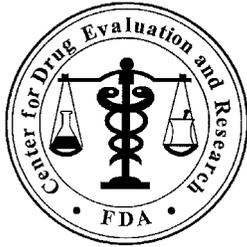


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022372Orig1s000

PROPRIETARY NAME REVIEW(S)



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

Date: May 6, 2010

To: Donna Griebel, MD, Director
Division of Gastroenterology Products

Through: Melina Griffis, R.Ph, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Anne Crandall, PharmD. Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Suprep Bowel Prep Kit (Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate) Oral Solution, 17.5 g/3.13 g/1.6 g

Application Type/Number: NDA 022372

Applicant: Braintree Laboratories, Inc

OSE RCM #: 2010-809

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Suprep Bowel Prep Kit, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Suprep Bowel Prep Kit, acceptable in OSE Review #2008-1436 dated April 16, 2009 and OSE Reviews #2009-888 dated August 10, 2009 and January 10, 2010. DDMAC reviewed the proposed name on September 17, 2008 and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Suprep Bowel Prep Kit, during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria used in OSE Review #2008-1436 for the proposed proprietary name, Suprep Bowel Prep Kit. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases did not yield any new names thought to look or sound similar to Suprep Bowel Prep Kit and represent a potential source of drug name confusion. Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 30, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The re-review of the proposed proprietary name, Suprep Bowel Prep Kit, did not identify any additional names thought to look or sound similar to the proposed name since our last review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Suprep Bowel Prep Kit, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE reviews # 2008-1436 Proprietary Name and Label Review of Suprep Bowel Prep Kit and #2009-888 Final Proprietary Name Reviews of Suprep Bowel Prep Kit; Crandall, Anne.

2. **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.

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

USAN Stems List contains all the recognized USAN stems.

4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22372	ORIG-1	BRAINTREE LABORATORIES INC	SUPREP BOWEL PREP KIT

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/s/

ANNE CRANDALL
05/06/2010

MELINA N GRIFFIS
05/06/2010

DENISE P TOYER
05/06/2010



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

Date: January 14, 2010

To: Donna Griebel, MD, Director
Division of Gastroenterology Products

Through: Melina Griffis, R.Ph, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Anne Crandall, PharmD. Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Suprep Bowel Prep Kit (Sodium sulfate, Potassium sulfate, and Magnesium sulfate) Oral Solution, 17.5 g/3.13 g/1.6 g

Application Type/Number: NDA 022372

Applicant: Braintree Laboratories, Inc

OSE RCM #: 2009-888

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Suprep Bowel Prep Kit, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Suprep Bowel Prep Kit, acceptable in OSE Reviews #2008-1436 dated April 16, 2009 and #2009-888 dated August 10, 2009. DDMAC reviewed the proposed name on September 17, 2008 and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Suprep Bowel Prep Kit during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria used in OSE Review #2008-1436 for the proposed proprietary name, Suprep Bowel Prep Kit. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern.

Although none of the product characteristics have been changed, the Applicant altered the presentation of the proprietary name to all capital letters for the first component of the name; SUPREP Bowel Prep Kit (previously Suprep Bowel Prep Kit). Therefore, the search was conducted using all capitals and standard case presentation.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases did not yield any new names thought to look or sound similar to Suprep Bowel Prep Kit and represent a potential source of drug name confusion. Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 5, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The re-review of the proposed proprietary name, Suprep Bowel Prep Kit, did not identify any additional names thought to look or sound similar to the proposed name since our last review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Suprep Bowel Prep Kit, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE reviews # 2008-1436 Proprietary Name and Label Review of Suprep Bowel Prep Kit and #2009-888 Final Proprietary Name Review of Suprep Bowel Prep Kit; Crandall, Anne.

