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APPLICATION NUMBER:

202535Orig1s000

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: June 25, 2012

Reviewer: Carlos M Mena-Grillasca
Division of Medication Error Prevention and Analysis

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Drug Name and Strength: Prepopik
(Sodium Picosulfate, 10 mg
Magnesium Oxide, 3.5 gram
Citric Acid, 12 gram) Powder for Oral Solution

Application Type/Number: NDA 202535

Applicant/Sponsor: Ferring Pharmaceuticals

OSE RCM #: 2012-1205

*** 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 name, Prepopik, 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

Ferring Pharmaceuticals, Inc submitted a request for review of the proposed proprietary name, Picoprep (Sodium Picosulfate, Magnesium Oxide, and Citric Acid for oral solution), NDA 202535 on January 20, 2012. DMEPA found the proposed proprietary name unacceptable in OSE RCM# 2012, 313, dated April 26, 2012. Subsequently, the Applicant submitted a request for review of the proposed proprietary name, Prepopik on May 23, 2012.

Concurrent with the submission of the Application on September 16, 2011, the FDA received a Citizen's Petition to request the FDA refrain from approving any products containing Sodium Picosulfate.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 23, 2012 proprietary name submission.

- Active Ingredients: Sodium Picosulfate, Magnesium Oxide, and Citric Acid
- Indication of Use: Cleansing of the colon as a preparation for colonoscopy in adults
- Route of Administration: Oral
- Dosage Form: Powder for Oral Solution
- Strength: 10 mg/3.5 g/12 g
- Dose and Frequency of Administration: One dose of Prepopik consists of 2 packets of powder for oral solution, each dissolved in 5 ounces of cold water and administered at separate times. Additional fluids must be consumed.
 1. Split-Dose regimen: The first Prepopik packet is taken the night before the colonoscopy, and the second is taken the next day, in the morning of colonoscopy.
 2. Day-Before regimen: The first Prepopik packet is taken in the afternoon or early evening and the second is taken approximately 6 hours later, the night before the colonoscopy.
- How Supplied: Supplied in cartons containing 2 packets of powder for oral solution, along with a pre-marked dosing cup.
- Storage: 25°C (77°F). Excursions permitted at 15°C to 30°C (59°F to 86°F)

- Container and Closure Systems: Prepopik is filled in a sachet (b) (4)

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 name is acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors Products 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 safety evaluation.

2.2.1 *United States Adopted Names (USAN) SEARCH*

The June 13, 2012, United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the proposed name, Prepopik, connotes a preparation for colonoscopy.

The proposed name is comprised of a single word that contains the prefix 'Prep', which refers to a preparation for colonoscopy which is the indicated use for this product. 'Prep' has been used in other bowel cleansing preparations in the market (e.g. Moviprep and Osmoprep). In these cases it is used in the suffix of the name. To date we have no reported errors with this suffix. We do not anticipate placement of 'Prep' at the beginning of the name to be a source of error. The look- and sound-alike nature of this placement is evaluated in section 2.2.5. of this review.

In addition, the proposed name contains the letters 'po', which is a standard medical abbreviation for "oral". Typically, we discourage routes of administration within proprietary names because it limits the use of the same name for future product line extensions where oral may not be the route of administration. Given the placement of 'po' within the middle of the name, we do not deem the use of the letter string misleading or confusing.

2.2.3 *FDA Name Simulation Studies*

Nineteen practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Six participants (inpatient= 3 and outpatient= 6) interpreted the name correctly as 'Prepopik'. Four participants in the inpatient prescription studies misinterpreted the letter 'i' as the letter 'e', four participants in the outpatient prescription studies misinterpreted the letter

'i' as the letter 'a', and four participant in the voice prescription studies misinterpreted the letter 'k' as the letter 'c'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, May 31, 2012 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Prepopik. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Prepopik identified by the primary reviewer and the Expert Panel Discussion (EPD), and other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and Other Disciplines)					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Depapred-40	EPD	Pregnyl	EPD	Propalmex	EPD
Depapred-80	EPD	Prempro	EPD	Propecia	EPD
DepoCyt	EPD	Prepcat	EPD	Propofol	EPD
Depoject-40	EPD	Prepidil	EPD	Propulsid	EPD
Depoject-80	EPD	Procapan	EPD	Protropin	EPD
Depopred	EPD	Propacet 100	EPD		
Look and Sound Similar					
Picoprep***	EPD	PreProtein	EPD	Protropic	EPD
Prep Kit	EPD	Prevpac	EPD		

Our analysis of the 22 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the names will pose a risk for confusion as described in Appendix D and E

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors Products via e-mail on June 15, 2012. At that time we also requested additional information or concerns that could inform our review. The Division of Gastroenterology and Inborn Errors did not state any additional concerns with the proposed proprietary name, Prepopik.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Prepopik, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your May 23, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

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. 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.

10. 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.

11. 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.

12. 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.

13. Red Book (www.thomsonhc.com/home/dispatch)

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

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

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

15. Medical Abbreviations (www.medilexicon.com)

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

16. CVS/Pharmacy (www.CVS.com)

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. 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.

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

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.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

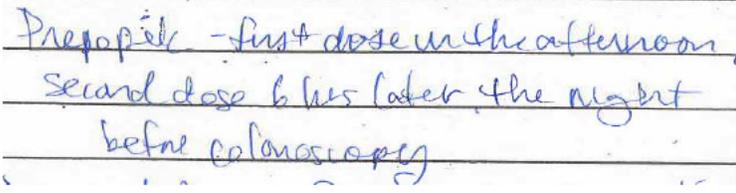
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval 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 with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Picoprep	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘P’	‘D’, ‘R’, ‘F’, ‘O’	‘B’
Lower case ‘p’	‘yn’, ‘ys’, ‘g’, ‘j’, ‘q’, ‘l’, ‘e’, ‘c’, ‘x’, ‘n’, ‘f’	‘b’
Lower case ‘r’	‘s’, ‘n’, ‘e’, ‘v’	‘wr’
Lower case ‘e’	‘c’, ‘i’, ‘o’, ‘l’, ‘a’	Any vowel
Lower case ‘i’	‘e’, ‘l’, ‘r’	Any vowel
Lower case ‘o’	‘e’, ‘i’, ‘a’, ‘c’, ‘u’	‘oh’
Lower case ‘k’	‘l’, ‘h’	‘c’, ‘q’

Appendix C: Prescription Simulation Samples and Results

Figure 1. Prepopik Study (Conducted on 6/5/12)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Prepopik</p> <p>First dose in the afternoon. Second dose, 6 hours later the night before colonoscopy.</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study
20 People Responded

