confusion. Upon evaluation of the names, four were eliminated from further consideration for the following reasons: two names lacked sufficient orthographic and/or phonetic similarity (Appendix D), one name is no longer marketed and has no generic equivalents (Appendix E), and one name was identified in our database search and found to be the subject of this review (Appendix F).

Failure mode and effects analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining eighteen names and lead to medication errors. This analysis determined that the name similarity between Rapivab and all eighteen of the identified names was unlikely to result in medication errors for the reasons presented in Appendix G.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Rapivab, is not promotional nor is it vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Rapivab, for this product at this time.

If you have further questions or need clarifications, please contact Brantley Dorch, OSE Project Manager, at 301-796-0150.

5.1 COMMENTS TO THE SPONSOR

We have completed our review of the proposed proprietary name, Rapivab, and have concluded that it is acceptable. Rapivab must be re-evaluated upon submission of the NDA.

6 REFERENCES

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

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

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. 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.

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

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

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Sponsor and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the 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>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also 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)

Natural Medicines 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)

Stat!Ref contains full-text information from approximately 30 texts; it 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>)

USAN Stems List contains all the recognized USAN stems.

- 14. Red Book Pharmacy's Fundamental Reference**

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

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

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

- 16. Medical Abbreviations Book**

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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. 3

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. 4 DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used 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. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because 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 proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, 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 staff 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.⁵ DMEPA provides the product characteristics considered for this review in section one.

3 National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

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

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares 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. DMEPA staff also examines 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 even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Sponsor’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice.

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 Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also considers the potential for the proposed proprietary 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. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA staff conducts searches 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 the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic 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 DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff 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 primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. 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 the proposed proprietary name 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 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 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 DMEPA.

4. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment 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.⁶ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, 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 orthographically or phonetically similar 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 primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. 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 Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name 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 the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the 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, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes 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 not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name 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 the use of an alternate proprietary name.

⁶ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

- a. 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 PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. 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)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, 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.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Sponsor 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. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Sponsor. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, 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 Section 4 for limitations of the process).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in proposed name, Rapivab	Scripted may appear as	Spoken may be interpreted as
Capital 'R'	B, K	
lower case 'a'	c, -ci-, -ce-, el	
lower case 'p'	x, q,	
lower case 'i'	e, l,	Any vowel
lower case 'v'	r, n	f
Lower case 'a'	See above	
Lower case 'b'	l, li, h	Silent (may not be heard), d

Appendix C: FDA Prescription Study Responses for Rapivab (conducted October 13, 2010)

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Rapizab	Rapivals	Rapavab
Rapivah	Rapivals	Rabavab
Rapirab	rapivals	Rapavab
Rapivak	Rapivals	Rapabad
Rapirvab	Rapivab	Rapavab
Rapivah	Rapivak	Rapavab
Rapivials	Rapivals	rapasab
Rapivab	Rapivak	Rapavan
Rapivab	Rapivab	Rapavab
Rapivah	Rapivab	Rapadav
Rapizab	Rapivab	Rapidab
Rapivab	Rapivals	Rapavab
Rapivab	Rapivab	Rapavad
	Rapivab	Rapivad
	Rapivak	

Appendix D: Proprietary names that lack convincing orthographic and/or phonetic similarities

Proprietary Name	Similarity to Rapivab
Ribavirin	Sound
Prevacid	Sound

Appendix E: Name no longer marketed and no generic alternatives exist

Proprietary Name	Similarity to Rapivab	Reason
Bepidil (established name for Bepadin and Vascor) 200 mg, 300 mg tablets	Look	Marketing discontinued in the U.S. in 2003 and there are no generic products available.

Appendix F: Drug name that is the subject of this review.

Proprietary Name	Source
Rapivab	SAEGIS, USPTO

Appendix G: Potentially confusing names with orthographic and/or phonetic differences and differentiating product characteristics that decrease the risk of medication errors.