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

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

USAN Stems List contains all the recognized USAN stems.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22372	ORIG-1	BRAINTREE LABORATORIES INC	SUPREP BOWEL PREP KIT

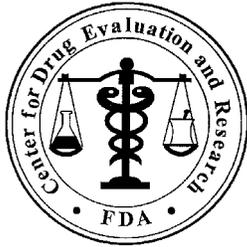
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/s/

ANNE CRANDALL
01/14/2010

MELINA N GRIFFIS
01/15/2010

DENISE P TOYER
01/15/2010



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

Date: August 10, 2009

To: Donna Griebel, MD, Director
Division of Gastroenterology Products

Through: Melina Griffis, R.Ph, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Anne Crandall, PharmD. Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Final Proprietary Name Review

Drug Name(s): Suprep Bowel Prep Kit (Sodium sulfate, Potassium sulfate, and Magnesium sulfate) Oral Solution, 17.5 g/3.13 g/1.6 g

Application Type/Number: NDA 22-372

Applicant: Braintree Laboratories, Inc

OSE RCM #: 2009-888

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1 INTRODUCTION

This review is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Suprep Bowel Prep Kit, acceptable in OSE Review #2008-1436, dated April 16, 2009. Since that review, none of Suprep Bowel Prep Kit's product characteristics have been altered. Additionally, on September 17, 2008, DDMAC reviewed the proposed name and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Suprep Bowel Prep Kit during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same searches criteria used in OSE Review #2008-1436 for the proposed proprietary name, Suprep Bowel Prep Kit. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases did not yield any new names thought to look or sound similar to Suprep Bowel Prep Kit and represent a potential source of drug name confusion.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of August 5, 2009.

3 CONCLUSIONS AND RECOMMENDATIONS

The re-review of Suprep Bowel Prep Kit did not identify any additional names thought to look or sound similar to the proposed name since our last review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Suprep Bowel Prep Kit, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE review # 2008-1436, Proprietary Name and Label Review of Suprep Bowel Prep Kit; Crandall, Anne.

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

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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.

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

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

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

USAN Stems List contains all the recognized USAN stems.

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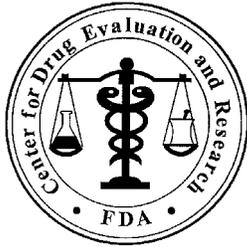
/s/

ANNE CRANDALL
08/10/2009

MELINA N GRIFFIS
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DENISE P TOYER
08/10/2009

CAROL A HOLQUIST
08/10/2009



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

Date: April 16, 2009

To: Donna Griebel, M.D. Director
Division of Gastroenterology Products

Through: Kristina Arnwine, Pharm.D., Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, RPh., Director
Division of Medication Error Prevention and Analysis

From: Anne Crandall, PharmD. Safety Evaluator,
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name and Labeling Review

Drug Name(s): SuPrep Bowel Prep Kit (Sodium sulfate, Potassium sulfate, and Magnesium sulfate) for Oral Solution, 17.5 g/3.13 g/1.6 g

Application Type/Number: NDA # 22-372

Applicant: Braintree Laboratories, Inc.

OSE RCM #: 2008-1436

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EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found that the proposed name, SuPrep Bowel Prep Kit, is not vulnerable to name confusion that could lead to medication errors. Thus, we do not object to the use of the proprietary name SuPrep Bowel Prep Kit for this product.

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

The results of the Labeling Risk Assessment identified areas of needed improvement. A detailed discussion can be found in Section 4.2. DMEPA cannot comment on the patient instructions provided in Spanish as this is beyond the scope and capacity of our review.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from the Division of Gastroenterology Products for assessment of the proprietary name to evaluate SuPrep Bowel Prep Kit for its potential to contribute to medication errors. The proposed name, SuPrep Bowel Prep Kit is evaluated to determine if the name could potentially be confused with other proprietary or established drug names in a clinical setting. Additionally, the container label, carton and package insert labeling were submitted for review and comment.

1.2 REGULATORY HISTORY

The NDA was submitted July 1, 2008 with a user fee goal date of May 2, 2009.