Study Name: Prepopik

Total	8	5	7	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
ESPRIOPIC	0	1	0	1
PRAOPIC	0	1	0	1
PREOPIC	0	1	0	1
PREPAPAK	0	0	1	1
PREPOPAK	1	0	3	4
PREPOPEK	2	0	0	2
PREPOPELE	1	0	0	1
PREPOPET	1	0	0	1
PREPOPIK	3	0	3	6
PRIOPIC	0	1	0	1
PRIOPIQ	0	1	0	1

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

Proprietary Name	Active Ingredient	Similarity to Prepopik	Failure preventions
Prempro	Conjugated estrogens and medroxyprogesterone	Look	The name pair has sufficient orthographic and/or phonetic differences.
Propecia	Finasteride	Look	The name pair has sufficient orthographic and/or phonetic differences.
Procapan	Procainamide Hydrochloride	Look	The name pair has sufficient orthographic and/or phonetic differences.
Protropin	Somatrem	Look	The name pair has sufficient orthographic and/or phonetic differences.
Propalmex	Saw Palmetto	Look	The name pair has sufficient orthographic and/or phonetic differences.
Depapred-40 Depapred-80	Methylprednisolone Acetate	Look	Name identified in Red Book online database. Unable to find product characteristics in commonly used drug databases (e.g. drugs@fda, dailymed, Clinical Pharmacology, Facts and Comparison, RxList, CVS.com, and Walgreens)
Depopred	Methylprednisolone Acetate	Look	Name identified in Red Book online database. Unable to find product characteristics in commonly used drug databases (e.g. drugs@fda, dailymed, Clinical Pharmacology, Facts and Comparison, RxList, CVS.com, and Walgreens). Orthographic differences: There is only one skinny letter ‘i’ between the last downstroke letter ‘p’ and the ending upstroke in Prepopik vs. two letters ‘re’ separating the last down stroke ‘p’ and ending upstroke ‘d’ in Depopred. In addition, the upstrokes at the end of the names, ‘k’ vs. ‘d’ have different shape as they face opposite directions. These differences may help differentiate the names when scripted.

Proprietary Name	Active Ingredient	Similarity to Prepopik	Failure preventions
Depoject-40 Depoject-80	Methylprednisolone Acetate	Look	Name identified in Red Book online database. Unable to find product characteristics in commonly used drug databases (e.g. drugs@fda, dailymed, Clinical Pharmacology, Facts and Comparison, RxList, CVS.com, and Walgreens)
Prep Kit	n/a	Look and sound	Name identified in Micromedex database. However, the primary safety evaluator was not able to replicate this search either in the same database or other commonly used drug databases.
PreProtein	n/a	Look and sound	Name identified in Micromedex online database. Unable to find product characteristics in commonly used drug databases (e.g. drugs@fda, dailymed, Clinical Pharmacology, Facts and Comparison, RxList, CVS.com, and Walgreens).
Picoprep	Sodium Picosulfate, Magnesium Oxide, Citric Acid	Look and sound	Proposed proprietary name found unacceptable by DMEPA (OSE RCM# 2012-313). The alternate name for this product, Propopik, is the subject of this review.
Propacet 100	Acetaminophen and Propoxyphene napsylate	Look	Product withdrawn from the market due to safety concerns.
Propulsid	Cisapride Monohydrate	Look	Voluntarily withdrawn from the US market in July 2000 because of the risk of serious cardiac arrhythmias and death. Drug available to licensed physicians in the US through an investigational limited access program.

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.

<p>Proposed name: Prepopik (Sodium Picosulfate, Magnesium Oxide, Citric Acid)</p>	<p>Strength(s): 10 mg/3.5 g/12 g</p>	<p>Usual dose: Dissolve each packet of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>DepoCyt (Cytarabine liposome) Injection 50 mg/5 mL</p> <p>Usual Dose:</p> <p>Induction therapy: DepoCyt, 50 mg, administered intrathecally (intraventricular or lumbar puncture) every 14 days for 2 doses (weeks 1 and 3).</p> <p>Consolidation therapy: DepoCyt, 50 mg, administered intrathecally (intraventricular or lumbar puncture) every 14 days for 3 doses (weeks 5, 7 and 9) followed by 1 additional dose at week 13.</p> <p>Maintenance: DepoCyt, 50 mg, administered intrathecally (intraventricular or lumbar puncture) every 28 days for 4 doses (weeks 17, 21, 25 and 29).</p> <p>If drug related neurotoxicity develops, the dose should be reduced to 25 mg.</p>	<p>Orthographic: The first letters ‘P’ and ‘D’ may look similar when scripted. Both names contain similar number of letters (8 vs. 7). Both names contain two downstrokes and an upstroke in similar positions. Both names share the letter string ‘epo’ in a similar position.</p> <p>Strength: Single strength</p>	<p>Frequency of Administration: First packet taken the night before, and the second packet in the morning prior to colonoscopy or first packet in the afternoon or early evening, and the second packet 6 hours later, the night before colonoscopy vs. every 14 days for 2 doses during induction therapy; every 14 days for 3 doses followed by 1 additional dose at week 13 during consolidation therapy; every 28 days for 4 doses during maintenance therapy.</p> <p>Usual Dose: Dissolve each packet of powder in 5 ounces of cold water vs. 50 mg</p>

Proposed name: Prepopik (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each packet of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Prevpac (Amoxicillin, Clarithromycin, Lansoprazole) Capsules, Tablets, and Capsules 500 mg/500 mg/30 mg</p> <p>Usual Dose: The recommended adult oral dose is 30 mg Prevacid (one capsule), 1 g amoxicillin (four capsules), and 500 mg Clarithromycin (one tablet) administered together twice daily (morning and evening) for 10 or 14 days. Or prescribed 'as directed'.</p>	<p>Orthographic: Both names begin with the letter 'P' and contain a letter 'p' in a similar position (4th vs. 5th position).</p> <p>Phonetic: Both names begin with the same sounding syllable 'pre'. Both names end with a similar sounding syllables ('pik' vs. 'pac').</p> <p>Route of Administration: Oral</p> <p>Strength: Single strength</p> <p>Overlap in the Usual Dose and Frequency of Administration: May be prescribed 'as directed'</p>	<p>Orthographic: The extra downstroke letter 'p' (in the 6th position) and extra upstroke letter 'k' in Prepopik, provides a different shape when scripted.</p> <p>Phonetic: Prepopik has 3 syllables vs. 2 syllables in Prevpac. The additional syllable 'po' in the middle of the name in Prepopik provides phonetic differentiation between the names.</p>

