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RESEARCH**

APPLICATION NUMBER:

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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: January 24, 2014

Reviewer: Mónica Calderón, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Kabiven and Perikabiven (Lipid Injectable
Emulsion with Amino Acids and Electrolytes and
Dextrose) (b) (4)

Application Type/Number: NDA 200656

Submission Number: 2

Applicant/Sponsor: Fresenius Kabi USA, LLC

Panorama #: 2013-16662 and 2013-16663

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

DMEPA previously reviewed the proposed proprietary names, Kabiven and Perikabiven, under NDA 200656, and found them conditionally acceptable (OSE Review # 2011-3294 and 2011-3295). On November 11, 2011 a Complete Response letter was submitted to the Sponsor and the Sponsor resubmitted their application on November 22, 2013. In their resubmission, they submitted a request to the Agency for a re-assessment of the proposed names, Kabiven and Perikabiven, under NDA 200656.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 22, 2013 proprietary name submission:

- Active Ingredient: Lipid injection emulsion with amino acids and electrolytes and dextrose
- Indication of Use (b) (4)
(b) (4)
- Route of Administration: Intravenous infusion into peripheral or central vein (Perikabiven), or central vein only (Kabiven).
- Dosage Form: (b) (4)
- Strength: Kabiven (3.9%) Lipid Injectable Emulsion with (b) (4) (%) Amino Acids and Electrolytes and (9.8%) Dextrose; Perikabiven (3.5%) Lipid Injectable Emulsion with (b) (4) (%) Amino Acids and Electrolytes and (6.8%)
- Dose and Frequency: Individualized and dependent on the patient's clinical condition, body weight and nutritional requirement. Recommended infusion period is 12 to 24 hrs.
- How Supplied: Three chamber bag including Glucose solution (Chamber 1), Amino Acid Solution (Chamber 2) and Lipid Emulsion (Chamber 3) with volumes including 1026 mL, 1440 mL, 1540 mL, 1920 mL, 2053 mL, 2400 mL and 2566 mL per bag.
- Storage: 20° to 25°C (68° to 77°F) Controlled room temperature. Should be used immediately after mixing and the introduction of additives. If not used immediately, the storage time and conditions prior to use should not be stored longer than 24 hours at 2° to 8°C (36° to 46°F). After removal from storage at 2° to 8°C (36° to 46°F), the admixture should be infused within 24 hours

- Container and Closure Systems: Three chamber bag

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed names are acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors (DGIEP) concurred with the findings of OPDP's promotional assessment of the proposed names.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) SEARCH*

The December 31, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary names.

2.2.2 *Components of the Proposed Proprietary Name*

The proposed names Kabiven and Perikabiven share the root name 'Kabiven', and the proposed proprietary name, Perikabiven includes the prefix 'Peri' at the beginning of the name. The Applicant's intended pronunciation of the proprietary names is kā-bē-vən and puh-rif- kā-bē-vən. In their submission, the Applicant stated that the derivation of the proprietary name 'Kabiven' is an artificial name not considered promotional and was derived from terms associated with the company name and nature of administration of the product; 'Kabi' is part of the company name Fresenius Kabi, and 'Ven' is derived from "vein" as an intravenous infusion. The Applicant did not provide specific rationale for the proposed name 'Perikabiven' in their original September 7, 2011 submission. However, in their original June 2011 submission of the proposed proprietary names 'Kabiven' and '(b) (4)', they stated that they assigned to distinct proprietary names to these products "to ensure sufficient differentiation between the product indicated for central venous administration, and the product that can be administered via peripheral veins." We also note that this product is marketed in numerous countries under varying proprietary names, including the name 'Perikabiven' in France. The Applicant also stated in the previous submission that no medication errors have been reported for the other proprietary names marketed.

2.2.4 *FDA Name Simulation Studies*

Kabiven Study

Fifty-nine practitioners participated in DMEPA's prescription studies. Fourteen interpreted the name correctly (outpatient n=14). The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. The following

misinterpretations occurred in the voice study; 2 participants misinterpreted the ‘b’ sound as a ‘p’ sound and 2 participants misinterpreted the ‘a’ sound as an ‘e’ sound, ‘b’ sound as a ‘v’ sound, ‘v’ sound as a ‘z’ sound, and ‘e’ sound as an ‘i’ sound. The following misinterpretation occurred in the outpatient study; 2 participants misinterpreted the scripted ‘v’ for a scripted ‘r’. The following misinterpretations occurred in the inpatient study; 16 participants misinterpreted the scripted ‘ven’ for scripted ‘ine’, and 2 participants dropped the scripted ‘n’ at the end of Kabiven. 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.

Perikabiven Study

Fifty-eight practitioners participated in DMEPA’s prescription studies. Twenty-nine interpreted the name correctly (outpatient n=14; inpatient n=15). The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. The following misinterpretations occurred in the voice study; 4 participants misinterpreted the ‘k’ sound as a ‘c’ sound, ‘b’ sound as a ‘p’ sound, and ‘v’ sound as a ‘z’ sound. Two participants misinterpreted the ‘en’ sound as an ‘ine’ sound. The following misinterpretation occurred in the outpatient study; 3 participants misinterpreted the scripted ‘i’ for an ‘e’. 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.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 19, 2013 e-mail, the Division of Gastroenterology and Inborn Errors (DGIEP) did not forward any comments or concerns relating to the proposed proprietary names at the initial phase of the review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary names, Kabiven and Perikabiven. Table 1 and Table 2 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Kabiven and Perikabiven, respectively, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 and Table 2 list names which were not initially identified and evaluated in OSE Review #2011-3294 and 2011-3295 dated November 10, 2011.

Table 1: Kabiven 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>
Bebulin	FDA	Betavent	FDA	Ketocon	FDA
Retrovir	FDA				

Table 1: Kabiven Collective List of Potentially Similar Names (DMEPA, EPD, and Other Disciplines)					
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Gablofen	FDA				
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	FDA	(b) (4)	FDA		

Table 2: Perikabiven 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>
(b) (4)	FDA				
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Peridin	FDA				
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Proketazine	FDA				

2.2.6.1 Kabiven Proprietary Name

Our analysis of the seven names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices D through E.

2.2.6.2 Perikabiven Proprietary Name

Our analysis of the three names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices F through G.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors (DGIEP) via e-mail on January 15, 2014. At that time we also requested

additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Gastroenterology and Inborn Errors (DGIEP) on January 24, 2014, they stated no additional concerns with the proposed proprietary names, Kabiven and Perikabiven.

3 CONCLUSIONS

The proposed proprietary names are acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Phong Do, OSE project manager, at 301-796-4795.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Kabiven and Perikabiven, and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your November 22, 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.¹

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

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

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. 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.²

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).

² 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	- 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	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	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.³ 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

³ 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 Name, Kabiven	Scripted May Appear as	Spoken May Be Interpreted as
Uppercase 'K'	R,X	C, Qu, Que, Ques, Q, T
Lowercase 'k'	x, h, la	c, g
Lowercase 'a'	el, ci, cl, do, o, u, c, e, o, er, ce	Any vowel
Lowercase 'b'	l, h, k, lo, 10, t, f, p, lr, tr, li, le, g	p, v, d
Lowercase 'i'	e, l, j, u	Y, a, o
Lowercase 'v'	r, u, w, n	D, f, p, ph, t, vv, z
Lowercase 'e'	a, i, l, o, u, p, c	Any vowel
Lowercase 'n'	m, u, x, r, h, s, v	dn, gn, kn, mn, pn, m
Letter Strings		
iv	w	

Letters in Name, Peri	Scripted May Appear as	Spoken May Be Interpreted as
Uppercase 'P'	D, f, Y, F	B
Lowercase 'p'	yn, ys, g, j, l, q	b
Lowercase 'e'	a, i, l, o, u, p, c	Any vowel
Lowercase 'r'	s, n, e, v, x, c, i	
Lowercase 'i'	e, l, j	y

Appendix C: Prescription Simulation Samples and Results

Figure 1. Kabiven Study (Conducted on December 20, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> <i>Kabiven infuse 50ml/hr IV x 12hrs</i>	Kabiven Bring to clinic Disp #1 bag
<u>Outpatient Prescription:</u> <i>Kabiven</i> <i>sig: Bring to clinic</i> <i>Disp: #1 bag</i>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study
59 People Responded

Study Name: Kabiven

Total	23	17	19	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CABEZIN	0	1	0	1
CAPAVIN	0	1	0	1
CAPAZIN	0	1	0	1
CAPIZEN	0	1	0	1
KABIEN	1	0	0	1

KABINE	0	0	15	15
KABINE INFUSE	0	0	1	1
KABIREN	2	0	0	2
KABIVE	0	0	1	1
KABIVE INFUSE	0	0	1	1
KABIVEN	14	0	0	14
KABREN	1	0	0	1
KABUEN	1	0	0	1
KABUVEN	1	0	0	1
KAGINE	0	0	1	1
KALWEN	1	0	0	1
KALWIN	1	0	0	1
KAPIVEN	0	2	0	2
KEBAVEN	0	1	0	1
KEPIVIN	0	1	0	1
KERBIVEN	1	0	0	1
KETAVIN	0	1	0	1
KEVAMID	0	1	0	1
KEVEVIN	0	1	0	1
KEVIDEN	0	1	0	1
KEVIGAN	0	1	0	1
KEVINIB	0	1	0	1
KEVIZIN	0	2	0	2
TEVOVEN	0	1	0	1

Figure 2. Perikabiven Study (Conducted on December 23, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> <i>Perikabiven Infuse 9ml/hr IV for 24 hrs x1</i>	Perikabiven Bring to clinic Disp #1 bag
<u>Outpatient Prescription:</u> <i>Perikabiven</i> <i>Sig: Bring to clinic</i> <i>Disp. #1 bag</i>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study

58 People Responded

Study Name: Perikabiven

Total	19	20	19	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CRESEMBAR	1	0	0	1
PARICABAVIN	0	1	0	1
PEREKABIVEN	3	0	0	3
PERIACABAVIN	0	1	0	1
PERIBABIVEN	0	0	1	1
PERICABAVINE	0	1	0	1

PERICABAZEM	0	1	0	1
PERICABAZINE	0	1	0	1
PERICABIVIN	0	1	0	1
PERICABIZEM	0	1	0	1
PERICABOZEN	0	1	0	1
PERICAPAVIN	0	1	0	1
PERICAPAZENE	0	1	0	1
PERICAPAZIN	0	1	0	1
PERICAPIZEM	0	1	0	1
PERICAPIZEN	0	2	0	2
PERICAPIZINE	0	2	0	2
PERICAPLAN	0	1	0	1
PERIKABAVINE	0	1	0	1
PERIKABIUEN SULFATE	0	0	1	1
PERIKABIVAN	0	1	1	2
PERIKABIVEN	14	0	8	22
PERIKABIVEN ??	0	0	1	1
PERIKABIVEN DIFULL	0	0	1	1
PERIKABIVEN INFALL	0	0	1	1
PERIKABIVEN SULFATE	0	0	4	4
PERIKAPIZEN	0	1	0	1
PERKABIVEN	1	0	0	1
PERKABIVEN INFULL	0	0	1	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 Kabiven	Failure preventions
1.	Betavent	Carbetapentane citrate and Guaifenesin	Look alike	Name identified in Redbook as a deactivated product, however unable to find product characteristics in commonly used databases (b) (4)
2.				
3.				
4.	Ketocon	Ketoconazole and Hydrocortisone	Look alike	Name identified in Walgreens database; however, unable to find product characteristics in commonly used databases.

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: Kabiven Dosage Form: Injection Strength: 3.9% Lipid Injectable Emulsion with (b) (4)% Amino Acids and Electrolytes and 9.8% Dextrose Usual Dose: Individualized and dependent on the patient's clinical condition, body weight and nutritional	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
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	requirement. Recommended infusion period is 12 to 24 hrs.		
1.	Bebulin (Factor IX Complex (Human) [(Factors II, IX, X)] Injection, Powder for reconstitution, Exact potency labeled on each vial Bebulin VH (Factor IX Complex (Human) [(Factors II, IX, X)] Injection, Powder for reconstitution, Exact potency labeled on each vial <u>Dosage:</u> Bebulin: Minor Bleeding: 25-35 international units/kg, generally single dose Moderate Bleeding: 50-65 international units/kg, 2 doses or until adequate wound healing Major Bleeding: 75-90 international units/kg, 2-3 doses or until adequate wound healing Bebulin VH: Minor Bleeding: 25-35 international units/kg, generally single dose Moderate Bleeding: 40-55 international units/kg, 2 doses or until adequate wound healing Major Bleeding: 60-70 international units/kg, 2-3 doses or until adequate wound healing	<u>Orthographic similarities:</u> Both names have the same number of letters and contain the first two upstrokes in the same position. Lowercase letter 'e' may look like lowercase letter 'a', lowercase letter 'i' may look like lowercase letter 'u', and lowercase letter 'i' may look like lowercase letter 'e'. <u>Overlapping product characteristics:</u> Frequency of administration: Both can be given every 24 hours. <u>Phonetic similarities:</u> The names Kabiven and Bebulin are each comprised of 3 syllables, with the stress on the first syllable.	<u>Orthographic differences:</u> Bebulin contains an additional upstroke letter 'l' that is not present in Kabiven, which gives the names a different shape when scripted. <u>Phonetic Differences:</u> In the first syllable, Kabiven begins with the letter 'K' sound whereas Bebulin begins with the letter 'B' sound. The letter 'K' is a voiceless velar plosive sound and the letter 'B' is a voiced bilabial plosive sound which are two distinct sounds. In the third syllable, Kabiven contains the letter 'v' sound and Bebulin contains the letter 'l' sound. The letter 'v' is a voiced labio-dental fricative sound and the letter 'l' is a voiced alveolar lateral sound which are two distinct sounds. <u>Product Characteristics Differences:</u> Administration: Kabiven is given via continuous infusion vs. Bebulin is given as a one-time dose. Dose: Grams of Amino acids or Dextrose vs. x international units. Strength: Kabiven is single strength vs. Bebulin comes in vials with multiple strengths/potency.