Failure Mode: Name confusion	Causes (could be multiple)	Rationale:
<p>Proposed name: Rapivab (peramivir) Injection</p>	<p>Strength: 10 mg/mL, 20 mL vial</p>	<p>Usual dose: 600 mg intravenously over 15 to 30 minutes once daily (b) (4)</p>
<p>Bepreve (bepotastine besilate) ophthalmic solution 1.5% <i>Usual dose:</i> 1 drop into affected eye(s) twice daily</p>	<p>Orthographic similarities stem from similarity of their first letters ('B' vs. 'R') in some handwriting samples and sharing the same down stroke ('p') in the same position within their names. Additionally, both names are the same length (7 letters). Overlapping product characteristics include dosage form (solution). Both products are single strength which would increase the risk of omitting this information from prescriptions/orders.</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting. <i>Rationale:</i> The proposed name, Rapivab, contains an up stroke ('b') at the end of its name which creates a different shape from the marketed name, Bepreve. Differing product characteristics include dose (1 drop vs. 600 mg), route of administration (eye vs. intravenous), and frequency of administration (twice daily vs. once daily). These differences should help to distinguish between this name pair.</p>
<p>Rapamune (sirolimus) oral tablet 0.5 mg, 1 mg, 2 mg <i>Usual dose:</i> 2 mg to 6 mg once daily up to 40 mg per day</p>	<p>Orthographic similarities stem from having the same first three letters ('Rap-') within their names. Overlapping product characteristics include frequency of administration (daily).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting. <i>Rationale:</i> The proposed name, Rapivab, contains an up stroke ('b') at the end of its name which creates a different shape from the marketed name, Rapamune. Additionally, the inclusion of the letters 'm' and 'n' in Rapamune give this name an extended length. The orthographic differences should decrease the risk of confusion between these two names. Differing product characteristics include dosage form (tablet vs. injection) and route of administration (oral vs. intravenous). Additionally, Rapamune is available in multiple strengths which has to be clarified to dispense/administer the medication as intended.</p>

<p>Ropinirole is the established name for the proprietary name, Requip</p> <p>0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 5 mg tablets</p> <p><i>Usual dose:</i> 0.25 mg three times daily up to 24 mg per day</p>	<p>Orthographic similarity stems from sharing the same first and third letters ('R' and 'p') and having an up stroke ('l' and 'b') located in similar locations in their names.</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The distinguishing orthographic difference between these two names is the distance between their down strokes and up strokes. There are five letters between the 'p' and 'l' in the marketed name, ropinirole vs. three letters between the letters 'p' and 'b' in Rapiwab. This feature enhances the differences in length between these names.</p> <p>Differing product characteristics include dosage form (tablet vs. injection), dose (0.25 mg vs. 600 mg), route of administration (oral vs. intravenous), and frequency of administration (three times daily vs. once daily). Additionally, ropinirole is available in multiple strengths and this information needs to be stated on a prescription to dispense/administer the medication as intended.</p> <p>These orthographic and product characteristic differences are likely to minimize the risk of confusion between this name pair.</p>
<p>Buprenex (buprenorphine)</p> <p>Injection: 0.3 mg/mL</p> <p>Sublingual tablet : 2 mg, 8 mg</p> <p>Patch: 5 mcg/hr, 10 mcg/hr, 20 mcg/hr</p> <p><i>Usual dose:</i></p> <p>0.3 mg intramuscularly or intravenously over 2 minutes up to 6 hour intervals as needed</p>	<p>Orthographic similarities stem from the similar appearance of their first letters ('B' vs. 'R') in some handwriting samples and the fact that they share the same third letter ('p').</p> <p>Overlapping product characteristics include dosage form (injection), route of administration (intravenous), and possibly the frequency of administration (once daily).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The proposed name, Rapivab, contains an up stroke ('b') at the end of its name versus a cross stroke ('x') in the marketed name, Buprenex. Additionally, the inclusion of the letters 'r' and 'n' give a lengthened appearance to the name, 'Buprenex'. These differences may help to distinguish this name pair.</p> <p>Differing product characteristics include dose (0.3 mg vs. 600 mg), duration of infusion (2 minutes vs. 15 to 30 minutes), and length of treatment (up to 6 hour intervals as needed vs. once daily (b) (4))</p>
<p>Kapidex (dexlansoprazole) delayed-release oral capsule</p> <p>30 mg, 60 mg</p> <p><i>Usual dose:</i></p>	<p>Orthographic similarity stems from the similar appearance of their first letter ('K' vs. 'R') in some handwriting samples and the fact that they share the same</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The proposed name, Rapivab, contains an up stroke ('b') at the end of its name versus an up stroke ('d') appearing in the infix for the marketed name,</p>