1.3 PRODUCT INFORMATION

SuPrep Bowel Prep Kit is a gastrointestinal lavage indicated for the cleansing of the colon in preparation for colonoscopies in adults. The recommended directions for SuPrep Bowel Prep Kit are based upon (b) (4) initiate therapy the day before the procedure (b) (4)

The Overnight Preparation involves:

- Administration of one six ounce bottle one day prior to colonoscopy.
- Administration of second dose occurs 10 to 12 hours after first dose, with the second six ounce bottle.

(b) (4)

(b) (4)

(b) (4)

SuPrep Bowel Prep Kit is a kit which contains (two) six ounce bottles of liquid concentrate (each bottle contains: 17.5 g of Sodium sulfate, 3.13 g of Potassium sulfate, and 1.6 g of Magnesium sulfate), (one) 16 ounce mixing cup (b) (4)

Each six ounce bottle must be diluted with 16 ounces of water, therefore a 16 ounce mixing cup is provided. The liquid concentrate, once diluted is intended for oral ingestion.

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by the Division of Medication Error Prevention and Analysis' staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment) and label, labeling, and/or packaging risk assessment (see 2.2 Labeling Risk Assessment). The primary focus for both of the assessments is to identify and remedy potential sources of medication error prior to drug approval. The Division 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

2.1 PROPRIETARY NAME RISK ASSESSMENT

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

For the proprietary name, SuPrep Bowel Prep Kit, the DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). The Division also conducts internal FDA prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see detail 2.1.4).

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see detail 2.1.2). The overall risk assessment is based on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.² FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. We use the clinical expertise of the DMEPA staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed drug name include, but are not limited to established name of the

¹ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>.

² Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

proposed product, the proposed indication, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, we consider 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

2.1.1 Search Criteria

The DMEPA staff considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letter ‘S’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{4,5}

To identify drug names that may look similar to SuPrep Bowel Prep Kit, the DMEPA staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (four words, 18 letters), capital letters (five, ‘S’, ‘P’, ‘B’, ‘K’), up-strokes (two, ‘l’, ‘t’), down strokes (one, ‘p’), cross-strokes (one, ‘t’) and dotted letters (one, ‘i’). Additionally, several letters in SuPrep Bowel Prep Kit may be vulnerable to ambiguity when scripted, including the capital letter ‘S’ may appear as capital letter ‘G’; lower case ‘u’ may appear as ‘a’ or ‘o’; upper case ‘P’ may look like upper case ‘R’, ‘K’ or ‘B’; lower case ‘p’ may look like lower case ‘q’ or ‘g’; lower case ‘e’ may look like ‘i’ and lower case ‘r’ may look like ‘n’ or ‘s’. As such, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to SuPrep Bowel Prep Kit.

Although the entire name consists of SuPrep Bowel Prep Kit, the word analyzed most thoroughly in the content of the name is ‘SuPrep’ as this is newly introduced word into the marketplace. The ‘Bowel Prep Kit’ aspect of the name is widely accepted and known in the medication use process and is routinely dispensed or prescribed prior to colonoscopies (e.g. Bisacodyl Bowel Prep Kit). Additionally, it is not uncommon for prescribers to drop descriptor components of the name, in this case ‘Bowel Prep Kit’ and simply refer to this medication as SuPrep. Because omission of a modifier is cited as a common cause of medication error, DMEPA considers “SuPrep Bowel Prep Kit” as a complete name as well as ‘SuPrep’ the root term, omitting the modifying term, ‘Bowel Prep Kit’. The DMEPA staff also considered the possibility of the prescribers not capitalizing the ‘P’ in SuPrep, and analyzed the name as ‘Suprep’ in addition to ‘SuPrep’.