2.	Gablofen (Baclofen) Intrathecal Solution, 50 mcg, mL; preservative free, 10,000 mcg/20 mL; 20,000 mcg/20 mL; 40,000 mcg/20 mL Dosage: Intrathecal: Test dose: 50-100 mcg, doses >50 mcg should be given in 25 mcg increments, separated by 24 hours. A screening dose of 25 mcg may be considered in very small patients. Patients not responding to screening dose of 100 mcg should not be considered for chronic infusion/implanted pump. Maintenance: After positive response to test dose, a maintenance intrathecal infusion can be administered via an implanted intrathecal pump. Initial dose via pump: Infusion at a 24-hourly rate dosed at twice the test dose. Avoid abrupt discontinuation.	<u>Orthographic similarities:</u> Both names have similar number of letters (7 vs. 8), contain the letters 'ab' in the same position, and contain the first two upstrokes in the same position. <u>Overlapping product characteristics:</u> Administration: Both can be given via continuous infusion. Dose: 50 g vs. 50 mcg <u>Phonetic similarities:</u> The names Kabiven and Gablofen are each comprised of 3 syllables, with the stress on the first syllable. In the third syllable, Kabiven contains the letter 'v' sound and Gablofen contains the letter 'f' sound. Both 'v' and 'f' originate in the labio-dental area of the mouth and both are fricative sounds and therefore sound very similar.	<u>Orthographic differences:</u> Gablofen contains two additional upstrokes, 'l' and 'f', that are not present in Kabiven, which gives the names a different shape when scripted. <u>Phonetic Differences:</u> In the first syllable, Kabiven begins with the letter 'K' sound whereas Gablofen begins with the letter 'G' sound. The letter 'K' is a voiceless velar plosive sound and the letter 'G' is a voiced velar plosive sound which are two distinct sounds. <u>Product Characteristics Differences:</u> Route of administration: Kabiven is given intravenously vs. Gablofen is given intrathecally. Strength: Kabiven is available as a single strength vs. Gablofen is available in multiple strength vials.
3.	Retrovir (Zidovudine) Capsule, 100 mg; Tablet, 300 mg; Intravenous solution, 10 mg/mL; Oral syrup, 50 mg/mL Dosage: Prevention of maternal-fetal HIV transmission: During labor and delivery, administer zidovudine I.V. at 2 mg/kg as	<u>Orthographic similarities:</u> Both names have similar number of letters (7 vs. 8) and contain the first two upstrokes in the same position. Lowercase letter 'e' may look like lowercase letter 'a', lowercase letter 't' may look like lowercase letter 'b'. <u>Phonetic similarities:</u> The names Kabiven and Gablofen are each comprised of 3 syllables, with the stress on the first syllable.	<u>Phonetic differences:</u> In the first syllable, Kabiven begins with the letter 'K' sound whereas Retrovir begins with the letter 'R' sound. The letter 'K' is a voiceless velar plosive sound whereas the letter 'R' is a voiced alveolar approximant sound which are two distinct sounds. In the second syllable, Kabiven contains the letter 'b' sound and Retrovir contains the letter 't' sound. The letter 'b' is a voiced bilabial plosive sound whereas the letter 't' is a voiceless alveolar plosive sound which are two distinct sounds. In the third syllable, Kabiven contains the letter 'n' sound and Retrovir contains the letter 'r' sound. The letter 'n' is a voiced alveolar nasal sound

loading dose followed by a continuous I.V. infusion of 1 mg/kg/hour until delivery. For scheduled cesarean delivery, begin I.V. zidovudine 3 hours before surgery HIV infection: Oral: 300 mg twice daily or 200 mg 3 times/day I.V.: 1 mg/kg/dose administered every 4 hours around-the-clock (5-6 doses/day) Pediatric dosage: Prevention of maternal-fetal HIV transmission (in neonates): <i>Oral</i>: Manufacturer's labeling: Full-term infants: 2 mg/kg every 6 hours DHHS [perinatal], 2012: Infants ≥ 35 weeks: 4 mg/kg/dose twice daily Infants ≥ 30 weeks and < 35 weeks gestation at birth: 2 mg/kg/dose every 12 hours; at 15 days of age, advance to 3 mg/kg/dose every 12 hours Infants < 30 weeks gestation at birth: 2 mg/kg/dose every 12 hours; at 4 weeks of age, advance to 3 mg/kg/dose every 12 hours <i>I.V. (infants unable to receive oral dosing):</i> Start as soon as possible after birth, preferably within 6-12 hours of delivery; continue dose from	Both contain the letter 'v' sound in the third syllable.	whereas the letter 'r' is a voiced alveolar approximant sound which are two distinct sounds. <u>Product Characteristics Differences:</u> Strength: Kabiven is available as a single strength vs. Retrovir is available in multiple strengths.
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birth through 6 weeks of age: DHHS [perinatal], 2012: Infants ≥ 35 weeks: 3 mg/kg/dose every 12 hours Infants ≥ 30 weeks and < 35 weeks gestation at birth: 1.5 mg/kg/dose every 12 hours; at 15 days of age, advance to 2.3 mg/kg/dose every 12 hours Infants < 30 weeks gestation at birth: 1.5 mg/kg/dose every 12 hours; at 4 weeks of age, advance to 2.3 mg/kg/dose every 12 hours Treatment of HIV infection: Children 4 weeks to < 18 years (U.S. labeling) Oral: Dose should be calculated by body weight (in kg) or body surface area and should not exceed the recommended adult dose. Note: Doses calculated by body weight may not be the same as those calculated by body surface area. <i>Dosing based on body surface area:</i> 240 mg/m² twice daily (maximum: 300 mg twice daily) or 160 mg/m²/dose 3 times daily (maximum: 200 mg 3 times daily) <i>Dosing based on weight (Note: 3 times daily dose is approved but rarely used in clinical practice):</i>		
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4 to <9 kg: 12 mg/kg/dose twice daily or 8 mg/kg/dose 3 times/day		
≥9 to <30 kg: 9 mg/kg/dose twice daily or 6 mg/kg/dose 3 times/day		
≥30 kg: 300 mg twice daily or 200 mg 3 times/day		

Appendix F: 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 Perikabiven	Failure preventions
1.	(b) (4)			
2.	Proketazine	Carphenazine maleate	Look and Sound alike	Withdrawn FR effective November 5, 1992, no generics available.

Appendix G: 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: Perikabiven Dosage Form: Injection Strength: 3.5% Lipid Injectable Emulsion with (b)(4)% Amino Acids and Electrolytes and 6.8% Usual Dose: Individualized and dependent on the patient's clinical condition, body	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
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	weight and nutritional requirement. Recommended infusion period is 12 to 24 hrs.		
1.	Peridin-C (Ascorbic acid-Hesperidin Complex-Hesperidin Methyl Chalcone) Tablets, 200 mg-150 mg-50 mg Dosage: Dietary supplement: 1 tablet daily or as directed. Relief of hot flashes: 2 tablets, 3 times per day after meals for the first month of use. After the first month at the suggested intake, gradually reduce the amount of PERIDIN-C you are taking until effective daily intake is determined	<u>Orthographic similarities:</u> Both names share the same letter string 'Peri' <u>Overlapping product characteristics:</u> Strength: Both are single strength products and thus no strength is required on a prescription.	<u>Orthographic differences:</u> Perikabiven contains 11 letters vs. 7 letters in Peridin, which looks longer when scripted. Perikabiven contains an additional upstroke 'b', which gives the name a different shape when scripted. <u>Product Characteristics Differences:</u> Dose: Grams of Amino acids or Dextrose vs. 1-2 tablets or 200 mg-150 mg-50 mg

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/s/

MONICA M CALDERON
01/24/2014

LUBNA A MERCHANT
01/24/2014

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: November 10, 2011

Reviewer(s): Cathy A. Miller, MPH, BSN, Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader: Zachary Oleszczuk, PharmD, Team Leader
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis

Drug Name(s): Kabiven and Perikabiven(Lipid Injectable Emulsion with
Amino Acids and Electrolytes and Dextrose) (b) (4)
1026 mL, 1440 mL, 1540 mL, 1920 mL, 2053 mL,
2566 mL, and 2400 mL volume bags

Application Type/Number: NDA 200656

Applicant/Sponsor: APP Pharmaceuticals

OSE RCM #: 2011-3294 and 2011-3295

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

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1 INTRODUCTION

This review evaluates the proposed proprietary names, Kabiven and Perikabiven, 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

This review responds to a request from APP Pharmaceuticals, LLC, dated September 7, 2011 for an assessment of the proposed proprietary names, Kabiven and Perikabiven, regarding potential name confusion with other proprietary or established drug names in the usual practice setting.

The Applicant submitted the original application to the Agency under NDA 200656 on January 28, 2011. On June 17, 2011, the Applicant submitted a request for review of the proposed names Kabiven and (b) (4). Both the Division of Gastroenterology and Inborn Error Products (DGIEP) and the Division of Medication Error Prevention and Analysis (DMEPA) had concerns about the Applicant's proposed nomenclature plan for these two products. While DMEPA found the proposed name 'Kabiven' acceptable from a safety and promotional aspect, both DMEPA and DGIEP had concerns about the proposed name (b) (4), because of the misleading nature of the (b) (4) for a product that can be administered peripherally or centrally, along with potential confusion that could lead to wrong route medication errors. The Applicant's alternate proposal included the use of the (b) (4) for the product that could be administered centrally only. However, DMEPA and DGIEP had similar concerns about this proposal due to the potential for confusion that could occur if the (b) (4) was inadvertently omitted and the name confusion lead to wrong route of administration medication errors.

On September 1, 2011, a teleconference was held including the Applicant, DGIEP and DMEPA to discuss our concerns as stated above. The discussion also included clarification about the Applicant's global nomenclature structure for this product line in other countries, which varies between countries. This drug product was initially registered in Sweden and Denmark in 1999 under the proprietary name, Kabiven. Since that time, the product has received registration approvals in over 60 other countries worldwide for marketing under this proprietary name. (See Appendix K for registration status of both Kabiven and (b) (4)). After considerable discussion about nomenclature options for this NDA and our concerns about the Applicant's current proposal to name the products 'Kabiven' and (b) (4), the Applicant agreed to withdraw the proprietary name request for the name pairs 'Kabiven' and (b) (4), and consider another name pair that included 'Kabiven', and an alternate name that does not include (b) (4).

On September 7, 2011, the Applicant submitted an amendment to NDA 200656, requesting the review of the proposed name pair 'Kabiven' for the central administration only product, and 'Perikabiven' for the central and peripheral administration product.

1.2 PRODUCT INFORMATION

The Applicant, APP Pharmaceuticals provided the following product information for Kabiven/Perikabiven Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose) (b) (4) as part of the June 17, 2011 submission:

- **Indications for use:** (b) (4)
- **Route:** Intravenous infusion into peripheral or central vein (Perikabiven), or central vein only (Kabiven)
- **Dosage Form:** (b) (4)
- **Strength:** Dextrose, amino acids, electrolytes and fat emulsion (See Appendix H for content of ingredients)
- **Dose:** Individualized and dependent on the patient's clinical condition, body weight and nutritional requirement
- **How supplied:** Three chamber bag including Glucose solution (Chamber 1), Amino Acid Solution (Chamber 2) and Lipid Emulsion (Chamber 3) with volumes including 1026 mL, 1440 mL, 1540 mL, 1920 mL, 2053 mL, 2400 mL, and 2566 mL per bag (See Appendix I for diagram of bag chambers).
- **Directions for Preparation and use of Three-Chamber Bag:** The contents of all three chambers should be mixed together after opening the vertical seals between the chambers (See Appendix J for preparation instructions and illustrations)
- **Storage:** Allows refrigeration of product for twenty-four hours at 2°C to 8°C/36°F to 46°F, and after breaking the vertical seals, chemical and physical in-use stability of the mixed three chamber bag has been demonstrated for twenty-four hours for infusion at room temperature (25°C/77°F). Exposure to heat should be minimized and product should be protected from freezing. If frozen, the bag should be discarded. Product should be used immediately after mixing and when additions have been made. If not used immediately, the in-use storage time and conditions prior to use should normally not be stored longer than twenty-four hours at 2°C to 8°C /36°F to 46°F. After removal from storage, the admixture should be infused within twenty-four hours.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed names are acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

The United States Adopted Name (USAN) stem search conducted on October 26, 2011, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proposed name Kabiven and Perikabiven share the root name ‘Kabiven’, and the proposed proprietary name, Perikabiven includes the prefix ‘Peri’ at the beginning of the name. The Applicant’s intended pronunciation of the proprietary names is kā-bē-vən and puh-rif- kā-bē-vən. In their submission, the Applicant stated that the derivation of the proprietary name ‘Kabiven’ is an artificial name not considered promotional and was derived from terms associated with the company name and nature of administration of the product; ‘Kabi’ is part of the company name Fresenius Kabi, and ‘Ven’ is derived from “vein” as an intravenous infusion. The Applicant did not provide specific rationale for the proposed name ‘Perikabiven’ in their September 7, 2011 submission. However, in their original June 2011 submission of the proposed proprietary names ‘Kabiven’ and ‘(b) (4)’, they stated that they assigned to distinct proprietary names to these products “to ensure sufficient differentiation between the product indicated for central venous administration, and the product that can be administered via peripheral veins.” We also note that this product is marketed in numerous countries under varying proprietary names, including the name ‘Perikabiven’ in France. The Applicant also stated in this submission that no medication errors have been reported for the other proprietary names marketed (See Appendix K for a listing of the Applicant’s Worldwide marketing of this product by name and country).