<p>30 mg orally once daily</p>	<p>second, third and fourth letters ('api'-). Both names are the same length.</p> <p>Shared product characteristics include frequency of administration (daily).</p> <p>The strength for Kapidex (60 mg) overlaps numerically with the dose for Rapivab (600 mg).</p>	<p>Kapidex.</p> <p>Differing product characteristics include dosage form (capsule vs. injection), route of administration (oral vs. intravenous), and dose (30 mg vs. 600 mg). Additionally, Kapidex is available in more than one strength and this information needs to be stated by the prescriber to dispense/administer the medication as intended.</p> <p>These differences may minimize the risk of confusion between this name pair.</p>
<p>Kogenate (antihemophilic factor VIII) for injection</p> <p>Each vial contains the labeled amount of recombinant factor VIII activity expressed in units. One unit is approximately equal to the level of factor VIII activity found in 1 mL of fresh pooled human plasma.</p> <p><i>Usual dose:</i></p> <p>Dependent upon the severity of the deficiency, the severity of the hemorrhage, the presence of inhibitors, and the factor VIII level desired. It is critical to monitor factor VIII level assays during treatment. This product must be administered intravenously.</p>	<p>Orthographic similarity stems from the similarity between their first letters ('K' vs. 'R') in some handwriting samples as well as the presence of a down stroke ('g' vs. 'p') in the third position and an up stroke in the seventh position ('t' vs. 'b') within their names.</p> <p>Shared product characteristics include dosage form (injection) and route of administration (intravenous).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The marketed name, Kogenate has a terminal letter 'e' which gives this name a lengthened appearance in comparison to the proposed name, Rapivab.</p> <p>Differing product characteristics include dose (based upon factor VIII activity vs. 600 mg) and frequency of administration (as necessary vs. once daily). Additionally, the distribution system for these products is different. Kogenate would be provided by a blood bank or an organization which handles blood products and Rapivab would be dispensed by a pharmacist.</p>

(b) (4)

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

<p>Rovucid (Niacin 30 mg, Vitamin B6 10 mg, Folic Acid 800 mcg, Vitamin B12 200 mcg, Selenium 200 mcg) oral tablet</p> <p><i>Usual dose:</i> 2 tablets orally daily</p>	<p>Orthographic similarity stems from having the same first letter ('R') and ending in an up stroke ('d' vs. 'b'). Additionally, both names have the same number of letters.</p> <p>Overlapping product characteristics include frequency of administration (once daily)</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The marketed name, Rovucid lacks a down stroke and therefore has a different shape from the proposed proprietary name, Rapivab.</p> <p>Differing product characteristics include dosage form (tablet vs. injection), dose (2 tablets vs. 600 mg), and route of administration (oral vs. intravenous).</p> <p>These differences are likely to decrease the risk of confusion between this name pair.</p>
<p>Rabavert (rabies vaccine) for injection</p> <p>2.5 units of rabies antigen per mL</p> <p><i>Usual dose (for prophylaxis post exposure in immunocompetent patients):</i></p> <p>One milliliter intramuscularly on days 0, 3, 7, 14 and 28.</p>	<p>Orthographic similarity stems from sharing the same first ('R') and fifth ('v') letters. Additionally, both names end with an up stroke ('t' vs. 'b').</p> <p>Overlapping product characteristics include dosage form (injection), route of administration (parenteral) and frequency of administration in 24 hours (once).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The marketed name, Rabavert contains an upstroke in the third position ('b') whereas the proposed name, Rapivab has a down stroke ('p') in that position. This feature gives these names different shapes and may decrease the risk of confusion between them.</p> <p>Differing product characteristics include dose (1 mL vs. 600 mg) and specific dosing schedule (days 0, 3, 7, 14, and 28 vs. daily (b) (4))</p>
<p>Pepcid (famotidine) injection</p> <p>10 mg/mL, 20 mg/50 mL</p> <p><i>Usual dose:</i></p> <p>20 mg intravenous every 12 hours</p>	<p>Orthographic similarity stems from the similar appearance of their first letters ('P' vs. 'R') in some handwriting samples, having the same third letter ('p'), and having an up stroke in the last position ('d' vs. 'b').</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The marketed name, Pepcid has two letters between the down stroke and upstroke vs. three letters in the proposed name, Rapivab which expands the latter part of the (proposed) name.</p> <p>Additionally, differing product characteristics</p>