Proposed name: Prepopik (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each packet of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Pregnyl (Chorionic gonadotropin) For Injection 10,000 USP Units/vial</p> <p>Usual Dose: <i>Prepubertal cryptorchidism not due to anatomical obstruction. Therapy is usually instituted in children between the ages of 4 and 9.</i></p> <ol style="list-style-type: none"> 1. 4,000 USP Units three times weekly for three weeks. 2. 5,000 USP Units every second day for four injections. 3. 15 injections for 500 to 1,000 USP Units over a period of six weeks. 4. 500 USP Units three times weekly for four to six weeks. If this course of treatment is not successful, another series is begun one month later, giving 1,000 USP Units per injection. <p><i>Selected cases of hypogonadotropic hypogonadism in males.</i></p> <ol style="list-style-type: none"> 1. 500 to 1,000 USP Units three times a week for three weeks, followed by the same dose twice a week for three weeks. 2. 4,000 USP Units three times weekly for six 	<p>Orthographic: Both names contain similar number of letters (8 vs. 7). Both names begin with the letter string 'Pre' followed by a downstroke ('p' vs. 'g'). Both names contain two downstrokes and an upstroke in similar positions.</p> <p>Strength: Single strength</p>	<p>Frequency of Administration: First packet taken the night before, and the second packet in the morning prior to colonoscopy, or, first packet in the afternoon or early evening, and the second packet 6 hours later, the night before colonoscopy vs. variable (for example: 3 times weekly for 3 to 6 weeks; every second day for 4 injections; 15 injections over a period of six weeks, etc.)</p> <p>Usual Dose: Dissolve each packet of powder in 5 ounces of cold water vs. 500 USP Units to 10,000 USP Units.</p>

<p>to nine months, following which the dosage may be reduced to 2,000 USP Units three times weekly for an additional three months.</p> <p><i>Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure and who has been appropriately pretreated with human menopausal gonadotropins.</i></p> <p>(See prescribing information for menopausal gonadotropins for dosage and administration for that drug product.)</p> <p>5,000 to 10,000 USP Units one day following the last dose of menopausal gonadotropins. (A dosage of 10,000 USP Units is recommended in the labeling for menopausal gonadotropins.)</p>		
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Proposed name: Prepopik (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each packet of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Prepcat (Barium Sulfate) Oral Suspension, 1.5%</p> <p>Note: Product is off-market but other products available.</p> <p>Usual Dose: Oral dosage: For administration to allow radiographic examination of the gastrointestinal (GI) tract (gastrointestinal radiography): NOTE: Diagnostic procedures that involve administration of radiopaque agents must be carried out under the direction of personnel with the requisite training and thorough knowledge of the procedure to be performed.</p> <p>•for use as a contrast in upper GI studies: <u>Oral dosage:</u> Adults, Geriatric, Adolescents and Children: Individual technique and technology of the specific procedure, the desired level of contrast density and patient age/size will determine the barium suspension viscosity, quantity and concentration to be used. Products are labeled with suggested dilutions and volumes of administration that are product-specific.</p> <p>• for use as a contrast in lower GI studies (barium enema): <u>Rectal dosage:</u> Same as above</p>	<p>Orthographic: Both names contain similar number of letters (8 vs. 7). Both names begin with the same letter string ‘Prep’ and end in an upstroke (‘k’ vs. ‘t’).</p> <p>Strength: Single strength</p> <p>Route of administration: Oral</p>	<p>Orthographic: Prepopik contains an additional downstroke letter ‘p’, which may help differentiate the names.</p> <p>Frequency of Administration: First packet taken the night before, and the second packet in the morning prior to colonoscopy, or, first packet in the afternoon or early evening, and the second packet 6 hours later, the night before colonoscopy vs. one time during radiologic procedure.</p>

Proposed name: Prepopik (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each packet of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Prepidil (Dinoprostone) Gel, 0.5 mg</p> <p>Usual Dose: 0.5 mg every 6 hours based on course of clinical events. Maximum recommended cumulative dose for a 24- hour period is 1.5 mg.</p>	<p>Orthographic: Both names contains 8 letters, start with the letter string 'Prep' and end in an upstroke ('k' vs. 'l').</p> <p>Strength: Single strength</p>	<p>Orthographic: Prepopik has a downstroke letter 'p' in the same location where Prepidil has a upstroke letter 'd', which may help differentiate the names</p> <p>Setting of Use: Prepopik is to be used in preparation for a colonoscopy prior to the procedure vs. Prepidil is used for the induction of labor in the OR. In addition, Prepidil includes a labeled Warning for Hospital use only. To be administered by physicians in a hospital that can provide immediate intensive care and acute surgical facilities.</p> <p>Frequency of Administration: First packet taken the night before, and the second packet in the morning prior to colonoscopy, or, first packet in the afternoon or early evening, and the second packet 6 hours later, the night before colonoscopy vs. one time or every six hours during labor</p>

Proposed name: Prepopik (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each packet of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Propofol Injectable Emulsion 1% (10 mg/mL)</p> <p>Usual Dose: Individualized by patient based upon indication, age and co-morbidities. See Appendix F.</p>	<p>Orthographic: Both names contain 8 letters. The letter string 'Prepo' look similar to the letter string 'Propo'. Both names end in an upstroke ('k' vs. 'l').</p> <p>Strength: Single strength</p>	<p>Orthographic: Prepopik has a downstroke letter 'p' in the same location where Propofol has a upstroke letter 'f'. In addition, the skinny 'i' in Prepopik is in the same position as the rounded letter 'o' in Propofol, which may help differentiate the names.</p> <p>Setting of Use: Prepopik is to be used in preparation for a colonoscopy prior to the procedure vs. Propofol is used in the ICU, OR, or ER just prior or during a procedure under controlled conditions.</p> <p>Frequency of Administration: First packet taken the night before, and the second packet in the morning prior to colonoscopy, or, first packet in the afternoon or early evening, and the second packet 6 hours later, the night before colonoscopy vs. one time during procedure.</p> <p>Usual Dose: Dissolve each packet of powder in 5 ounces of cold water vs. weight based dosing</p>