DMEPA agrees that two distinct proprietary names are needed for these products, to help provide distinction between the centrally administered versus centrally or peripherally administered product, and the Applicant’s selection of names that are currently marketed in other countries also provide a degree of consistency to the Applicant’s global nomenclature plan.

DMEPA believes that the proposed nomenclature plan for the two proposed products provides orthographic and phonetic differentiation between the two products that will help provide distinction between the products during various phases of the medication use cycle. However, given the similarities in the products (TPN products) and proposed packaging (similarly sized volume bags with the same trade dress features on the outer package and bag), DMEPA and DGIEP have ongoing concerns about the potential confusion that could still occur between these two products that could result in wrong route of administration medication errors. DMEPA believes that distinction between these two products will also need to be provided through strong labels and labeling features, including packaging differentiation between Kabiven and Perikabiven, to provide distinction during all phases of the medication use cycle. DMEPA will review proposed labels and labeling for this NDA in a separate OSE Review and provide recommendations that address our concerns about the needed product differentiation between Kabiven and Perikabiven.

2.2.3 FDA Name Simulation Studies

Kabiven Study

Forty-four practitioners participated in DMEPA’s Kabiven prescription studies. Thirty-two of the participants interpreted the name correctly as ‘Kabiven’, with correct interpretations occurring most frequently in the written studies. Frequent misinterpretations included the letter ‘e’ being

misinterpreted as the letter 'i' in the written studies, and the letter 'K' being misinterpreted as the letter 'C' in the verbal studies. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

Perikabiven Study

Thirty-one practitioners participated in DMEPA's Perikabiven prescription studies. Seventeen of the participants interpreted the name correctly as 'Perikabiven', with correct interpretations occurring in the written studies. Frequent misinterpretations in the written studies included the letter string 'Per' begin misinterpreted as the letter string 'Pen'. Frequent misinterpretations in the verbal study included the first letter 'P' begin misinterpreted as the letter 'T'. See Appendix C for prescription samples and the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

The Division of Gastroenterology and Inborn Errors Products (DGIEP) communicated that they had no comments or concerns relating to the proposed names Kabiven and Perikabiven, at the initial phase of the name review in response to our e-mail inquiry on September 16, 2011.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Table 1 and 2 list the names identified by the Expert Panel (DMEPA EPD search) the primary reviewer independent safety evaluator search, and other disciplines, as having potential orthographic, phonetic, or spelling similarity to the proposed proprietary name, Kabiven (Table 1) and Perikabiven (Table 2). See Appendix B for possible orthographic and phonetic misinterpretations of letters contained in the proposed names Kabiven and Perikabiven.

Table 1: Collective List of Potentially Similar Names for Kabiven (DMEPA EPD search, independent safety evaluator search, other disciplines, or external study, if applicable)

Name	Source	Look-Alike or Sound-Alike
Actron	Independent Safety Evaluator Search	Look-Alike
Alkeran	Independent Safety Evaluator Search	Look-Alike
Asbron	Independent Safety Evaluator Search	Look-Alike
Ativan	DMEPA EPD Search	Look- and Sound-Alike
Betaseron	Independent Safety Evaluator Search	Look-Alike
Capoten	DMEPA EPD Search	Sound-Alike
Combivent	DMEPA EPD Search	Sound-Alike
Cubicin	DMEPA EPD Search	Look- and Sound-Alike
Enduron	Independent Safety Evaluator Search	Look-Alike
Halaven	DMEPA EPD Search	Look-Alike
Halcion	DMEPA EPD Search	Look-Alike
Haldrone	DMEPA EPD Search	Look-Alike
(b) (4)	DMEPA EPD Search	Look-Alike
(b) (4)	DMEPA EPD Search	Look-Alike
Hiberix	DMEPA EPD Search	Look-Alike

Name	Source	Look-Alike or Sound-Alike
Kabiven	DMEPA EPD Search	Look- and Sound-Alike
Kabolin	DMEPA EPD Search	Look- and Sound-Alike
Kadian	DMEPA EPD Search	Look- and Sound-Alike
Kalbitor	DMEPA EPD Search	Look-Alike
Kaletra	DMEPA EPD Search	Look-Alike
Kalexate	DMEPA EPD Search	Look-Alike
Kalirev	DMEPA EPD Search	Look-Alike
(b) (4)	Independent Safety Evaluator Search	Look-Alike
Kapvay	DMEPA EPD Search	Look- and Sound-Alike
Karbinal (b) (4)	DMEPA EPD Search	Look-Alike
Kariva	DMEPA EPD Search	Look-Alike
Kavacin	DMEPA EPD Search	Look-Alike
Kavakava	DMEPA EPD Search	Look-Alike
Kelnor	DMEPA EPD Search	Look-Alike
Kemadrin	Independent Safety Evaluator Search	Look-Alike
Kepivance	DMEPA EPD Search	Look-Alike
Leukeran	Independent Safety Evaluator Search	Look-Alike
Lotrimin	Independent Safety Evaluator Search	Look-Alike
Rabavert	DMEPA EPD Search	Look-Alike
Rabivac Vet	DMEPA EPD Search	Look-Alike
Rabivax	DMEPA EPD Search	Look-Alike
Ralivia	DMEPA EPD Search	Look-Alike
Refissa	DMEPA EPD Search	Look-Alike
Relafen	DMEPA EPD Search	Look-Alike
Relenza	DMEPA EPD Search	Look-Alike
Reloxin	DMEPA EPD Search	Look-Alike
Ribavirin	DMEPA EPD Search	Look-Alike
Ridaura	Independent Safety Evaluator Search	Look-Alike
Robaxin	DMEPA EPD Search	Look-Alike
Roferon A	Independent Safety Evaluator Search	Look-Alike
Saluron	Independent Safety Evaluator Search	Look-Alike

Table 2: Collective List of Potentially Similar Names for Perikabiven (DMEPA EPD search, independent safety evaluator search, other disciplines, or external study, if applicable)

Name	Source	Look-Alike or Sound-Alike
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Name	Source	Look-Alike or Sound-Alike
Baridium	DMEPA EPD Search	Look-Alike
Brevibloc	DMEPA EPD Search	Look-Alike
Darifenacin	DMEPA EPD Search	Look-Alike
Decitabine	DMEPA EPD Search	Look-Alike
Dorzolamide	DMEPA EPD Search	Look-Alike
Ferragen	DMEPA EPD Search	Sound-Alike
Ferriporphyrin	DMEPA EPD Search	Sound-Alike
Kabiven	DMEPA EPD Search	Look-Alike
Keri	DMEPA EPD Search	Look-Alike
Palifermin	Independent Safety Evaluator Search	Look-Alike
Paricalcitol	DMEPA EPD Search	Look-Alike
Parlodel	DMEPA EPD Search	Look-Alike
Penciclovir	DMEPA EPD Search	Look-Alike
Pentamidine	DMEPA EPD Search	Look-Alike
Peramivir	DMEPA EPD Search	Look-Alike
Perchloracap	DMEPA EPD Search	Look-Alike
Percodan-Demi	DMEPA EPD Search	Look-Alike
Perflutren	DMEPA EPD Search	Look-Alike
Periactin	DMEPA EPD Search	Look-Alike
Periclean	DMEPA EPD Search	Look-Alike
Peri-Colace	DMEPA EPD Search	Look-Alike
Perifosine	DMEPA EPD Search	Look-Alike
Perikabiven	DMEPA EPD Search	Look- and Sound-Alike
Perindopril	DMEPA EPD Search	Look-Alike
Periocheck	DMEPA EPD Search	Look-Alike
Periochip	DMEPA EPD Search	Look-Alike
Periostat	DMEPA EPD Search	Look-Alike
Perphenazine	DMEPA EPD Search	Look-Alike
Persantine	DMEPA EPD Search	Look-Alike
Pertofrane	DMEPA EPD Search	Look-Alike
Phencarb GG	DMEPA EPD Search	Look- and Sound-Alike
Piracetam	DMEPA EPD Search	Look-Alike
Pirarubicin	DMEPA EPD Search	Look- and Sound-Alike
Pirbuterol	DMEPA EPD Search	Look-Alike
Pirfenidone	DMEPA EPD Search	Look-Alike
Pirimicarb	DMEPA EPD Search	Look- and Sound-Alike
Prazepam	DMEPA EPD Search	Sound-Alike
Prednicarbate	Independent Safety Evaluator Search	Look-Alike
Pregabalin	DMEPA EPD Search	Look-Alike
Procetofene	Independent Safety Evaluator Search	Look-Alike
Proctofoam	DMEPA EPD Search	Look-Alike

Name	Source	Look-Alike or Sound-Alike
Provocholine	Independent Safety Evaluator Search	Look-Alike
Puralube	DMEPA EPD Search	Look-Alike
Remodulin	DMEPA EPD Search	Look-Alike
Rentamine	DMEPA EPD Search	Look-Alike

2.2.5.1 Kabiven Proprietary Name

Our analysis of the 46 names contained in Section 2.2.5, Table 1, considered the information obtained in the previous sections along with the product characteristics for the names. We determined that ten (n=10) names will not pose a risk for confusion as described in Appendix D. A Failure Mode and Effects Analysis (FMEA) was then conducted to determine if the proposed name could potentially be confused with the remaining 35 names and lead to medication errors. This analysis determined that the name similarity between Kabiven, and the remaining 35 names was unlikely to result in medication errors for the reasons presented in Appendix F.

2.2.5.2 Perikabiven Proprietary Name

Our analysis of the 45 names contained in Section 2.2.5, Table 2, considered the information obtained in the previous sections along with the product characteristics for the names. We determined that twelve (n=12) names will not pose a risk for confusion as described in Appendix E. A Failure Mode and Effects Analysis (FMEA) was then conducted to determine if the proposed name could potentially be confused with the remaining 33 names and lead to medication errors. This analysis determined that the name similarity between Perikabiven, and the remaining 33 names was unlikely to result in medication errors for the reasons presented in Appendix G.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary names, Kabiven and Perikabiven, are acceptable from a promotional perspective and a safety perspective.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Kabiven and Perikabiven, and have concluded that proposed names are acceptable.

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.

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. ***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. 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.

13. 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.

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 promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by DDMAC. DDMAC 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. DDMAC 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.¹

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

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.

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.² The product characteristics considered for this review appears in Appendix B1 of this review.

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

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

attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

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	- 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	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	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 Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DDMAC'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.³ 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 Appendix B1 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

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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. 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 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 with possible orthographic or phonetic misinterpretation

Letters in proposed name(s):	When scripted may appear as:	When spoken may be interpreted as:
'Kabiven'		
Capital 'K' or lower case 'k'	A, B, C, Cl, H, L, R,S, X	'C' sound
Lower case 'a'	Any lowercase letter that does not contain an downstroke below the line or upstroke above the line	Any vowel sound
Lower case 'b'	d, i, l,, lo, t	'd' or 'v' sound
Lower case 'i'	e, l, t, r, n	Any vowel sound
Lower case 'v'	n, m, r, u, w	'b' sound
lower case 'e'	Any lowercase letter that does not contain an downstroke below the line or upstroke above the line	Any vowel sound
lower case 'n'	Any lowercase letter that does not contain an downstroke below the line or upstroke above the line	'm' sound

(b) (4)		(b) (4)

Appendix C: Prescription Study Results for Kabiven and Perikabiven conducted on July 14, 2011 (Kabiven) and September 19, 2011 (Perikabiven)

Figure 1. Written and Verbal Samples for Kabiven

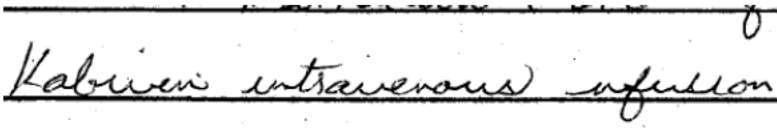
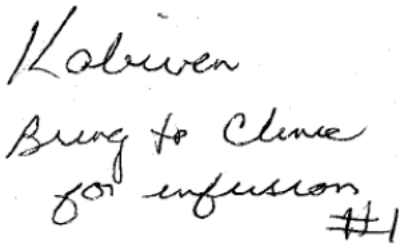
HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER	VERBAL PRESCRIPTION
<u>Inpatient Medication Order:</u> 	Kabiven Intravenous Infusion
<u>Outpatient Prescription:</u> 	