When searching to identify potential names that may sound similar to SuPrep Bowel Prep Kit, the DMEPA staff search for names with similar number of syllables (2), stresses (SU-prep; su-PREP), and placement of vowel and consonant sounds. In addition, several letters in SuPrep Bowel Prep Kit may be subject to interpretation when spoken, including the letter ‘Su’ which may be interpreted as ‘Zu’, Xu or Sue; or ‘p’ may be interpreted as ‘b’. The Applicant’s intended

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

⁴ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

⁵ Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

The staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the DMEPA staff were provided with the following information about the proposed product: the proposed proprietary name (SuPrep Bowel Prep Kit), the established name (Sodium sulfate, Potassium sulfate, and Magnesium sulfate), proposed indications (Gastrointestinal lavage indicated for cleansing of the colon in preparation for colonoscopy in adults), strength (17.5 g/3.13 g/1.6 g), dose (see Section 1.3), frequency of administration (twice, prior to colonoscopy), route of administration (oral) and dosage form (concentrated solution, requires dilution). Appendix A provides a more detailed listing of the product characteristics the medication error staff generally takes into consideration.

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

2.1.1.1 Database and Information Sources

The proposed proprietary name, SuPrep Bowel Prep Kit, was provided to the medication error staff to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to SuPrep Bowel Prep Kit using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, the medication error staff 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, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

2.1.1.2 CDER Expert Panel Discussion

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

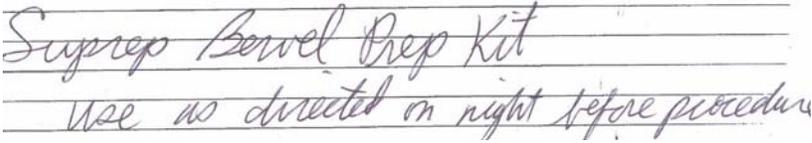
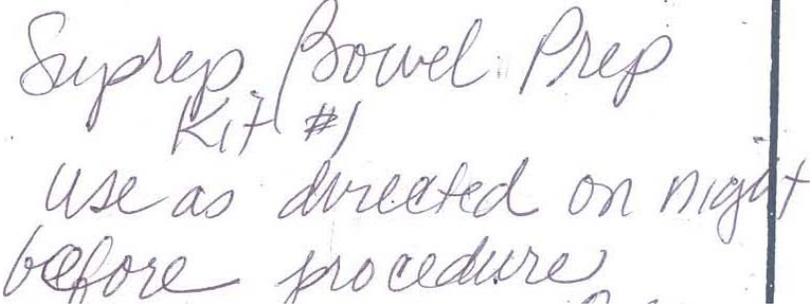
The pooled results of the DMEPA staff were presented to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name. As part of the Expert Panel Discussion, the group also provides handwriting samples of the proposed proprietary name along with other look-alike names identified by the panel and the Safety Evaluator.

2.1.2 FDA Prescription Analysis Studies

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

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

Figure 1. 1010 Study (conducted on October 8, 2008)

HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p>  <p>The handwritten text reads: "SuPrep Bowel Prep Kit" followed by "use as directed on night before procedure".</p>	<p>SuPrep Bowel Prep Kit Number 1 Use as directed on night before procedure</p>
<p><u>Outpatient Medication Order:</u></p>  <p>The handwritten text reads: "SuPrep Bowel Prep Kit #1" followed by "use as directed on night before procedure".</p>	

2.1.3 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Mode and Effects Analysis and provide an overall risk of name confusion. Failure Mode

and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁶ When applying FMEA to assess the risk of a proposed proprietary name, the Division seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, expert panel evaluation, and studies, and identifies potential failure modes by asking: “Is the name SuPrep Bowel Prep Kit convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?” An affirmative answer indicates a failure mode and represents a potential for SuPrep Bowel Prep Kit to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

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

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

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].