Proposed name: Prepopik (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each packet of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Protopic (Tacrolimus) Ointment, 0.03% and 0.1%</p> <p>Usual Dose: Apply a thin layer to the affected skin twice daily.</p>	<p>Orthographic: Both names contain 8 letters and share the letter strings 'Pr' and 'opi' in the same position. The ending letter 'k' may look like a 'l c', making the ending letter look like the ending letter 'c' in Protopic.</p> <p>Phonetic: Both names contain 3 syllables. The first syllable in both names begins with the sound 'pr'. The second syllable in both names contains the sound 'o'. The third syllable in both names sound the same ('pik' vs. 'pic').</p> <p>Overlap in the Usual Dose and Frequency of Administration: Both products may be prescribed 'as directed'.</p>	<p>Strength: Single strength vs. 0.03% and 0.1%</p> <p>Orthographic: Prepopik has a down stroke letter 'p' in the same position that Protopic has an up stroke letter 't'. Prepopik has an additional upstroke letter in the last position that is not seen in Protopic.</p> <p>Phonetic: The first syllable in Prepopik ends with an 'ε' sound vs. Protopic ends with an 'o' sound. The second syllable in Prepopik begins with a bilabial sound 'p' vs. an alveolar sound 't' in Protopic.</p>

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06/26/2012

**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: April 26, 2012

Reviewer: Manizheh Siahpoushan, PharmD
Division of Medication Error Prevention and Analysis

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

Deputy Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

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

Drug Name and Strength: Picoprep
(Sodium Picosulfate, 10 mg
Magnesium Oxide, 3.5 gram
Citric Acid, 12 gram) Powder for Oral Solution

Application Type/Number: NDA 202535

Applicant/Sponsor: Ferring Pharmaceuticals

OSE RCM #: 2012-313

*** 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 name, Picoprep, 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

Ferring Pharmaceuticals, Inc submitted a request for review of the proposed proprietary name, Picoprep (Sodium Picosulfate, Magnesium Oxide, and Citric Acid for oral solution), NDA 202535 on January 20, 2012. Concurrent with the submission of the Application on September 16, 2011, the FDA received a Citizen's Petition to request the FDA refrain from approving any products containing Sodium Picosulfate. Additionally, the Applicant did not submit a USAN name for Sodium Picosulfate (an NME), and was notified by the Agency that the lack of a USAN name is an approvability issue.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 31, 2012 proprietary name submission.

- Active Ingredients: Sodium Picosulfate, Magnesium Oxide, and Citric Acid
- Indication of Use: Cleansing of the colon as a preparation for colonoscopy in adults
- Route of Administration: Oral
- Dosage Form: Solution
- Strength: 10 mg/3.5 g/12 g
- Dose and Frequency of Administration: One dose of Picoprep consists of 2 pouches of powder for oral solution, each dissolved in 5 ounces of cold water and administered at separate times. Additional fluids must be consumed.
 1. Split-Dose regimen: The first Picoprep pouch is taken the night before the colonoscopy, and the second is taken the next day, in the morning of colonoscopy.
 2. Day-Before regimen: The first Picoprep pouch is taken in the afternoon or early evening and the second is taken approximately 6 hours later, the night before the colonoscopy.
- How Supplied: Supplied in cartons containing 2 pouches of powder for oral solution, along with a pre-marked dosing cup.
- Storage: 25°C (77°F). Excursions permitted at 15°C to 30°C (59°F to 86°F)
- Container and Closure Systems: Picoprep is filled in a sachet (b) (4)

[REDACTED]

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 name is acceptable from a promotional perspective. The Division of Gastroenterology and Inborn Errors Products concurred with the findings of OPDP's promotional assessment of the proposed name. However, in the initial assessment of the proposed name, DMEPA found the prefix 'Pico' may be misleading because 'pico' is a known designated metric prefix which defines a very small quantity (i.e. $p = 10^{-12}$). We are concerned that the use of this prefix may suggest a much smaller quantity of the product (10 ounces) or the amount of clear liquids required to be consumed prior to colonoscopy (64 ounces), to patients or healthcare providers. This concern was forwarded to OPDP on February 22, 2012. On February 28, 2012, OPDP responded that they maintain their position of 'no objection'.

Although OPDP did not find the name promotional, we still find the name misleading due to the inclusion of the prefix "pico" (see section 2.2.2 for discussion)

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

On February 9, 2012, the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

In their January 30, 2012 proposed proprietary name submission, the Applicant states that the proposed name connotes low-volume preparation for colonoscopy.

This proprietary name is comprised of a single word that contains the prefix 'Pico' and the suffix 'prep'. The prefix 'pico' is part of the name of one of the ingredients of this product (i.e. Sodium Picosulfate), however, the proposed proprietary name does not contain part of the name of the other two ingredients in this product (i.e. Magnesium Oxide and Citric Acid) in accordance with 21 CFR 201.6(b) which states:

The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

Thus, DMEPA finds this naming strategy unacceptable because it is misleading and suggests only one of the active ingredients.

Additionally, DMEPA finds the prefix ‘Pico’ misleading for this product because ‘pico’ is a known designated metric prefix which defines a very small quantity (i.e. $p = 10^{-12}$). We are concerned that the use of this prefix may suggest a much smaller quantity of the product (10 ounces) or the amount of clear liquids required to be consumed prior to colonoscopy (64 ounces) to patients or healthcare providers.

The suffix ‘prep’ refers to a preparation for colonoscopy which is the indicated use for this product and has been used in other bowel cleansing preparations in the market (ex. Moviprep and Osmoprep). Therefore, the use of the suffix ‘prep’ is acceptable for this product.

2.2.4 FDA Name Simulation Studies

Twenty-five practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Sixteen participants (inpatient= 7, voice= 1, and outpatient= 8) interpreted the name correctly as ‘Picoprep’. One participant in the inpatient prescription studies misinterpreted the first letter ‘P’ as the letter ‘D’ and one participant in the voice prescription studies misinterpreted the first letter ‘P’ as the letter ‘F’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, February 10, 2012 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name 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 name, Picoprep. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Picoprep identified by the primary reviewer and the Expert Panel Discussion (EPD). Table 1 also includes the names identified by (b) (4) not identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD (b) (4))

Look Similar					
Name	Source	Name	Source	Name	Source
Prepidil	EPD	Pilopine HS	EPD	Electroprep	EPD
Suprep	EPD	Dicopac Kit	EPD	Diazepam	EPD
Divalproex Sodium	EPD	Principen	EPD	Penapar-VK	EPD

Table 1 (continued): Collective List of Potentially Similar Names (DMEPA, EPD (b) (4))

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Prograf	EPD	Duraprep	EPD	Osmoprep	EPD
Decapryn	EPD	Decaspray	EPD	Dacogen	EPD
Prevpac	EPD	(b) (4)***	EPD	(b) (4)***	EPD
Docefrez	EPD	Moviprep	EPD	Pen prep	Primary Reviewer
LoSo Prep	Primary Reviewer				
Sound Similar					
Glycoprep	EPD	Prilosec	EPD		
Look and Sound Similar					
Cetapred	(b) (4)	Pilocarpine	(b) (4)	Pneumovax 23	(b) (4)
X-prep	(b) (4)	Picoprep	EPD	Picoprep-3	EPD
Pediapred	(b) (4)				

Our analysis of the 31 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 28 of the 31 total number of names will not pose a risk for confusion as described in Appendix D and E. However, the proposed name could be confused with LoSo Prep, Pen prep, and Duraprep. The rationale for the risk of confusion is described in section 4.1.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors Products via e-mail on February 28, 2012. At that time we also requested additional information or concerns that could inform our review. The Division of Gastroenterology and Inborn Errors did not state any additional concerns with the proposed proprietary name, Picoprep.