Figure 2. Written and Verbal Samples for Perikabiven

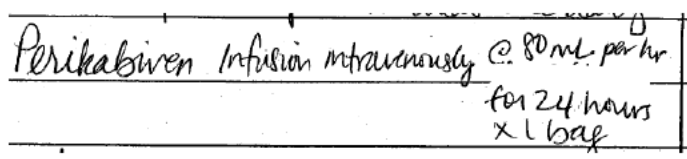
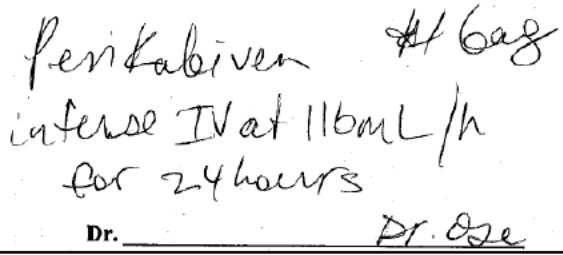
HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER	VERBAL PRESCRIPTION
<u>Inpatient Medication Order:</u> 	Perikabiven Infusion Intravenously at 80 mL/hour for 24 hours
<u>Outpatient Prescription:</u> 	

Figure 3: Kabiven and Perikabiven Prescription Study Written and Verbal Sample Results

Kabiven Results (n=44)			Perikabiven Results (n=31)		
INPATIENT	VOICE	OUTPATIENT	INPATIENT	VOICE	OUTPATIENT
KABIVEN	CABADEN	KABIVEN	Perikabiven	Pericapithen	Penkabiven
KABIVEN	CABAVEN	KABIVEN	Perikabiven	Tericabian	Penkabiven
KABIVEN	CABODEN	KABIVEN	Perikabiven	Tericapicin	Penkabiven
KABIVEN	CAPAZAN	KABIVEN	Perikabiven	Tericapitan	Penkabiven
KABIVEN	CAPIDEM	KABIVEN	Perikabiven	Tericapiven	Penkabiven
KABIVEN	CAPIVEN	KABIVEN	Perikabiven	Terricabinvin	Perikabiven
KABIVEN	CAVADENT	KABIVEN	Perikabiven	Terricaptiven	Perikabiven
KABIVEN	CAVAVENT	KABIVEN	Perikabiven	Terricaptoven	Perikabiven
KABIVEN	KABAVEN	KABIVEN			Perikabiven
KABIVEN	KABIVEN	KABIVEN			Perikabiven
KABIVIN	KABIVEN	KABIVEN			Perikabiven
KABRIVEN	KABIVEN	KABIVEN			Perikabiven
KABRIVEN	KABOVENT	KABIVEN			Perikabiven
		KABIVEN			Perikabiven
		KABIVEN			Perikaleiven
		KABIVEN			
		KAVIVEN			
		KOBIVEN			

Appendix D: Names eliminated from evaluation for reasons listed for Kabiven (n=10)

Proprietary Name		Similarity to proposed name(s)	Active Ingredient	Reason Eliminated
1	Asbron	Look-Alike	Theophylline Sodium Glycinate	Withdrawn from the market 6/20/1995
2	Haldrone	Look-Alike	Paramethasone Acetate	Withdrawn from the market 1/9/1997
3	(b) (4)			
4	(b) (4)			
5	Kabiven	Look and Sound Alike	Lipid Injectable	Lacks convincing orthographic or phonetic similarity to the name Perikabiven
6	(b) (4)			
7	Kavacin	Look-Alike	Kava Root Extract	Root extract herb
8	Rabivax	Look-Alike	Rabies Vaccine	Foreign product manufactured in Thailand
9	Ralivia	Look-Alike	Tramadol	Foreign product manufactured in Canada
10	Reloxin ***	Look-Alike	Botulinum Type A Toxin Heamagglutinin Complex	Proposed name found unacceptable in OSE #2008-1130 9/22/2008 due to promotional DDMAC concerns

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

Appendix E: Names eliminated from evaluation for reasons listed Perikabiven (n=12)

Proprietary Name		Similarity to proposed name(s)	Active Ingredient	Reason Eliminated
1	Ferragen	Sound-Alike	Cyanocobalamin, Ferrous Fumarate, Intrinsic Factor and Ascorbic Acid	Lacks convincing orthographic or phonetic similarity
2	Kabiven	Look- and Sound-Alike	(b) (4)	Same product under review for this application
3	Keri	Look-Alike	Skin Lotion	Lacks convincing orthographic or phonetic similarity
4	Perchloracap	Look-Alike	Potassium Perchlorate	Withdrawn from the market 6/18/2009
5	Perikabiven	Look- and Sound-Alike	(b) (4)	Same product under review for this application
6	Phencarb GG	Look- and Sound-Alike	Carbetapentane and Phenylephrine Hydrochloride	Limited product information found in commonly used drug databases
7	Piracetam	Look-Alike	Piracetam	Compounding agent; not a marketed drug product
8	Pirimicarb	Sound-Alike	Carbamate Insecticide	Ingredient used in insecticide products; not a marketed drug
9	Prazepam	Sound-Alike	Prazepam	Withdrawn from the market 3/2/1994
10	Pirarubicin	Look-Alike	Epirubicin Hydrochloride	Not marketed in the U.S. under the proprietary name 'Pirarubicin'; marketed in China, Japan and South Korea only
11	Procetofene	Look-Alike	Procetofene	Active ingredient with limited information found in commonly used drug databases
12	Rentamine	Look-Alike	Carbetapentane, Chlorpheniramine, Ephedrine and Phenylephrine	Withdrawn from the market in (b) (4)

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
1	Actron (Ketoprofen) extended-release capsule Strength: 25 mg, 50 mg, 75 mg, 150 mg and 200 mg Dose: 25 mg to 200 mg one to three times daily	Orthographic similarities: The first letter 'A' can appear like the first letter 'K', both names contain an upstroke letter 't' versus 'b' in the third letter position and end with the letter string 'ron' versus 'ven'.	Variations in product characteristics minimize the potential for confusion. No overlap in strength or dose
2	Alkeran (Melphalan Hydrochloride) For Injection Strength: 50 mg per vial Dose: 16 mg/m ² via intravenous infusion as single infusion over fifteen to twenty minutes.	Orthographic similarities: Both names contain seven letter in the root name; the first letter 'A' can appear like the first letter 'K', both names contain an upstroke letter 'k' versus 'b' in the third letter position and end with the letters 'ran' versus 'ven'. Overlapping product characteristics: Injection dosage form Intravenous route of administration Numeric overlap in the mL/kg/day versus mg/m ² dose	Orthographic differences in the names minimize the potential for confusion. The second upstroke letter 'l' in the name Alkeran not present in Kabiven and (b) (4) provides orthographic distinction in the names.

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)	STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) [REDACTED] Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
3 Ativan (Lorazepam) Tablets and Injection Strength: 0.5 mg, 1 mg and 2 mg tablets; 2 mg/mL and 4 mg/mL injection Dose: 0.5 mg to 6 mg per day in single or divided doses; 0.05 mg/kg with a maximum dose of 4 mg dose.	Orthographic and phonetic similarities: The first letter 'A' can appear like the first letter 'K', there is an upstroke letter 't' versus 'b' in similar letter positions and both names end with the letters 'van' versus 'ven'. Both names contain three syllables with the 'a' sound in the first syllable, the 'ti' versus 'bi' sound in the second syllable and the 'van' versus 'ven' sound in the third syllable. Overlapping product characteristics: Injection dosage form Intravenous route of administration	Orthographic and phonetic differences along with variations in product characteristics minimize the potential for confusion. Orthographic and Phonetic differences: For the proposed name [REDACTED] (b) (4) [REDACTED] The 'K' sound in the first syllable of Kabiven/ (b) (4) [REDACTED] provides phonetic distinction from the name Ativan. Differentiating product characteristics: No overlap in strength or dose Intermittent dosing versus continuous infusion
4 Betaseron (Interferon Beta 1b) For Injection Strength: 0.3 mg per vial Dose: Titration from 0.0625 mg subcutaneously every other day titrated to 0.25 mL every other day by week seven	Orthographic similarities: The first letter 'B' can appear like the first letter 'K', both names contain an upstroke letter 't' versus 'b' in the third letter position and end with the letters 'ron' versus 'ven'. Overlapping product characteristics: For Injection versus Injection dosage form Single strength availability Injection route of administration	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There are nine letters in the name Betaseron while there are only seven letters in the root name 'Kabiven' making the name appear shorter in length when scripted. Differentiating product characteristics: No overlap in dose

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
5	Capoten (Captopril) Tablets Strength: 12.5 mg, 25 mg, 50 mg, and 100 mg Dose: 6.25 mg to 100 mg once or twice daily	Orthographic similarities: The first letter 'C' can appear like the first letter 'K' and both names end with the letters 'en'.	Variations in product characteristics minimize the potential for confusion. No overlap in strength or dose
6	Combivent (Ipratropium Bromide and Albuterol Sulfate) Inhalation Strength: 14.7 grams (200 metered actuations with 21 mcg Ipratropium and 120 mcg Albuterol per actuation) Dose: Two inhalations four times daily	Orthographic similarities: The first letter 'C' can appear like the first letter 'K', both names contain an upstroke letter 'b' and the letters 'ven' similarly placed in the names. Overlapping product characteristics: Single strength availability	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke/cross-stroke letter 't' in the last letter position of the name Combivent that is not present in the name Kabiven. Differentiating product characteristics: No overlap in dose

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
7	Cubicin (Daptomycin) for Injection Strength: 500 mg per vial Dose: 4 mg/kg to 6 mg/kg intravenous infusion	Orthographic and phonetic similarities: Both names contain seven letter in the root name, the first letter 'C' can appear like the first letter 'K', both names contain the upstroke letter 'b' similarly placed and contain the letters 'icin' versus 'iven' at the end of the name. Both names contain three syllables, the 'k' sound in the first syllable, soft 'i' sound in the second syllable and 'in' versus 'en' sound in the last syllable Overlapping product characteristics: For injection versus injection dosage form Single strength availability Intravenous route of administration	Orthographic and phonetic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic and Phonetic differences: The hard 'u' sound in the first syllable and the 's' sound in the third syllable of the name Cubicin provide phonetic distinction from the name Kabiven when pronounced. Differentiating product characteristics: There is no overlap in dose
8	Enduron (Methyclothiazide) Tablet Strength: 2.5 mg and 5 mg tablet Dose: 2.5 mg to 5 mg once daily	Orthographic similarities: Both names contain seven letters in the root name, an upstroke letter 'd' versus 'b' in the third letter position and end similarly with the letters 'ron' versus 'ven'.	Variations in product characteristics minimize the potential for confusion. No overlap in strength or dose Frequency of administration: Once daily versus continuous infusion over twelve to twenty-four hours

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
9	Halaven (Eribulin) Injection Strength: 1 mg/2 mL Dose: 1.4 mg/m ² intravenously over two to five minutes days one and eight	Orthographic similarities: Both names contain seven letters in the root name; the first letter 'H' can appear like the first letter 'K' and the remaining letters 'alaven' can appear like the letters 'ibiven' when scripted. Overlapping product characteristics: Single strength availability Injection dosage form Intravenous route of administration	Variations in product characteristics minimize the potential for confusion. Differentiating product characteristics: No overlap in dose Frequency of administration: Dose infusions per therapy versus continuous infusion over twelve to twenty-four hours
10	Halcion (Triazolam) Tablets Strength: 0.125 and 0.25 mg Dose: 0.125 mg to 0.5 mg once daily at bedtime	Orthographic similarities: Both names contain seven letters in the root name; the first letter 'H' can appear like the first letter 'K' and the letters 'lcion' can appear like the letters 'biven' when scripted.	Variations in product characteristics minimize the potential for confusion. No overlap in strength or dose Frequency of administration: Once daily versus continuous infusion

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; ^{(b) (4)}  Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
11	Hiberix (Haemophilus B Conjugate Vaccine Tetanus Toxoid Conjugate) For Injection Strength: Single dose vial containing lyophilized vaccine Dose: 0.5 mL intramuscularly	Orthographic similarities: Both names contain seven letters; the first letter 'H' can appear like the first letter 'K' and the letters 'berix' can appear like the letters 'biven'. Overlapping product characteristics: Single strength availability For injection versus injection dosage form	Variations in product characteristics minimize the potential for confusion. No overlap in dose Frequency of administration: One time injection versus continuous infusion
12	Kabolin* (Nandrolone Decanoate) Injection 100 mg/mL and 200 mg/mL Dose: 25 mg to 200 mg weekly given via intramuscular injection *Kabolin discontinued but generic Nandrolone Decanoate still marketed.	Orthographic and phonetic similarities: Both names contain seven letters, begin with the letter string 'Kabo' versus 'Kabi' and the ending letter string 'in' can appear like 'en' when scripted. Both names contain three syllables, including the same syllable sound 'Kab' and the last syllable containing the 'in' sound can sound like 'en'. Injection dosage form	Orthographic and phonetic differences, along with variations in product characteristics minimize the potential for confusion. Orthographic and Phonetic differences: There are three upstroke letters 'K', 'b' and 'l' in Kabolin while there are only two upstroke letters 'K' and 'b' in the name Kabiven making the shapes of the names appear different. The 'l' versus 'v' sound in the last syllable provides phonetic distinction between the names. Differentiating product characteristics: No overlap in strength or dose Frequency of administration: Once weekly versus continuous infusion over twelve to twenty-four hours