	Overlapping product characteristics include dosage form (injection) and route of administration (intravenous)	include dose (20 mg vs. 600 mg) and frequency of administration (every 12 hours vs. once daily). These differences may decrease the risk of confusion between this name pair.
RapidVue hCG (test strip for pregnancy detection) <i>Usual dose:</i> One test strip briefly dipped in urine; if hCG is present in the sample at a level of 25 mIU/mL or greater, a pink test line along with a blue control line will appear. If hCG is not present only a blue control line will appear.	Orthographic similarity stems from sharing the same first four letters ('Rapi-') as well as having an upstroke ('d' vs. 'b').	Confusion between these drug names is unlikely to occur in the usual practice setting. <i>Rationale:</i> The marketed name, RapidVue has three letters ('vue') after its up stroke ('d') which makes this name appear longer than the proposed name, Rapivab. Differing product characteristics include dosage form (strip vs. injection), dose (one strip vs. 600 mg.), route of administration (not applicable vs. intravenous), and frequency of administration (one time vs. once daily). These differences are likely to differentiate this name pair.
Rapaflo (sildenafil) oral tablet 4 mg, 8 mg <i>Usual dose:</i> 8 mg orally once daily with meal	Orthographic similarity stems from sharing the same first three letters ('Rap-') and having at least one upstroke ('f' vs. 'b') in their names. Both names have seven letters making them similar in length. Overlapping product characteristic includes frequency of administration (once daily).	Confusion between these drug names is unlikely to occur in the usual practice setting. <i>Rationale:</i> The marketed name, Rapaflo contains two sequential upstrokes ('f' and 'l') versus one up stroke ('b') at the end of the proposed name, Rapivab. This difference gives these names different shapes and may distinguish them from each other. Differing product characteristics include dosage form (tablet vs. injection), dose (8 mg vs. 600 mg.), and route of administration (oral vs. intravenous). Additionally, Rapaflo is available in more than one strength and this information must be stated on a prescription to dispense/administer the medication as intended.
Raptiva (efalizumab) for injection 125 mg <i>Usual dose:</i> 0.7 mg/kg subcutaneously one time, then in one week 1 mg/kg subcutaneously every week	Orthographic similarity stems from sharing the same first three letters ('Rap-'). Overlapping product characteristics include dosage form (injection). Both products are available in a single strength which means that	Confusion between these drug names is unlikely to occur in the usual practice setting. <i>Rationale:</i> The marketed name, Raptiva, contains a downstroke immediately followed by a cross stroke ('t') which compares to the proposed name, Rapivab which contains an upstroke ('b') in the terminal position. This difference gives these names different shapes and is likely to distinguish this name pair.

	<p>this information does not have to be stated on a prescription.</p>	<p>Differing product characteristics include dose (0.7 mg/kg and 1 mg/kg vs. 600 mg), route of administration (subcutaneous vs. intravenous) and frequency of administration (once weekly vs. once daily).</p>
<p>Ribatab (ribavirin) oral tablet 400 mg, 600 mg 'No longer in the marketplace but generics are available' <i>Usual dose:</i> greater than 75 kg: 600 mg twice daily; if less than or equal to 75 kg: 400 mg in the morning and 600 mg in the evening</p>	<p>Orthographic similarity stems from sharing the same first ('R') and last ('b') letters. Overlapping product characteristics include dose (600 mg).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting. <i>Rationale:</i> The marketed name, Ribatab contains one upstroke in the third position and a cross stroke ('t') in the fifth position whereas the proposed name, Rapivab has a single down stroke ('p') in its name. This difference gives these names different shapes and may distinguish them from each other. Differing product characteristics include dosage form (tablet vs. injection), route of administration (oral vs. intravenous), and frequency of administration (twice daily vs. once daily). Additionally, Ribatab is available in more than one strength and this information must be stated on a prescription to dispense/administer the medication as intended. Finally, preliminary usage data for Ribatab suggests that the opportunities for confusion between Ribatab and Rapivab are low.</p>
<p>Naprelan (naproxen) Extended-release oral tablet 375 mg, 500 mg, 750 mg <i>Usual dose:</i> 750 mg to 1000 mg orally daily</p>	<p>Orthographic similarity stems from sharing the same second and third letters ('ap'). Overlapping product characteristics include frequency of administration (once daily).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting. <i>Rationale:</i> The marketed name, Naprelan, has two letters ('an') following its up stroke ('l') which makes this name look longer and gives it a different shape from the proposed name, Rapivab. Differing product characteristics include dosage form (tablet vs. injection), dose (750 mg to 1000 mg vs. 600 mg), and route of administration (oral vs. intravenous). Additionally, Naprelan is available in more than one strength and this information must be stated on a prescription to dispense/administer the medication as intended.</p>