3 DISCUSSION

The proposed proprietary name is composed of the prefix ‘Pico’ and the suffix ‘prep’. The suffix ‘prep’ refers to a preparation for colonoscopy which is the indicated use for this product and has been used in other bowel cleansing preparations in the market (ex.

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Moviprep and Osmoprep). We are unaware of any errors due to the use of the suffix ‘prep’ for bowel preparations, therefore, the use of the suffix ‘prep’ is acceptable for this product.

DMEPA finds the prefix ‘Pico’ misleading for this product because ‘Pico’ is part of the name of one of the ingredients in this product (i.e. Sodium Picosulfate), however, the proposed proprietary name does not contain part of the name of the other two ingredients in this product (i.e. Magnesium Oxide and Citric Acid). Additionally, ‘Pico’ is a known designated metric prefix which defines a very small quantity (i.e. $p = 10^{-12}$). We are concerned that the use of this prefix may suggest a much smaller quantity of the product (10 ounces) or the amount of clear liquids required to be consumed prior to colonoscopy (64 ounces), to patients or healthcare providers. Furthermore, we identified three marketed product names, LoSo Prep, Pen prep, and Duraprep to be orthographically similar to, and share other product characteristics with the proposed name, Picoprep, and are discussed in section 4.1.

4 CONCLUSIONS

The proposed proprietary name is acceptable from a promotional perspective but is not acceptable from a safety perspective. The proposed name is misleading because of the use of the prefix ‘Pico’, and the proposed name is vulnerable to name confusion with LoSo Prep, Pen prep, and Duraprep. Therefore, the decision to deny the name will be communicated to the Applicant via letter (See section 4.1).

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

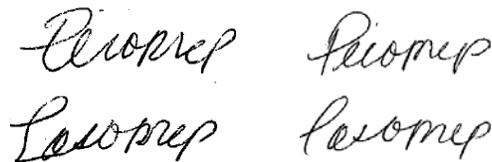
4.1 COMMENTS TO THE APPLICANT

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

- 1) The proposed proprietary name, Picoprep, is orthographically similar to the proprietary names: Loso prep, Pen prep, and Duraprep. We acknowledge that the proposed Picoprep is a prescription drug product, while LoSo prep, Pen prep, and Duraprep are over-the-counter drug products. However, we have determined that this difference in marketing will not prevent errors between these products because postmarketing experience with other drug products demonstrates that name confusion can occur between similarly named over-the-counter drug products and prescription drug products.¹ The similarity of the names is described below.

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1. ¹ “Sudafed-Sotalol mix-ups.” ISMP Medication Safety Alert! Community/Ambulatory Care Edition. Volume 5, Issue 5. May 2006.
 2. “Benazepril confused with Benadryl.” ISMP Medication Safety Alert! Community/Ambulatory Care Edition. Volume 7, Issue 12. December 2008.
 3. “Sound-alike names.” ISMP Medication Safety Alert! Community/Ambulatory Care Edition. Volume 8, Issue 9. September 2008.  Regarding cetirizine and sertraline confusion.

- A. The proposed proprietary name, Picoprep is orthographically similar to and shares overlapping product characteristics with the over-the-counter product, LoSo prep, a low sodium bowel cleansing system containing one 1.3 ounce packet of Magnesium Carbonate, Citric Acid, and Potassium Citrate effervescent powder for oral solution, four Bisacodyl tablets, 5 mg each, and one Bisacodyl suppository, 10 mg, available at some pharmacies and Gastroenterologists' offices. The orthographic similarity stems from the same shape and length of the names, same letter string 'oprep', similar letters in the second position ('I' vs. 'o'), and beginning letters that may appear similar when scripted ('P' vs. 'L'). Although LoSo prep appears as two words in the list of references, prescribers may script the name as one word (i.e. Losoprep) or with minimum space between 'Loso' and 'prep'. Similarly, the name Picoprep may be inadvertently scripted with a gap between 'Pico' and 'prep'.



The image shows four handwritten examples of the names 'Picoprep' and 'Losoprep' in cursive script. The top row shows 'Picoprep' and 'Pico prep' with a gap. The bottom row shows 'Losoprep' and 'Loso prep' with a gap. This illustrates how the similar letter shapes and spacing in cursive can lead to confusion between the two names.

In addition to the orthographic similarity of this name pair, Picoprep and LoSo prep share product characteristics which include the following: both products are single strength, therefore the strength may be omitted on prescription orders, dose and instructions for use (both may be written as 'Use as directed), frequency of administration (once before the procedure), overlapping dosage form (solution), overlapping route of administration (oral), and similar patient and prescriber population (patients preparing for colonoscopy and Gastroenterologists). Although LoSo prep is an over-the-counter product, over-the-counter products can be written on a prescription. Therefore, we are concerned that a written order for "LoSo prep as directed before colonoscopy" could be misinterpreted as "Picoprep as directed before colonoscopy". Therefore, the orthographic similarities and overlapping product characteristics increase the likelihood of a medication error to occur in the usual practice setting.

We note that the name LoSo prep was also identified as a potential look and sound-alike name to Picoprep by ^{(b)(4)} EPD in the external study.

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4. "Mucinex-Mucomyst: Too close for comfort." ISMP Medication Safety Alert! Community/Ambulatory Care Edition. Volume 4, Issue 1. January 2005.
 5. "From the database." ISMP Medication Safety Alert! Community/Ambulatory Care Edition. Volume 8, Issue 2. February 2009. Regarding Motrin and Neurontin confusion.
 6. "More on confirmation bias." ISMP Medication Safety Alert! Volume 1, Issue 23. November 20, 1996. Regarding Cozaar and Colace confusion
 7. "Safety briefs: Mirapex and Miralax confusion." ISMP Medication Safety Alert! Volume 7, Issue 20. October 3, 2002."

However, (b)(4) did not consider this name further after it was reviewed by the FMEA panel because it was determined that the name, LoSo prep, has enough sound-alike and/or look-alike difference, and/or product profile characteristic differences with Picoprep, and therefore (b)(4) determined the risk for confusion between the names at any point under the proposed prescribing conditions was considered to be minimal. We disagree with (b)(4) orthographic assessment as outlined above.