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
13	Kadian (Morphine Sulfate) Capsule Strength: 10 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg Dose: 10 mg to 360 mg in single or divided doses	Orthographic similarities: Both names begin with the letters 'Kad' versus 'Kab' and end with the letters 'an' versus 'en'. Overlapping product characteristics: Injection dosage form Single strength availability Injection route of administration	Variations in product characteristics minimize the potential for confusion. No overlap in strength or dose Frequency of administration: Single or divided doses versus continuous intravenous infusion
14	Kalbitor (Eccallantide) Injection Strength: 10 mg/mL Dose: 30 mg (3 mL) subcutaneously times one dose; may repeat one time	Orthographic similarities: Both names begin with the letters 'Ka' and contain an upstroke letter 'b' similarly placed in the names; both names end with the letters 'or' versus 'en' which appear similar when scripted. Overlapping product characteristics: Injection dosage form Single strength availability Injection route of administration	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an added upstroke letter 'l' and 't' in the name Kalbitor that are not present in the name Kabiven or (b) (4) Differentiating product characteristics: No overlap in dose Frequency of administration: One time dose versus continuous infusion
15	Kaletra (Lopinavir and Ritonavir) Tablet and Oral solution Strength: 400 mg/100 mg twice daily or 800 mg/200 mg once daily	Orthographic similarities: Both names contain seven letters and begin with the letters 'Kal' versus 'Kab'.	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke/cross-stroke letter 't' in the name Kaletra that is not present in the name Kabiven. Differentiating product characteristics: No overlap in strength or dose

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
16	Kalexate (Sodium Polystyrene Sulfonate) for Oral Solution Strength: 454 grams/bottle Dose: Average daily dose 15 grams four times daily via rectal enema (maximum dose of 60 grams daily)	Orthographic similarities: Both names begin with the letters 'Kal' versus 'Kab' in the names. Overlapping product characteristics: Single strength Numeric overlap in dose	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke/cross-stroke letter 't' in the name Kalexate that is not present in the name Kabiven Differentiating product characteristics: Frequency of administration: One to four times daily versus continuous infusion
17	Kapvay (Clonidine Hydrochloride) Extended-release tablet Strength: 0.1 mg and 0.2 mg Dose: 0.1 mg to 0.2 mg once or twice daily	Orthographic similarities: Both names begin with the letters 'Ka' and contain the letter 'v' similarly placed in the names.	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is a downstroke letter 'p' and 'y' in the name Kapvay that is not present in the name Kabiven and (b) (4) Differentiating product characteristics: No overlap in strength or dose Frequency of administration: Once or twice daily versus continuous infusion

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)	STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) [REDACTED] Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
18 Karbinal (b) (4) *** (Carbinoxamine) Extended-release oral suspension Strength: 4mg per 5 mL Dose: ¾ to 4 teaspoonfuls (3 mg to 16 mg) every twelve hours ***Proposed name for NDA 022556 currently under review OSE #2011-2219	Orthographic similarities: Both names begin with the letters 'Ka' and contain the letters 'bi' similarly placed in the names. The modifier (b) (4) could be omitted during prescribing. Overlapping product characteristics: Single strength availability	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke letter 'l' in the last letter position that is not present in the names Kabiven or (b) (4). Differentiating product characteristics: No overlap in dose
19 Kariva (Desogestrel and Ethinyl Estradiol and Ethinyl Estradiol) Strength: 0.15 mg/0.02 mg/0.01 mg Dose: One tablet once daily or use as directed	Orthographic similarities: Both names begin with the letters 'Ka' and contain the letter 'v' similarly placed. Overlapping product characteristics: Single strength availability	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke letter 'b' in the proposed names Kabiven and (b) (4) that is not present in the name Kariva. Differentiating product characteristics: Dosage form: Tablet versus injection No overlap in dose Route of administration: Oral versus Intravenous Frequency of administration: Once daily versus continuous infusion over twelve to twenty-four hours

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
20	Kavakava (Piper Methysticum) Tablet or capsule Strength: 500 mg Dose: Take one tablet once daily	Orthographic similarities: Both names begin with the letters 'Ka' and contain a letter 'v' similarly placed in the names. Overlapping product characteristics: Single strength availability	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke letter 'k' in the fifth letter position of the name Kavakava versus the upstroke letter 'b' which is in the third letter position of the proposed names Kabiven and (b) (4) Differentiating product characteristics: No overlap in dose Frequency of administration: Once daily versus continuous infusion over twelve to twenty-four hours
21	Kelnor (Ethinodiol Diacetate and Ethinyl Estradiol) Tablet Strength: 1 mg/0.035 mg Dose: Take one tablet once daily or use as directed	Orthographic similarities: Both names begin with the letter 'K' and contain an upstroke letter 'l' versus 'b' in the third letter position of the names. Overlapping product characteristics: Single strength availability	Variations in product characteristics minimize the potential for confusion. Differentiating product characteristics: No overlap in dose Frequency of administration: Once daily versus continuous infusion over twelve to twenty-four hours

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
22	Kemadrin (Procyclidine Hydrochloride) Tablet Strength: 5 mg Dose: 2.5 mg to 5 mg one to three times daily	Orthographic similarities: Both names begin with the letters 'Ke' versus 'Ka' and end with the letters 'rin' versus 'ven' which can appear similarly when scripted. Overlapping product characteristics: Single strength availability	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke letter 'd' in the fifth letter position of the name Kemadrin versus the upstroke letter 'b' in the third letter position of the names Kabiven and (b) (4). Differentiating product characteristics: No overlap in dose Frequency of administration: Once daily versus continuous infusion over twelve to twenty-four hours
23	Kepivance (Palifermin) For Injection Strength: 6.25 mg per vial Dose: 60 mcg/kg/day intravenously for three consecutive days before and after Myelotoxix therapy	Orthographic similarities: Both names begin with the letters 'Ke' versus 'Ka' and contain the letters 'iv' similarly placed in the names. Overlapping product characteristics: Single strength availability For injection versus injection dosage form Intravenous route of administration	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is a downstroke letter 'p' in the name Kepivance that is not present in the name Kabiven or (b) (4). Differentiating product characteristics: There is no overlap in dose

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
24	Leukeran (Chlorambucil) Tablet Strength: 2 mg Dose: 0.1 mg/kg to 0.2 mg/kg for three to six weeks daily as required	Orthographic similarities: The first letter 'L' can appear like the first letter 'K' when scripted and the ending letters 'ran' can appear like the ending letters 'ven' when scripted. There is an upstroke letter 'k' versus 'b' similarly placed in the names. Overlapping product characteristics: Single strength availability Possible numeric overlap in dose infusion rate	Variations in product characteristics minimize the potential for confusion. Frequency of administration: Once daily versus continuous intravenous infusion over twelve to twenty-four hours.
25	Lotrimin (Clotrimazole) Topical cream, lotion and solution Strength: 1% Dose: Use as directed	Orthographic similarities: Both names contain seven letters; the first letter 'L' can appear like the first letter 'K', the third upstroke letter 't' can appear like the third upstroke letter 'b' and the ending letters 'min' can appear like the ending letters 'ven'. Overlapping product characteristics: Single strength availability	Variations in product characteristics minimize the potential for confusion. Differentiating product characteristics: No overlap in dose

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
26	Rabavert (Rabies Vaccine) For Injection Strength: Single dose of rabies vaccine per vial Dose: 1 mL intramuscularly	Orthographic similarities: The letters 'Rab' can appear like the letters 'Kab' and both names contain the letter 'v' similarly placed in the names. Overlapping product characteristics: Single strength availability Injection dosage form	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke letter 't' in the last letter position of the name Rabavert that is not present in the names Kabiven and (b) (4). Differentiating product characteristics: No overlap in dose Frequency of administration: Single dose injection versus continuous intravenous infusion over twelve to twenty-four hours
27	Rabivac Vet (Inactivated Rabies Virus Propagated in BHK-21) Injection Strength: 5 mL inactivated vaccine per vial Dose: 2.5 mL per dose in vaccination series intramuscularly	Orthographic similarities: Both names contain seven letters in the root name and the letters 'Rabiv' can appear like the beginning letters 'Kabiv'. The modifier 'Vet' could be omitted during prescribing. Overlapping product characteristics: Single strength availability Injection dosage form Injection route of administration	Variations in product characteristics minimize the potential for confusion. Differentiating product characteristics: No overlap in dose Frequency of administration: Single dose injection versus continuous intravenous infusion over twelve to twenty-four hours

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
28	Refissa (Tretinoin) Topical Cream Strength: 0.05% Dose: Use as directed or apply to affected area once daily	Orthographic similarities: Both names contain seven letters and the letters 'Refi' can appear like the letters 'Kabi' when scripted. Overlapping product characteristics: Single strength availability	Variations in product characteristics minimize the potential for confusion. No overlap in dose
29	Relafen (Nabumetone) Tablet Strength: 500 mg and 750 mg Dose: 1000 mg single dose; 1500 mg to 2000 mg daily	Orthographic similarities: Both of the names contain seven letters and the letters 'Rel' can appear like the letters 'Kab'. Overlapping product characteristics: Single strength availability	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There is an upstroke (or downstroke) letter 'f' in the fifth letter position of the name Relafen that is not present in the names Kabiven (b) (4) Differentiating product characteristics: No overlap in strength or dose Frequency of administration: Once daily versus continuous infusion
30	Relenza (Zanamivir) Inhalation Powder Strength: 5 mg per disk Dose: Two inhalations (one 5 mg blister per inhalation) once or twice daily	Orthographic similarities: Both names contain seven letters, and the letters 'Rel' can appear like the letters 'Kab' when scripted. Overlapping product characteristics: Single strength availability	Variations in product characteristics minimize the potential for confusion. No overlap in dose Frequency of administration: Once or twice daily versus continuous infusion over twelve to twenty-four

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
31	Ribavirin (Ribavirin) Capsule Strength: 200 mg Dose: 400 mg to 600 mg once or twice daily	Orthographic similarities: The letters 'Rib' can appear like the letters 'Kab' when scripted, and both names contain the ending letters 'virin' versus 'iven' which look similar when scripted. Overlapping product characteristics: Single strength availability	Orthographic differences in the names along with variations in product characteristics minimize the potential for confusion. Orthographic differences: There are nine letters in the name Ribavirin versus only seven letters in the root name Kabiven making the name appear shorter in length when scripted. Differentiating product characteristics: No overlap in dose Frequency of administration: Once or twice daily versus continuous infusion over twelve to twenty-four
32	Ridaura (Auranofin) Capsule Strength: 3 mg Dose: 3 mg to 6 mg once or twice daily	Orthographic similarities: Both names contain seven letters and the letters 'Rid' can appear like the letters 'Kab' when scripted. Overlapping product characteristics: Single strength availability	Variations in product characteristics minimize the potential for confusion. No overlap in dose Frequency of administration: Once or twice daily versus continuous infusion over twelve to twenty-four

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
33	Robaxin (Methocarbamol) Injection and Tablet Strength: 100 mg/mL; 500 mg and 750 mg tablets Dose: 30 mL (3 vials) daily for three days intravenously diluted or undiluted, or given intramuscularly. Undiluted Robaxin should be given at a rate no greater than 3 mL per minute; diluted Robaxin should be mixed in 250 mL D5W; Pediatric dose 15 m/kg or 500 mg/m2 recommended and may be repeated every six hours; 500 mg to 750 mg oral four times daily	Orthographic similarities: Both names contain seven letters, the letters 'Rob' can appear like the letters 'Kab' and the letters 'xin' can appear like the letters 'ven'. Overlapping product characteristics: Injection dosage form Intravenous route of administration Numeric overlap in dose	Variations in product characteristics minimize the potential for confusion. Orthographic differences: Differentiating product characteristics: Kabiven is a total parenteral nutrition supplement requiring physician's orders that would likely include the total volume, the individualized added nutrients and the rate of intravenous administration. Given facility protocols for ordering and administering TPN and Lipid products, including preprinted order forms with % of all amino acids, electrolytes and lipids, name confusion between Robaxin and Kabiven would be reconciled and averted once the preparation and dispensing phase of the drug usage phase is initiated.
34	Roferon A (Interferon Alfa 2a) Injection Strength: 3 million, 6 million and 9 million international units (MIU) Dose: 3 MIU to 9 MIMU three times weekly via subcutaneous injection	Orthographic similarities: Both names contain seven letters in the root name; the beginning letters 'Rof' can appear like the beginning letters 'Kab' and the ending letters 'ron' can appear like the ending letters 'ven' when scripted. The modifier 'A' could be omitted during prescribing. Injection dosage form Injection route of administration	Variations in product characteristics minimize the potential for confusion. No overlap in strength or dose

Appendix F: Kabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=36)

Kabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1026 mL, 1540 mL, 2053 mL and 2566 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 19 mL/kg/day to 38 mL/kg/day for adults; (b) (4) Infuse intravenously at a maximum infusion rate of 2.6 mL/kg/hour over twelve to twenty-four hours *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1026 mL, 1540 mL and 2053 mL)
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
35	Saluron (Hydroflumethiazide) Tablet Strength: 50 mg Dose: 50 mg to 200 mg in one or two divided doses daily	Orthographic similarities: Both names contain seven letters and the letters 'aluron' can appear like the letters 'abiven' when scripted. Overlapping product characteristics: Numeric overlap in dose '50' versus infusion rate	Variations in product characteristics minimize the potential for confusion. Frequency of administration: Once or twice daily versus continuous infusion over twelve to twenty-four hours
36	(b) (4)		