<p>Vepesid (etoposide) injection</p> <p>20 mg/mL</p> <p><i>Usual dose:</i></p> <p>35 mg/m²/day IV for 4 days to 50 mg/m²/day for 5 days each cycle</p>	<p>Orthographic similarity stems from sharing the same letter ('p') in the same position and having an up stroke ('d' vs. 'b') at the end of their names.</p> <p>Overlapping product characteristics include dosage form (injection), route of administration (intravenous), and frequency of administration (daily).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The first letter of the proposed name, Rapivab, compared to that of the marketed name, Vepesid, does not look similar when scripted and this distinction may minimize the risk of confusion between these two names.</p> <p>Differing product characteristics include the dose (35 mg/m²/day to 50 mg/m²/day vs. 600 mg).</p> <p>Additionally, based upon preliminary usage data for the name, Vepesid, the opportunities for confusion between these two names is low.</p>
<p>Vaprisol (conivaptan) injection</p> <p>20 mg/100 mL</p> <p><i>Usual dose:</i></p> <p>Infuse 20 mg intravenously over 30 minutes, then 20 mg as a continuous infusion up to 40 mg per day for 1 to 3 days</p>	<p>Orthographic similarity stems from sharing the same letter ('p') in the same position and having an up stroke ('l' vs. 'b') at the end of their names.</p> <p>Overlapping product characteristics include dosage form (injection), route of administration (intravenous), and frequency of administration (daily).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The first letter of the proposed name, Rapivab, compared to that of the marketed name, Vaprisol, does not look similar when scripted. Additionally, the combination letters between their respective down strokes ('p') and terminal upstrokes ('b' vs. 'l') are different ('-iva-' vs '-riso-') and may further distinguish these names from each other.</p> <p>Differing product characteristics include the dose (20 mg intravenously over 30 minutes, then 20 mg as a continuous infusion vs. 600 mg).</p> <p>Thus, these differences may minimize the risk of confusion between these names</p>
<p>Vaprisol (conivaptan) in 5% Dextrose in plastic container</p> <p>20 mg/100 mL</p> <p><i>Usual dose:</i></p> <p>Infuse 20 mg intravenously over 30 minutes, then 20 mg as a continuous infusion up to 40 mg per day for 1 to 3 days</p>	<p>Orthographic similarity between Vaprisol and Rapivab stems from sharing the same letter ('p') in the same position and having an up stroke ('l' vs. 'b') at the end of their names.</p> <p>Overlapping product characteristics include dosage form (injection), route of administration (intravenous), and frequency of administration (daily).</p>	<p>Confusion between these drug names is unlikely to occur in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The first letter of the proposed name, Rapivab, compared to that of the marketed name, Vaprisol, does not look similar when scripted. Additionally, the combination letters between their respective down strokes ('p') and terminal upstrokes ('b' vs. 'l') are different ('-iva-' vs '-riso-'). Finally, the statement, 'in 5% Dextrose in plastic container' makes this name longer in length when written and is likely to further differentiate this name pair.</p> <p>Differing product characteristics include the dose (20 mg intravenously over 30 minutes, then 20 mg as a continuous infusion vs. 600 mg).</p>

		Thus, these differences may minimize the risk of confusion between these names
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/s/

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