- B. The proposed name, Picoprep is orthographically similar to and shares overlapping product characteristics with the over-the-counter product, Pen Prep. Pen prep is available as both Magnesium Citrate (17 grams in 10 fluid ounces), a monograph product indicated for relief of occasional constipation (product available on the Daily Med database), and as a colon lavage kit consisting of four 10 fluid ounce bottles of Polyethylene Glycol and two 10 fluid ounce bottles of Magnesium Citrate. This product is available directly from the manufacturer. The orthographic similarity stems from the same shape and similar length of the names, same suffix ‘prep’, same beginning letter ‘P’, and similar letters in the second (‘i’ vs. ‘e’) and third positions (‘c’ vs. ‘n’). Although Pen prep appears as two words in the list of references, prescribers may script the name as one word (i.e. Penprep) or with minimum space between ‘Pen’ and ‘prep’. Similarly, the name Picoprep may be inadvertently scripted with a gap between ‘Pico’ and ‘prep’.



The image shows two lines of handwritten text in cursive. The first line is 'Picoprep' and the second line is 'Penprep'. The handwriting is fluid and somewhat slanted, illustrating the visual similarity between the two names, particularly in the spacing and the shape of the letters.

In addition to the orthographic similarity of this name pair, Picoprep and Pen prep share product characteristics which include the following: both products are single strength, therefore the strength may be omitted on prescription orders, dose and instructions for use (both may be written as ‘Use as directed), overlapping frequency of administration (once before the procedure), overlapping dosage form (solution), route of administration (oral), and similar patient and prescriber population (patients preparing for colonoscopy and Gastroenterologists). Although Pen prep is only available directly from the manufacturer, a pharmacist may have Pen prep (Magnesium Citrate) readily available in the pharmacy, for use as a laxative due to patient (or healthcare provider) demand. Additionally, a patient may take a prescription to a pharmacy to have the pharmacy order the product. Therefore, we are concerned that a written order for “Picoprep use as directed” could be misinterpreted as “Pen prep use as directed” or vice versa. Thus, the orthographic similarities and overlapping product characteristics increase the likelihood of a medication error to occur in the usual practice setting.

- C. The proposed proprietary name, Picoprep is orthographically similar to and shares overlapping product characteristics with the over-the-counter product, Duraprep, a surgical solution containing Iodine and Isopropyl Alcohol, used as a preoperative skin preparation. The orthographic similarity stems from the same shape and length of the names, same suffix ‘prep’, similar letters in the second (‘i’ vs. ‘u’), third (‘c’ vs. ‘r’), and fourth (‘o’ vs. ‘a’) positions, and similar beginning letters (‘P’ vs. ‘D’) when scripted. Additionally, the letter ‘P’ was misinterpreted as the letter ‘D’ in our prescription analysis studies .



The image shows four handwritten examples of the names 'Picoprep' and 'Duraprep' in cursive script. The top row shows 'Picoprep' on the left and 'Duraprep' on the right. The bottom row shows 'Duraprep' on the left and 'Duraprep' on the right. The handwriting is fluid and cursive, illustrating the orthographic similarities between the two names.

In addition to orthographic similarity of this name pair, Picoprep and Duraprep share product characteristics which include the following: both products are single strength, therefore, the strength may be omitted on prescription orders, dose and instructions for use (both may be prescribed as ‘use as directed prior to procedure’, overlap in the frequency of administration (once before procedure), and despite differing dosage forms, both products can be given by a single route of administration, thus the dosage form and the route of administration may be omitted by the prescriber. Although Duraprep is an over-the-counter skin preparation, it could be used in inpatient settings, and inpatient orders could be written for Duraprep, particularly if the patient was undergoing a procedure at the bedside. Additionally, bowel preparations can also be used in inpatient settings and can also be sent to a patient’s bedside. Therefore, an order written for ‘Picoprep use as directed prior to procedure’ for a patient who requires colon lavage prior to an operation, may be misinterpreted as ‘Duraprep use as directed prior to procedure’ by an inpatient pharmacy. Thus, the orthographic similarities and overlapping product characteristics increase the likelihood of a medication error to occur in the usual practice setting.

We note that the name Duraprep was also identified as a potential sound-alike name to Picoprep by (b) (4) EPD in the external study. However, (b) (4) did not consider this name further after it was reviewed by the FMEA panel because it was determined that the name, Duraprep, has enough sound-alike and/or look-alike difference, and/or product profile characteristic differences with Picoprep, and therefore the risk for confusion between the names at any point under the proposed prescribing conditions was considered to be minimal. We disagree with (b) (4) assessment as outlined above. We further acknowledge that Picoprep and Duraprep have different dosage forms and route of administrations, however, we have learned from post-marketing experience that differentiating product characteristics such as dosage form and route of administration may not help prevent medication errors between names

with strong orthographic similarities particularly because these elements may not always be specified on prescriptions.

- 2) We find the inclusion of the “Pico-“ prefix in your Picoprep name concerning because it a) suggests the name of one, but not all of your active ingredients, and b) it defines a very small quantity.

- A. The prefix ‘pico’ in the proposed proprietary name, Picoprep is part of the name of one of the ingredients in this product (i.e. Sodium Picosulfate), however, the proposed proprietary name does not contain part of the name of the other two ingredients in this product (i.e. Magnesium Oxide and Citric Acid). As such, we find the name misleading in accordance with 21 CFR 201.6(b) which states:

The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

- B. The prefix ‘Pico’ in the proposed proprietary name, Picoprep is a known designated metric prefix which defines a very small quantity (i.e. $p = 10^{-12}$). We are concerned that the use of this prefix may suggest a much smaller quantity of the product (i.e. smaller than the proposed total of 10 ounces for this product) or smaller amount of clear liquids required to be consumed prior to colonoscopy (smaller than the recommended total of 64 ounces for this product), to patients or healthcare providers. Therefore, we find the prefix ‘Pico’ misleading for this product.

5 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. *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.

10. *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.

11. *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.

12. *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.

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

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

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

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

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

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

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

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

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

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

18. Rx List (www.rxlist.com)

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

19. 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.

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.²

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.

² National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.³

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).