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Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
1	Baridium (Phenazopyrindine Hydrochloride) Tablet 97.2 mg Dose: One tablet every eight hours	Orthographic: The first letter 'B' can appear like the first letter 'P', the letter string 'arid' can appear like the letter string 'erik' and the ending letter string 'ium' can appear like the ending letter string 'iven'.	Orthographic difference: There are eight letters in the name Baridium versus eleven letters in the name Perikabiven making the name appear longer when scripted. Additionally, there are two upstroke letters 'B' and 'd' in the name Baridium versus three upstroke letters 'P', 'k' and 'b', in the name Perikabiven making the shapes of the names appear different when scripted. No overlap in dose Frequency of administration: Every eight hours versus continuous infusion Single strength versus multiple volume sizes Route of administration: Oral versus Central or Peripheral
2	Brevibloc (Esmolol) Injection 10 mg/mL and 20 mg/mL Dose: 0.5 mg/kg infused over one minute followed by maintenance 0.05 mg/kg/min for next four minutes; maintenance infusion may be continued at 0.05 mg/kg/min or increased step-wise 0.1 mg/kg/min to 0.2 mg/kg/min depending on response	Orthographic: The first letter 'B' can appear like the first letter 'P', the letter string 'revi' can appear like the letter string 'eri' and both names contain there upstroke letters 'B', 'b' and 'l' versus 'P', 'k' or 'b'. Injection dosage form Intravenous route of administration	Orthographic difference: There are nine letters in the name Brevibloc versus eleven letters in the name Perikabiven making the name appear longer when scripted. Although both names contain three upstroke letters, two of the upstroke letters 'bl' appear consecutively in the name Brevibloc versus appearing in varied letter positions one, five and seven in the name Perikabiven, making the shapes of the names appear different. No overlap in strength or dose

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)	STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
3 Darifenacin (Darifenacin; proprietary name is Enablex) Extended-release tablet 7.5 mg and 15 mg Dose: 7.5 mg to 15 mg once daily	Orthographic: Both names contain eleven letters in the names, the first letter 'D' can appear like the first letter 'P', the upstroke letter 'f' can appear like the upstroke letter 'k' and is similarly placed in the name, and the ending letter string 'acin' can appear like like ending letter string 'iven' when scripted.	Orthographic differences: There are two upstroke letters 'D' and 'f' in the name Darifenacin versus three upstroke letters 'P', 'k' and 'b' in the name Perikabiven making the shapes of the names appear different when scripted. No overlap in strength or dose Frequency of administration: Once daily versus continuous infusion Route of administration: Oral versus Central or Peripheral

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)	STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
4 Decitabine (Decitabine; proprietary name is Dacogen) For Injection 50 mg per vial Dose: 15 mg/m² continuous IV infusion over three hours repeated every eight hours for three days; or 20 mg/m² continuous infusion over one hour repeated daily every five days	Orthographic similarities: The first letter 'D' can appear like the first letter 'P', both names contain three upstroke letters 'P', 't' and 'b' similarly placed in the names and the ending letter string 'ine' can appear like the ending letter string 'iven' when scripted. Injection versus For injection dosage form Intravenous route of administration	Frequency of administration: Infuse over three hours for three days or one hour for five days versus infuse over 12-24 hours daily. (b) (4)

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
5	Dorzolamide (Dorzolamide Hydrochloride) Ophthalmic solution 2% Dose: One drop into affected eye three times daily	Orthographic similarities: Both names contain eleven letters, the first letter 'D' can appear like the first letter 'P' when scripted, and both names contain three upstroke letters 'D', 'l' and 'd' versus 'P', 'k' and 'b'. For injection versus Injection dosage form Intravenous route of administration Continuous infusion	Orthographic differences: The last upstroke letter is position near the end of the name Dorzolamide versus the eighth letter position of the name Perikabiven. No overlap in strength or dose Route of administration: Ophthalmic versus Central or Peripheral Frequency of administration: Three times daily versus continuous infusion
6	Ferriporphyrin (Ferriporphyrin Chloride) For Injection 313 mg per vial Dose: 1 mg/kg/day to 4 mg/kg/day intravenously for three to fourteen days; in severe cases may repeat dose no earlier than 12 hours; maximum 6 mg/kg in twenty-four hours for adults	Phonetic similarities: Both names contain five syllables with the 'Ferri' versus 'Peri' sound in the first syllable and the 'ven' versus 'rin' sound in the last syllables. For injection versus Injection dosage form Intravenous route of administration Continuous infusion	Phonetic differences: The 'p' sound in the third and fourth syllable of the name Ferriporphyrin sound different than the 'k' and 'b' sound in the third and fourth syllable of the name Perikabiven. No overlap in strength or dose

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
7	Paricalcitol (Paricalcitol; proprietary name is Zemplar) Capsules and Injection 1 mcg, 2 mcg and 4 mcg capsules 2 mcg/mL and 5 mcg/mL Injection Capsule Dose: 1 mcg to 2 mcg daily; 2 mcg to 4 mcg three times weekly Injection Dose: 0.04 mcg/kg to 1 mcg/kg as intravenous bolus every other day at any time during dialysis	Orthographic similarities: Both names begin the letters 'Pari' versus 'Peri', and the upstroke letters 'l' and 't' in the name Paricalcitol can appear like the upstroke letters 'k' and 'b' in the name Perikabiven. Injection dosage form Intravenous route of administration	Orthographic differences: There are four versus three upstroke letters in the name Paricalcitol versus Perikabiven, including an upstroke 'l' in the last letter position of the name Paricalcitol not present in the name Perikabiven. No overlap in strength or dose
8	Parlodel (Bromocriptine Mesylate) Tablets and Capsules 2.5 mg and 5 mg Dose: 0.5 mg to 2.5 mg once or twice daily	Orthographic similarities: Both names begin with the letters 'Par' versus 'Per', and the upstroke letters 'l' and 'd' can appear like the upstroke letters 'k' and 'b'.	Orthographic differences: There are eight letters in the name Parlodel including an upstroke letter 'l' in the last letter position, versus eleven letters in the name Perikabiven making the name appear longer when scripted and does not have an upstroke letter in the last letter position. No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Once or twice daily versus continuous infusion

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
9	Penciclovir (Penciclovir; proprietary name is Denavir) Topical Cream 1% Dose: Apply every two hours to genitals	Orthographic similarities: Both names contain eleven letters, begin with the letters 'Penci' versus 'Peri', the upstroke letter 'l' can appear like the upstroke letter 'b' and the ending letter string 'vir' can appear like the ending letter string 'ven' when scripted.	Orthographic differences: There are only two upstroke letters 'P' and 'l' in the name Penciclovir versus three upstroke letters 'P', 'k' and 'b' in the name Perikabiven making the shapes of the names appear different when scripted. No overlap in strength or dose Route of administration: Topical versus central or peripheral Frequency of administration: Every two hours versus continuous infusion
10	Pentamidine (Pentamidine Isethionate; proprietary name is Nebupent) For Inhalation 300 mg per vial Dose: 300 mg once every four weeks administered via Respirgard	Orthographic similarities: Both names contain eleven letters, begin with the letters 'Pen' versus 'Per', contain three upstroke letters 'P', 't' and 'd' versus 'P', 'k' and 'b' similarly placed in the names	No overlap in strength or dose Route of administration: Oral inhalation versus central or peripheral Frequency of administration: Every four weeks versus continuous infusion
11	Peramivir (Peramivir) For Injection 10 mg/mL and 20 mg/mL Dose: 6 mg/kg to 12 mg/kg intravenously over sixty minutes daily for five to ten days	Orthographic similarities: Both names begin with the letters 'Per' and the ending letter string 'ivir' can appear like the ending letter string 'iven' when scripted. For injection versus Injection dosage form Intravenous route of administration Infusion frequency of administration	Orthographic differences: There is only one upstroke letter 'P' in the name Peramivir while there are three upstroke letters 'P', 'k' and 'b' in the name Perikabiven. No overlap in strength or dose

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
12	Percodan-Demi (Aspirin and Oxycodone Hydrochloride) Tablet 325 mg/4.8355 mg Dose: One tablet every six hours; maximum daily dose of twelve tablets	Orthographic similarities: Both names begin with the letters 'Per' and the ending letter string 'an' can appear like the ending letter string 'en'. If scripted as one word, 'Percodandemi', the shapes of the two names appear similar including both names containing three upstroke letters 'P', 'd' and 'd' versus 'P', 'k' and 'b'.	Variations in product characteristics minimize the potential for confusion. Route of administration: Oral versus central or peripheral Frequency of administration: Every six hours versus continuous infusion over twelve to twenty-four hours
13	Pirfenidone*** (Pirfenidone; proprietary name is Esbriet) Capsule 267 mg Dose: 267 mg three times daily with food ***Proposed name Esbriet for NDA 022535 currently under review	Orthographic similarities: Both names contain eleven letters, begin with the letters 'Pir', contain three upstroke letters 'P', 'f' and 'd' versus 'P', 'k' and 'b' similarly placed in the names and the ending letter string 'one' can appear like the ending letter string 'ven' when scripted.	Route of administration: Oral versus central or peripheral No overlap in strength or dose Frequency of administration: Three times daily versus continuous infusion

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Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
14	Perflutren (Perflutren Lipid Microsphere; proprietary name is Definity) For Injectable Suspension 6.52 mg/mL Dose: 10 microliters/kg via intravenous bolus within thirty to sixty seconds followed by a 10 mL saline flush or 4 mL/minute intravenous infusion, titrate to achieve optimal image enhancement	Orthographic similarities: Both names begin with the letters 'Per', the upstroke letters 'f' and 't' in Perflutren are similarly placed to the upstroke letters 'k' and 'b' in Perikabiven and the ending letter string 'ren' can appear like the ending letter string 'ven' when scripted. Injection dosage form Intravenous route of administration Continuous intravenous infusion frequency of administration	Orthographic differences: There are four upstroke letters 'P', 'f', 'l' and 't' in the name Perflutren while there are only three upstroke letters 'P', 'k' and 'b' in the name Perikabiven. No overlap in strength or dose
15	Periactin (Cyproheptadine Hydrochloride) Tablet and Oral Solution 4 mg tablet 2 mg/5 mL oral solution Dose: 0.25 mg/kg/day or 8 mg/m ² for ages two to size; 4 mg to 20 mg per day for ages 7 to adult	Orthographic similarities: Both names begin with the letters 'Peri' and the ending letter string 'in' can appear like the ending letter string 'en' when scripted.	Orthographic differences: There are only nine letters in the name Periactin while there are eleven letters in the name Perikabiven making it appear longer when scripted. Additionally, there are only two upstroke letters 'P' and 't' in the name Periactin while there are three upstroke letters 'P', 'k' and 'b' in the name Perikabiven making the shapes of the names appear different when scripted. Route of administration: Oral versus central or peripheral No overlap in strength or dose Frequency of administration: Once daily versus continuous infusion

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
16	Periclean (Chloroxylenol) Topical spray and solution 1% Apply to affected area as needed	Orthographic similarities: Both names begin with the letters 'Peri', the second upstroke letter 'l' can appear like the second upstroke 'k' and the ending letter string 'ean' can appear like the ending letter string 'ven' when scripted.	There are nine letters in the name Periclean while there are eleven letters in the name Perikabiven making it appear longer when scripted. Additionally, there are two upstroke letters 'P' and 'l' in the name Periclean while there are three upstroke letters 'P', 'k' and 'b' in the name Perikabiven making the shapes of the names appear different when scripted. No overlap in strength or dose Route of administration: Topical versus central or peripheral
17	Peri-Colace (Docusate Sodium and Sennoside) Tablet 50 mg/8.6 mg Dose: Take one to four tablets in single or divided doses	Orthographic similarities: Both names begin with the letters 'Peri' and the upstroke letter 'l' in the name Peri-Colace can appear like the upstroke letter 'b' in the name Perikabiven and is similarly placed in the names. Additionally, both names are presented with three upstroke letters 'P', 'C' and 'l' versus 'P', 'k' and 'b'.	No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Single or divided doses versus continuous intravenous infusion
18	Perifosine*** (Perifosine) Tablet 50 mg Dose: 50 mg once daily ***Orphan drug under development IND (b) (4)	Orthographic similarities: Both names begin with the letters 'Peri', the fourth upstroke letter 'f' can appear like the fourth upstroke letter 'k' and the ending letter string 'ine' can appear like the ending letter string 'iven'	Orthographic differences: There are two upstroke letters 'P', and 'f' in the name Perifosine while there are three upstroke letters 'P', 'k' and 'b' in the name Perikabiven making the shapes of the names appear different when scripted. No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Once daily versus continuous intravenous infusion

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

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
19	Perindopril (Perindopril Erbumine; proprietary name is Aceon) Tablet 2 mg, 4 mg and 8 mg Dose: 2 mg to 8 mg once daily	Orthographic similarities: Both names contain eleven letters, begin with the letters 'Peri' and the upstroke letter 'd' can appear like the upstroke letter 'k' and is similarly positioned in the name.	Orthographic differences: There is a downstroke letter 'p' in the eighth letter position and an upstroke letter 'l' in the last letter position of the name Perindopril that are not present in the name Perikabiven. No overlap in strength or dose Route of administration: Oral versus central or peripheral
20	Periocheck (Stannous Fluoride) Topical solution or Gel 0.4% Gel and 0.63% Solution Dose: Swish and expectorate as needed; cover brush with gel and brush thoroughly or Use as directed	Orthographic similarities: Both names begin with the letters 'Peri' and the upstroke letter 'h' can appear like the upstroke letter 'k' or 'b' in the name Perikabiven and is similarly positioned in the name.	Orthographic differences: There is an upstroke letter 'k' in the last letter position of the name Periocheck that is not present in the same letter position of the name Perikabiven. No overlap in strength or dose Route of administration: Oral/topical versus central or peripheral
21	Periochip (Chlorhexidine Gluconate) Topical Insert (chip) 2.5 mg Dose: One periochip inserted into periodontal pocket with probing pocket depth greater than or equal to 5 mm; up to eight periochips may be inserted in a single visit by trained healthcare provider	Orthographic similarities: Both names begin with the letters 'Peri' and contain an upstroke letter 'h' versus 'b' similarly placed in the names.	Orthographic differences: There is a downstroke letter 'p' in the last letter position of the name Periochip that does not appear in the same letter position of the name Perikabiven. Additional, there are two upstroke letters 'P' and 'h' in the name Periochip while there are three upstroke letters 'P', 'k' and 'b' in the name Perikabiven. No overlap in strength or dose Route of administration: Periodontal versus central or peripheral

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
22	Periostat (Doxycycline Hyclate) Tablet 20 mg Dose: 20 mg twice daily	Orthographic similarities: Both names begin with the letters 'Peri' and contain three upstroke letters 'P', 't' and 't' versus 'P', 'k' and 'b'.	Orthographic differences: There is an upstroke cross-stroke letter 't' in the last letter position of the name Periostat that does not appear in the same letter position of the name Perikabiven. No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Twice daily versus continuous intravenous infusion
23	Perphenazine (Perphenazine) Tablet 2 mg, 4 mg, 8 mg and 16 mg Dose: 2 mg to 16 mg two to four times daily	Orthographic similarities: Both names contain eleven letters, begin with the letters 'Per', and the ending letter string 'zine' can appear like the ending letter string 'iven' when scripted.	Orthographic differences: There is a downstroke letter 'p' and only two upstroke letters 'P' and 'h' in the name Perphenazine versus no downstroke letters and three upstroke letters 'P', 'k' and 'b' in the name Perikabiven. No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Multiple times daily versus continuous intravenous infusion
24	Persantine (Dipyridamole) Tablet 25 mg, 50 mg, and 75 mg Dose: 25 mg to 100 mg four times daily	Orthographic similarities: Both names begin with the letters 'Per', the upstroke letter 't' can appear like the upstroke letter 'b' and the ending letter string 'ine' can appear like the ending letter string 'iven' when scripted.	Orthographic differences: There are two upstroke letters 'P' and 't' in the name Persantine while there are three upstroke letters 'P', 'k' and 'b' in the name Perikabiven. No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Multiple times daily versus continuous intravenous infusion

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
25	Pertofrane (Desipramine Hydrochloride) Tablet 25 mg, 50 mg, 75 mg and 100 mg Dose: 25 mg to 300 mg once daily	Orthographic similarities: Both names begin with the letters 'Per' and contain three upstroke letters 'P', 't' and 'f' versus 'P', 'k' and 'b' similarly placed in the names.	No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Once daily versus continuous intravenous infusion
26	Pirbuterol (Pirbuterol Acetate; proprietary name is Maxair) Inhaler 256 mcg per actuation from valve or 200 mcg from mouthpiece Dose: One to two inhalations every four to six hours	Orthographic similarities: Both names begin with the letter string 'Pir' versus 'Per', the upstroke letter 'b' and 't' in the name Pirbuterol are similarly placed with the upstroke letters 'k' and 'b'	Orthographic differences: There is an upstroke letter 'l' in the last letter position of the name Pirbuterol that is not present in the name Perikabiven. No overlap in strength or dose Route of administration: Oral inhalation versus central or peripheral Frequency of administration: Multiple times daily versus continuous intravenous infusion
27	Pregabalin (Pregabalin) Capsule 50 mg, 75 mg and 150 mg Dose: 50 mg to 600 mg two to three times daily depending on indication of use	Orthographic similarities: Both names begin with the letters 'Per' versus 'Pre', contain three upstroke letters 'P', 'b' and 'l' versus 'P', 'k' and 'b' similarly placed in the names, and end with the letter string 'in' versus 'en'.	Orthographic differences: There is a downstroke letter 'g' in the name Pregabalin that is not present in the name Perikabiven. No overlap in strength or dose Route of administration: Oral versus central or peripheral Frequency of administration: Multiple times daily versus continuous intravenous infusion

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
28	Proctofoam (Pramoxine Hydrochloride) Topical Foam 1% Dose: Apply to affected area five times daily	Orthographic similarities: Both names begin with the letters 'Pro' versus 'Per', contain three upstroke letters 'P', 't' and 'f' versus 'P', 'k' and 'b' similarly placed in the names and the ending letter string 'oam' can appear like the ending letter string 'ven' when scripted.	No overlap in strength or dose Route of administration: Topical versus central or peripheral Frequency of administration: Multiple times daily versus continuous intravenous infusion
29	Puralube (Mineral Oil and White Petrolatum Base) Ophthalmic Gel 15%/85% Dose: Apply to affected eye as needed or Use as directed	Orthographic similarities: Both names begin with the letters 'Pur' versus 'Per' and contain three upstroke letters 'P', 'l' and 'b' versus 'P', 'k' and 'b'.	There are eight letters in the name Puralube while there are eleven letters in the name Perikabiven making the name appear longer when scripted. No overlap in strength or dose Route of administration: Topical Ophthalmic versus central or peripheral
30	Remodulin (Treprostinil) Injection 1 mg/mL, 2.5 mg/mL, 5 mg/mL and 10 mg/mL Dose: 0.625 ng/kg/min to 2.5 ng/kg/min intravenous infusion or subcutaneous injection via subcutaneous catheter via infusion pump	Orthographic similarities: The first letter 'R' can appear like the first letter 'P', there are three upstroke letters 'P', 'd' and 'l' versus 'P', 'k' and 'b' similarly placed in the names and the ending letter string 'in' can appear like the ending letter string 'en' when scripted. Injection dosage form Intravenous route of administration Continuous infusion frequency of administration	No overlap in strength or dose

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)		STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the INFUSION RATE (mL per hour) along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
31	Palifermin (Palifermin; proprietary name is Kepivance) For Injection 6.25 mg per vial Dose: 60 mcg/kg/day intravenous bolus for three consecutive days and three days after myelotoxic therapy	Orthographic similarities: Both names begin with the letters 'Pa' versus 'Pe', contain three upstroke letters 'P', 'l' and 'f' versus 'P', 'k' and 'b', and contain the ending letter string 'min' versus 'ven'. Injection dosage form Intravenous route of administration Intravenous infusion frequency of administration	Orthographic differences: The upstroke letters 'l' and 'f' appear in the in the third and fifth letter position of the name Palifermin while the upstroke letters 'k' and 'b' appear in the fifth and seventh letter position of the name Perikabiven making the shapes of the names appear different when scripted. No overlap in strength or dose
32	Prednicarbate (Prednicarbate) Topical cream and ointment 0.1% Dose: Apply thin film to affected skin twice daily	Orthographic similarities: Both names begin with the letters 'Pre' versus 'Per', contain an upstroke 'd' versus 'k' and an upstroke letter 'b' in similar letter positions of the names.	Orthographic differences: There are thirteen letters in the name Prednicarbate while there are only eleven letters in the name Perikarbiven making the name appear shorter when scripted. Additinoally, there are a total of four upstroke letters 'P', 'd', 'b' and 't' in the name Prednicarbate while there are only three upstroke letters 'P', 'k' and 'b' in the name Perikabiven. No overlap in strength or dose Route of administration: Topical versus central or peripheral Frequency of administration: Twice daily versus continuous intravenous infusion

Appendix G: Perikabiven potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n=33)

Perikabiven (Lipid Injectable Emulsion with Amino Acids and Electrolytes and Dextrose)	STRENGTH*: 1440 mL, 1920 mL and 2400 mL intravenous infusion bags containing Amino Acids, glucose Monohydrate (Dextrose), Purified Soybean Oil and Electrolytes	USUAL DOSE*: 27 mL/kg/day to 40 mL/kg/day for adults; (b) (4) Infuse intravenously at maximum infusion rate of 3.7 mL/kg/hour over twelve to twenty-four. *TPN Physician Orders are typically presented with the <u>INFUSION RATE (mL per hour)</u> along with the bag volume size (i.e. 1440 mL, 1920 mL or 2400 mL
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
33 Provocholine (Methacholine Chloride) Powder for Inhalation 100 mg per vial Dose: Schedule of Povochohline challenge based on baseline pulmonary function; Five breaths at serial concentration of 0.025 mg/mL to 25 mg/mL	Orthographic similarities: Both names begin with the letters 'Pro' versus 'Per', contain three upstroke letters include 'P', 'h' and 'l' versus 'P', 'k' and 'b' similarly placed in the names, and contain the ending letter string 'ine' versus 'iven'.	No overlap in strength or dose Route of administration: Oral inhalation versus central or peripheral Frequency of administration: Performed during pulmonary testing versus continuous intravenous infusion

Appendix H: Kabiven and Perikabiven Content of Ingredients

Kabiven

How Supplied	2566 mL	2053 mL	1540 mL	1026 mL	(b) (4)
					(b) (4)
Composition					
Soybean Oil, USP (g/100 mL)			3.9		
Dextrose (b) (4) USP (g/100 mL)			9.8		
Amino Acids, USP (g/100 mL)			3.31		
Total Nitrogen (mg/100 mL)			526		
Essential amino acids (mg/100 mL)	Leucine, USP		231		
	Isoleucine, USP		164		
	Valine, USP		213		
	Lysine, USP (added as the hydrochloride salt)		263		
	Phenylalanine, USP		231		
	Threonine, USP		164		
	Methionine, USP		164		
	Tryptophan, USP		55		
Nonessential amino acids (mg/100 mL)	Alanine, USP		467		
	Arginine, USP		330		
	Aspartic Acid, USP		99		
	Glutamic Acid		164		
	Glycine, USP		231		
	Histidine, USP		199		
	Proline, USP		199		
	Serine, USP		131		
Electrolytes (mg/100 mL)	Tyrosine, USP		6.7		
	Sodium Acetate Trihydrate, USP		239		
	Potassium Chloride, USP		174		
	Sodium Glycerophosphate Anhydrous		147		
	Magnesium (b) (4) Heptahydrate, USP		96		
Electrolyte Profile ¹ (mEq/L)	Calcium Chloride Dihydrate, USP		29		
	Sodium ²		31 (31 mmol/L)		
	Potassium		23 (23 mmol/L)		
	Magnesium		7.8 (3.9 mmol/L)		
	Calcium		3.8 (1.9 mmol/L)		
	Phosphorous ³		N.A. (9.7 mmol/L)		
	Acetate ⁴		38 (38 mmol/L)		
	Chloride ⁵		45 (45 mmol/L)		
Caloric Content (kcal/L)	(b) (4)		7.8 (3.9 mmol/L)		
	From Dextrose		330		
	From Lipid		(b) (4)		
	From Amino Acids		130		
Total			(b) (4)		
pH ⁷			5.6		
Osmolarity (mOsm/L)			1060		

Dosage and Administration

- Adult dosage: 19 to 38 mL/kg/day (0.63 to 1.26 g/kg/day of amino acids, 0.74 to 1.48 g/kg/day of fat, 1.85 to 3.71 g/kg/day of dextrose) (2)
- (b) (4)
- The maximum infusion rate is 2.6 mL/kg/hour (corresponding to 0.25 g/kg/hour of dextrose, the limiting factor, 0.09 g/kg/h of amino acids, and 0.1 g/kg/hour of fat). Recommended infusion period is 12 to 24 hours (2)

Perikabiven

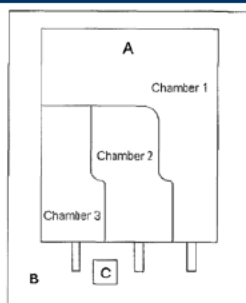
	2400 mL	1920 mL	1440 mL
How Supplied	(b) (4)		
(b) (4)			
Composition			
Soybean Oil, USP (g/100 mL)		3.5	
Dextrose (b) (4) USP (g/100 mL)		6.8	
Amino Acids, USP (g/100 mL)		2.36	
Total Nitrogen (mg/100 mL)		375	
Essential amino acids (mg/100 mL)	Leucine, USP	164	
	Isoleucine, USP	116	
	Valine, USP	152	
	Lysine, USP (added as the hydrochloride salt)	187	
	Phenylalanine, USP	164	
	Threonine, USP	116	
	Methionine, USP	116	
	Tryptophan, USP	40	
Nonessential amino acids (mg/100 mL)	Alanine, USP	333	
	Arginine, USP	235	
	Aspartic Acid, USP	71	
	Glutamic Acid	116	
	Glycine, USP	164	
	Histidine, USP	141	
	Proline, USP	141	
	Serine, USP	94	
Tyrosine, USP	4.8		
Electrolytes (mg/100 mL)	Sodium Acetate Trihydrate, USP	170	
	Potassium Chloride, USP	124	
	Sodium Glycerophosphate Anhydrous	105	
	Magnesium (b) (4) Heptahydrate, USP	68	
	Calcium Chloride Dihydrate, USP	20	
Electrolyte Profile ¹ (mEq/L)	Sodium ²	22 (22 mmol/L)	
	Potassium	17 (17 mmol/L)	
	Magnesium	5.6 (2.8 mmol/L)	
	Calcium	2.8 (1.4 mmol/L)	
	Phosphorous ³	N.A. (7.5 mmol/L)	
	Acetate ⁴	27 (27 mmol/L)	
	Chloride ⁵	32 (32 mmol/L)	
	(b) (4)	5.6 (2.8 mmol/L)	
Calorie Content (kcal/L)	From Dextrose	230	
	From Lipid	(b) (4)	
	From Amino Acids	95	
	Total	(b) (4)	
pH ⁷		5.6	
Osmolarity (mOsm/L)		750	