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

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

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ 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

⁴ 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

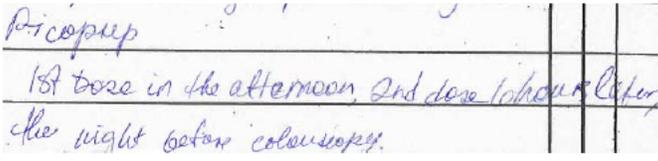
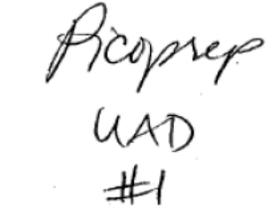
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval 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 with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Picoprep	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘P’	‘D’, ‘R’, ‘F’, ‘O’	‘B’
Lower case ‘p’	‘yn’, ‘ys’, ‘g’, ‘j’, ‘q’, ‘l’, ‘e’, ‘c’, ‘x’, ‘n’, ‘f’	‘b’
Lower case ‘i’	‘e’, ‘l’, ‘r’	Any vowel
Lower case ‘c’	‘e’, ‘l’, ‘a’, ‘l’, ‘n’, ‘r’	‘z’, ‘k’, ‘s’
Lower case ‘o’	‘e’, ‘i’, ‘a’, ‘c’, ‘u’	‘oh’
Lower case ‘r’	‘s’, ‘n’, ‘e’, ‘v’	‘wr’
Lower case ‘e’	‘c’, ‘i’, ‘o’, ‘l’, ‘a’	Any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Picoprep Study (Conducted on 2/10/12)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Picoprep Use as directed #1</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study
25 People Responded

Study Name: Picoprep

Total	8	8	9	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
DICOPREP	1	0	0	1
FECOPREP	0	1	0	1
PICKELPROC	0	1	0	1
PICKELPRUP	0	1	0	1
PICKO PREP	0	1	0	1
PICKOPREP	0	1	0	1
PICKUBTRUCK	0	1	0	1
PICLEPRUK	0	1	0	1
PICOPREP	7	1	8	16
PICPREP	0	0	1	1

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

Proprietary Name	Active Ingredient	Similarity to Picoprep	Failure preventions
Prepidil	Dinoprostone	Look	The name pair has sufficient orthographic and/or phonetic differences.
Pilopine HS	Pilocarpine Hydrochloride	Look	The name pair has sufficient orthographic and/or phonetic differences.
Electroprep	PEG 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride for oral solution and Bisacodyl Tablets USP	Look	The name pair has sufficient orthographic and/or phonetic differences.
Suprep	Sodium Sulfate, Potassium Sulfate, Magnesium Sulfate	Look	The name pair has sufficient orthographic and/or phonetic differences.
Glycoprep	PEG 3350-, Potassium Chloride, Sodium Bicarbonate, Sodium Chloride, Sodium Sulfate Anhydrous	Sound	The name pair has sufficient orthographic and/or phonetic differences. Additionally, Application withdrawn FR effective 2/2/01.
Prilosec	Omeprazole Magnesium	Sound	The name pair has sufficient orthographic and/or phonetic differences.
Cetapred	Sulfacetamide Sodium, Prednisolone Acetate Ophthalmic ointment	Look and sound (b) (4)	The name pair has sufficient orthographic and/or phonetic differences.
Pilocarpine	Pilocarpine	Look and sound (b) (4)	The name pair has sufficient orthographic and/or phonetic differences.
Pneumovax 23	Pneumococcal 23-val P-sac Vaccine	Look and sound (b) (4)	The name pair has sufficient orthographic and/or phonetic differences.
X-prep	Senna, Sucrose	Look and sound (b) (4)	The name pair has sufficient orthographic and/or phonetic differences.

Picoprep	Sodium Picosulfate, Magnesium Oxide, Citric Acid	Look and sound	Product is the subject of this review. Additionally, Picoprep is a registered product by the same Applicant (Ferring Pharmaceuticals) in Canada, Mexico, Benelux, Australia, and China.
Picoprep-3	Sodium Picosulfate	Look and sound	Product only found in a February 2004 Australian article titled ‘Picoprep-3 is a superior colonoscopy preparation to Fleet- a randomized, controlled trial comparing the two bowel preparations’, comparing Picoprep-3 to Fleet.
Pediapred	Prednisolone Sodium Phosphate	Look and sound ^{(b) (4)}	The name pair has sufficient orthographic and/or phonetic differences.
Dicopac Kit	Cyanocobalamin, Cyanocobalamin CO-57, Cyanocobalamin CO-58	Look	The name pair has sufficient orthographic and/or phonetic differences. Additionally, Application was withdrawn FR effective 9/17/03.
Diazepam	Established name for Valium	Look	The name pair has sufficient orthographic and/or phonetic differences.
Divalproex Sodium	Established name for Depakote	Look	The name pair has sufficient orthographic and/or phonetic differences.
Principen	Ampicillin/Ampicillin Trihydrate	Look	ANDA 061392, Application withdrawn FR effective 2/2/07, ANDA 061394, Application withdrawn FR effective 7/8/11, ANDA 062888, Application withdrawn FR effective 11/22/06.
Penapar-VK	Penicillin V Potassium	Look	The name pair has sufficient orthographic and/or phonetic differences. Additionally, ANDA’s 062001 and 062002; Applications withdrawn FR effective 1/7/92.
Decapryn	Doxylamine Succinate	Look	The name pair has sufficient orthographic and/or phonetic differences. Additionally, Application was withdrawn FR effective 4/4/05.
Decaspray	Dexamethasone Aerosol Spray	Look	Application withdrawn FR effective 9/17/03 (Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons.) Additionally, there are no generic equivalents of Dexamethasone 0.04% aerosol spray available in the market, and no product characteristics could be located in any of the available 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.

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Dacogen (Decitabine) Injection 50 mg/vial</p> <p>Usual Dose: Administer at a dose of 15 mg/m² by continuous intravenous infusion over 3 hours repeated every 8 hours for 3 days. Repeat cycle every 6 weeks. Or administer at a dose of 20 mg/m² by continuous intravenous infusion over 1 hour repeated daily for 5 days. Repeat cycle every 4 weeks.</p>	<p>Orthographic: Both names share the letter string ‘-co-‘ in the same position, the same letter ‘e’ in a similar position (7th vs. 6th position), and contain a downstroke in the 5th position (‘p’ vs. ‘g’). Additionally, the letter string ‘Pi-‘ in Picoprep may appear similar to the letter string ‘Da-‘ in Dacogen when scripted.</p> <p>Strength: Single strength</p>	<p>Frequency of Administration: First pouch taken the night before, and the second pouch in the morning prior to colonoscopy or first pouch in the afternoon or early evening, and the second pouch 6 hours later, the night before colonoscopy vs. over 3 hours every 8 hours for 3 days or over 1 hour for 5 days.</p> <p>Usual Dose: Dissolve each pouch of powder in 5 ounces of cold water vs. 15 mg/m² to 20 mg/m².</p>