Dosage and Administration:

- Adult dosage: 27 to 40 mL/kg/day (0.64 to 0.94g/kg/day of amino acids, 0.95 to 1.4 g/kg/day of fat, 1.83 to 2.71 g/kg/day of dextrose) (2)
- (b) (4)
- The maximum infusion rate is 3.7 mL/kg/h (corresponding to 0.25 g/kg/h of dextrose, the limiting factor, 0.09 g/kg/h of amino acids, 0.13 g/kg/h fat). The recommended infusion period is 12 to 24 hours (2)

Appendix I: Kabiven/Perikabiven Three-Chamber Bag System

Container / Closure



- Chamber 1 = Glucose solution
- Chamber 2 = Amino acid solution
- Chamber 3 = Lipid Emulsion
- A = (b) (4) primary bag
- B = (b) (4)
- C = Oxygen absorber

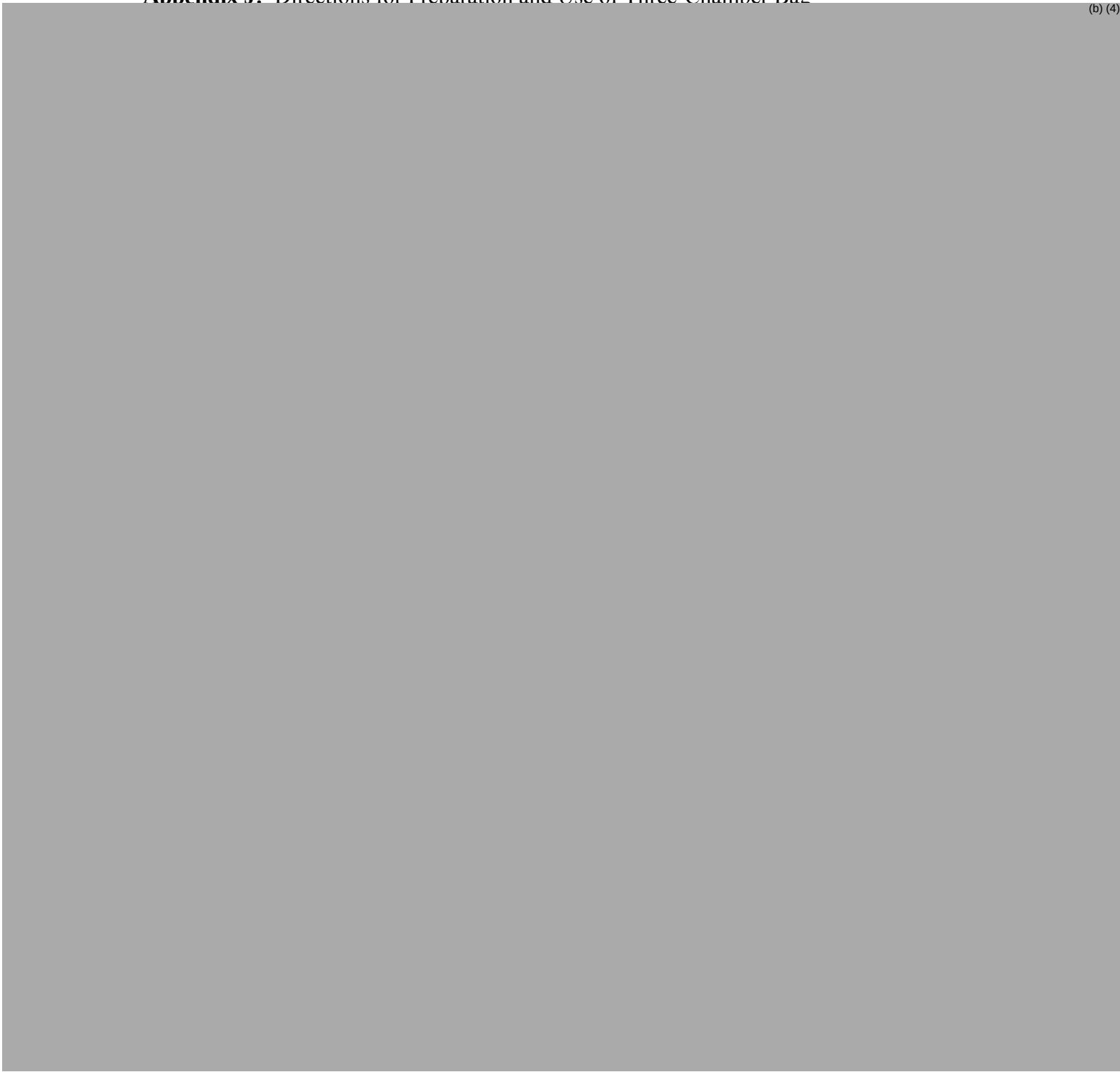
7

NDA 200-856

(b) (4)

Appendix J: Directions for Preparation and Use of Three-Chamber Bag

(b) (4)



Appendix K: Kabiven and (b) (4) Registration Worldwide
Kabiven Registration

Kabiven Status of Registration			
Country	Reg. Date (mm/dd/yy)	Trade Name	Reg. No
Denmark	09/16/99	Kabiven	20313/30883
Greece	10/19/99	Kabiven	21470/7-4-2011
France	11/08/99	Kabiven	NL 24758
Ireland	11/12/99	Kabiven	PA 566/3/1
United Kingdom	11/19/99	Kabiven	PL 08828/0131
Portugal	11/26/99	Kabiven	3022787
Netherlands	11/30/99	Kabiven	RVG 24292
Germany	12/01/99	Kabiven	46292.00.00
Sweden	12/03/99	Kabiven	14745
Belgium	12/13/99	Kabiven	BE208293
Finland	12/27/99	Kabiven	14207
Luxembourg	12/29/99	Kabiven	271597
Spain	05/09/00	KABIVEN emulsión para perfusión	62.985
Norway	05/15/00	Kabiven inf. væske, emulsjon	99-1181
Italy	10/11/00	Kabiven	34382010/M
Peru	03/19/01	Kabiven Emulsion para Infusion Inyectable	E-13724
Czech Republic	06/13/01		76/199/01-C
India	06/22/01		3179
Israel	07/15/01	Kabiven central	1226730262 00
South Korea	07/25/01		Daejon 31-1
Mexico	08/09/01	Kabiven	382M2001 SSA, IV
Singapore	09/04/01		SIN11657P
Slovakia	05/01/10		76/0302/01-S
Switzerland	10/08/01	Kabiven centralvenös	55573
Poland	11/14/01	Kabiven	9052
Slovenia	01/09/02	KABIVEN emulzija za infundiranje	5363-I-1556/08
Hungary	02/20/02	Kabiven emulziós infúzió	OGYI-T-8356/01-08
Hong Kong	03/11/02		HK-49268
Romania	05/10/02	Kabiven	2619/2002/01-04
South Africa	05/17/02	Kabiven Central	34/25.2/0440
New Zealand	06/27/02		TT 50-6821
Kuwait	09/14/02		4716
Brazil	01/08/03	Kabiven	Multiple
Argentina	01/24/03	Kabiven	50622
Bulgaria	02/03/03		20030099/03.02.2003
Lithuania	03/28/03	Kabiven	LT R 03/8090/3
Taiwan	04/30/03	Kabiven	23710
Chile	05/26/03	Kabiven Central	F-12822/08
Iceland	05/27/03	Kabiven	IS/1/03/023/01
Turkey	06/09/03	Kabiven iv infüzyon için emülsiyon	09.06.2003 114-12
Latvia	08/04/03	Kabiven emulsija infuzijam	03-0296
Thailand	09/03/03	Kabiven	2C 39/46
Malaysia	10/28/03	Kabiven	MAL 20034442A
Philippines	10/29/03	Kabiven Central	DR-XY29113
Namibia	08/04/01		04/25.2/0318
China	01/08/04		H20040007
Serbia	01/09/04	Kabiven	1461/2009/12
Estonia	02/06/04	Kabiven, infusiooniemulsioon	431104
Australia	06/08/04	Kabiven G19%	97889
Oman	03/01/05	Kabiven	4792/A, B, C
Croatia	06/28/05	Kabiven	Multiple
Russia	07/01/05	Kabiven central	~C-000417
Cyprus	07/11/05	Kabiven	S00150
Indonesia	08/03/05	Kabiven Central	DKI0574501249A1
Albania	10/31/05	KABIVEN	3721
Colombia	01/16/06	Kabiven	INV/IMA 2006M-0005177
Belarus	08/31/06	Kabiven - Emulsion for infusion	Jun-48
Panama	01/08/07	Kabiven emulsión para infusión i.v.	64774

Perikabiven Registration

(b) (4)

Status of Registration

<i>Country</i>	<i>Reg. Date (mm/dd/yy)</i>	<i>Trade Name</i>	<i>Reg. No</i>
Sweden	12/29/99	Kabiven Perifer	15636
Denmark	08/23/00	Kabiven Perifer	20313/31494
Netherlands	08/29/00	Kabiven Perifeer	RVG 25389
Finland	08/31/00	Kabiven Perifer	15633
Iceland	09/07/00	Kabiven Perifer	IS/1/00/012/01
Norway	09/12/00	Kabiven Perifer inf. væske, emulsjon	00-2053
United Kingdom	09/21/00	Kabiven Peripheral	PL 08828/0148
Ireland	09/29/00	Kabiven Peripheral	PA 566/3/2, 4
France	10/06/00	Perikabiven	NL 25 708
Belgium	10/16/00	Kabiven Peri	BE218224
Greece	12/05/00		27681/20-4-2011
Spain	01/18/01	KABIVEN PERIFÉRICO emulsión para perfusión	63.596
Germany	03/30/01	Kabiven peripher	49525.00.00
Czech Republic	06/13/01		76/200/01-C
Portugal	06/18/01	Kabiven Peripheral	3490489
Luxembourg	07/12/01	Kabiven peripher	302323
Israel	07/15/01		1228630282 00
South Korea	07/25/01		Daejon 31-2
Mexico	08/09/01		382M2001 SSA, IV
Slovakia	10/05/01		7610303/01-S
Singapore	11/16/01		SIN 11718 P
Thailand	12/28/01		2C 73/44
Hong Kong	01/11/02		HK-49006
Hungary	02/20/02		OGYI-T-8360/01-06
Poland	04/04/02	Kabiven Peripheral	9290
Romania	05/10/02	Kabiven Peripheral	2620/2002/01-03
New Zealand	06/27/02		TT50-6821/1
Slovenia	09/10/02	KABIVEN PERIPHERAL emulzija za infundiranje	5363-I-1366/08
Italy	09/21/02	Periven	035508011/M
Argentina	01/24/03	Kabiven Periférico	50622
Bulgaria	02/03/03		20030100/03.02.2003
Taiwan	04/30/03	Kabiven PI	23709
Chile	05/26/03	Kabiven Periferico	F-12821/08
Malaysia	05/29/03	Kabiven Peripheral	MAL 20033362A
Philippines	10/29/03	Kabiven Peripheral	DR-XY29112
China	01/08/04	Kabiven PI	H20040008
Serbia	01/09/04	Kabiven Peripheral	1463/2009/12
Turkey	03/10/04	Kabiven Peripheral IV infüzyon için emülsiyon	10.03.2004 115-70
Estonia	03/26/04	Kabiven Peripheral, infusiooniemulsioon	437204
Lithuania	04/13/04	Kabiven Peripheral	LT/1/04/0035/001
Australia	06/08/04	Kabiven G11%	97893
Oman	03/01/05	Kabiven Peripheral	4791/A, B
Brazil	04/14/05	Kabiven Peripheral	1.0041.9938
Indonesia	06/24/05	Kabiven Peripheral	DKI0574501149A1
Croatia	06/28/05	Kabiven peripheral	UP/I-530-09/05-01/665
Russia	07/01/05		~C-000418
Colombia	07/26/05	Kabiven Peripheral	INVIMA 2005M-0004596
India	08/01/05	Kabiven Peripheral	FF-53-5955
Albania	10/31/05	KABIVEN PERIFER	3720
Botswana	01/02/06		BOT0600845
South Africa	05/17/06		38/25/2/0165
Belarus	09/21/06	Kabiven Peripheral - Emulsion for infusion	Jun-62
Panama	01/08/07	Kabiven PI emulsión para infusión IV	64771
Syria	04/29/07		2744
Uruguay	07/25/07	Kabiven Periferico	41281
Ukraine	10/28/08		UA9045/01/01
United Arab Emirates	01/18/09	Kabiven Peripheral	5135-6346-1
Macedonia	01/30/09	Kabiven Peripheral emulsion for infuzion	15-4054/09
Paraguay	04/06/09		15751-01-EF

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/s/

CATHY A MILLER
11/10/2011

ZACHARY A OLESZCZUK
11/10/2011

CAROL A HOLQUIST
11/10/2011