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Prevpac (Amoxicillin, Clarithromycin, Lansoprazole) Capsules, Tablets, and Capsules 500 mg/500 mg/30 mg</p> <p>Usual Dose: The recommended adult oral dose is 30 mg Prevacid (one capsule), 1 g amoxicillin (four capsules), and 500 mg Clarithromycin (one tablet) administered together twice daily (morning and evening) for 10 or 14 days. Or prescribed 'as directed'.</p>	<p>Orthographic: Both names begin with the letter 'P' and contain the letter 'p' in a similar position (4th vs. 5th position). Additionally, letter string '-ico-', letter 'e' and letter 'p' (in the 8th position) in Picoprep may appear similar to letter string '-rev-', letter 'a', and letter 'c' in Prevpac, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Strength: Single strength</p> <p>Overlap in the Usual Dose and Frequency of Administration: May be prescribed 'as directed'</p>	<p>Orthographic: The extra letter 'p' (in the 8th position) in Picoprep, provides a different shape and a longer length for Picoprep vs. Prevpac, when scripted.</p>

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode

(b) (4)

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

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode

(b) (4)

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

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Prograf (Tacrolimus) Tablet, 0.5 mg, 1 mg, 5 mg Injection, 5 mg/mL</p> <p>Usual Dose: Recommended initial oral dose: Two divided doses of 0.075 mg/kg/day to 0.2 mg/kg/day every 12 hours. The recommended starting dose of Prograf injection is 0.03-0.05 mg/kg/day in kidney and liver transplant and 0.01 mg/kg/day in heart transplant given as a continuous IV infusion.</p>	<p>Orthographic: Both names begin with letter 'P', contain letter 'o' and 'r' in similar positions (3rd vs. 4th and 5th vs. 6th positions, respectively). Additionally, letter 'p' (5th position) and letter 'p' (8th position) may appear similar to letters 'g' and 'f', respectively, when scripted.</p> <p>Overlap in the Route of Administration: Oral</p>	<p>Frequency of Administration: First pouch taken the night before, and the second pouch in the morning prior to colonoscopy, or, first pouch in the afternoon or early evening, and the second pouch 6 hours later, the night before colonoscopy vs. every 12 hours or continuous infusion.</p> <p>Usual Dose: Dissolve each pouch of powder in 5 ounces of cold water vs. 0.03 mg/kg/day to 0.2 mg/kg/day</p>

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Osmoprep (Sodium Phosphate Dibasic, Anhydrous/ Sodium Phosphate Monobasic, Monohydrate) Tablet 0.398 gram/1.102 gram</p> <p>Usual Dose: The recommended dose for adults is 32 tablets taken 4 at a time (the night before and the day of colonoscopy). Patients should drink at least 2 quarts of clear liquids with OsmoPrep.</p>	<p>Orthographic: Both names consist of 8 letters, share letter string '-prep' and letter 'o' in the same position (4th position), and begin with letters that may appear similar when scripted ('P' vs. 'O').</p> <p>Route of Administration: Oral</p> <p>Strength: Single strength</p> <p>Overlap in the Usual Dose and Frequency of Administration: Both may be prescribed 'as directed before colonoscopy.'</p>	<p>Orthographic: The skinny letter 'i' in Picoprep and letter 'm' in Osmoprep provide different shapes for these two names (i.e. longer prefix, 'Osmo' vs. shorter prefix, 'Pico') and can help differentiate Picoprep and Osmoprep when scripted.</p>

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Docefrez (Docetaxel) Injection 20 mg/vial and 80 mg/vial</p> <p>Usual Dose: Administer intravenously over 1 hr every 3 weeks. BC locally advanced or metastatic: 60 mg/m² to 100 mg/m² single agent NSCLC: after platinum therapy failure: 75 mg/m² single agent HRPC: 75 mg/m² with 5 mg prednisone twice a day continuously</p>	<p>Orthographic: Both names consist of 8 letters, share the letter string '-re-' in the same position, contain a letter string ('-ico-' vs. '-oce-'), and a beginning letter ('P' vs. 'D') that may appear similar when scripted. Additionally, letters 'p' (in the 5th position) and 'p' (in the 8th position) in Picoprep may appear similar to letters 'f' and 'z' in Decefrez, respectively, when scripted.</p>	<p>Strength: Single strength vs. 20 mg/vial and 80 mg/vial</p> <p>Frequency of Administration: First pouch taken the night before, and the second pouch in the morning prior to colonoscopy, or, first pouch in the afternoon or early evening, and the second pouch 6 hours later, the night before colonoscopy vs. over one hour every 3 weeks or twice daily continuously.</p> <p>Usual Dose: Dissolve each pouch of powder in 5 ounces of cold water vs. 60 mg/m² to 100 mg/m².</p>

Proposed name: Picoprep (Sodium Picosulfate, Magnesium Oxide, Citric Acid)	Strength(s): 10 mg/3.5 g/12 g	Usual dose: Dissolve each pouch of powder in 5 ounces of cold water and administer at separate times, followed by additional fluids.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Moviprep (Ascorbic Acid, PEG 3350, Potassium Chloride, Sodium Ascorbate, Sodium Chloride, Sodium Sulfate) Solution 4.7 gram, 100 gram, 1.015 gram, 5.9 gram, 2.69 gram, 7.5 gram</p> <p>Usual Dose: Split-dose regimen: The evening before the colonoscopy, take the first liter of Moviprep solution (8 ounces every 15 minutes) followed by 16 ounces of clear liquid. On the morning of, take the second liter solution over one hour followed by 16 ounces of clear liquid. Evening only (full-dose) regimen: Around 6 PM in the evening before the colonoscopy, take the first liter of Moviprep solution (8 ounces every 15 minutes), then about 1½ hours later take the second liter solution followed by 32 ounces of clear liquids.</p>	<p>Orthographic: Both names consist of 8 letters and share the letter string '-prep'. Additionally, letter string '-ico' in Picoprep may appear similar to letter string '-ovi-' when scripted.</p> <p>Route of Administration: Oral</p> <p>Overlap in the Dosage Form: Solution</p> <p>Strength: Single strength</p> <p>Overlap in the Usual Dose and Frequency of Administration: May be prescribed 'as directed before colonoscopy'.</p>	<p>Orthographic: The beginning letters ('P' vs. 'M') appear different when scripted and can help differentiate Picoprep and Moviprep when scripted.</p>

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MANIZHEH SIAHPOUSHAN
04/26/2012

ZACHARY A OLESZCZUK
04/26/2012

KELLIE A TAYLOR
04/26/2012

KELLIE A TAYLOR on behalf of CAROL A HOLQUIST
04/26/2012