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

2. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. DMEPA identifies a potential source of medication error within the proposed proprietary name. The proprietary name may be misleading, or inadvertently introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

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

If none of these conditions are met, then DMEPA will not object to the use of the proprietary name. If any of these conditions are met, then we will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Applicant; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the Institute of Medicine, World Health Organization, Joint Commission on the Accreditation of Healthcare Organizations and the Institute for Safe Medication Practices, who have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

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

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

If we object to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the FMEA process is used to identify strategies to reduce the risk of medication errors. We are likely to recommend that the Applicant select an alternative

proprietary name and submit the alternate name to the Agency for us to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name, and so we may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

2.2 LABEL AND LABELING RISK ASSESSMENT

The label and labeling of a drug product are the primary means by which practitioners and patients (depending on configuration) interact with the pharmaceutical product. The container label and carton labeling communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on. The insert labeling is intended to communicate to practitioners all information relevant to the approved uses of the drug, including the correct dosing and administration.

Given the critical role that the label and labeling has in the safe use of drug products, it is not surprising that 33 percent of medication errors reported to the USP-ISMP Medication Error Reporting Program may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.⁷

Because the DMEPA staff analyzes reported misuse of drugs, the staff are able to use this experience to identify potential errors with all medication similarly packaged, labeled or prescribed. We use FMEA and the principles of human factors to identify potential sources of error with the proposed product labels and insert labeling, and provided recommendations that aim at reducing the risk of medication errors.

For this product, the review division forwarded the following label and labeling for our review on September 9, 2008 (See Appendix E):

- Container Label
- Carton Labeling
-  (b) (4)
- Insert Labeling (no image)

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Database and Information Sources

For this review, the DMEPA staff identified 15 names as having some similarity to the name SuPrep Bowel Prep Kit. The names Supprelin, Dulcolax Bowel Prep Kit,  (b) (4), and Halflytely & Bisacodyl Bowel Prep Kit were thought to look like SuPrep Bowel Prep Kit. Suprane, Subutex, Suprema Powder, Suprema Tablets, Supresol, Supressin, and Supprelin LA were thought to sound like SuPrep Bowel Prep Kit. The four remaining names, Suprax, Supres, Suprex, and Suprep were thought to look and sound like SuPrep Bowel Prep Kit.

A search of the United States Adopted Name stem list on October 10, 2008 identified no USAN stem names within the proposed name, SuPrep Bowel Prep Kit.

⁷ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006. p275.

3.1.2 Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by the staff (see section 3.1.1. above) but did not identify any additional names with similarity to SuPrep Bowel Prep Kit. The Expert Panel discussed safety issues regarding the mixing of the 2 bottles. Should the package include two mixing bottles to ensure that patients understand that two different doses are required, or can this be handled in the labeling? The panel also discussed the Spanish instructions and whether DMEPA should provide a review for other languages. Additionally, the panel discussed the likelihood of providers capitalizing the letter ‘P’ and how this would effect the scripting of the proprietary name.

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

3.1.3 FDA Prescription Analysis Studies

A total of 29 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. About 52% of the participants (n=15) interpreted the name correctly as “SuPrep Bowel Prep Kit” with correct interpretation occurring more frequently in the written studies. The majority of misinterpretations occurred in the phonetic prescription study, and misinterpreted the ‘u’ as ‘y’, ‘ep’ for ‘ex’ or ‘es’ and the ‘Su’ as ‘Food’, ‘Fu’ or ‘Flu’. Of note, about 24% of the participants (n=7) dropped the ending ‘Bowel Prep Kit’ and only reported Suprep on the prescription response. Additionally, neither outpatient, inpatient prescriptions or the voice prescriptions were written with the ‘P’ capitalized, therefore no responses had the capital letter ‘P’. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 Safety Evaluator Risk Assessment

Independent searches by the primary Safety Evaluator did not identify any additional names which were thought to look or sound similar to SuPrep Bowel Prep Kit and represent a potential source of drug name confusion. Attempts to identify two drug names identified by EPD, Suprema Powder and Suprema Tablets were unsuccessful. The names Suprema C Powder and Suprema C Tablets were identified, thus we assume that these names were misspelled during the search process (i.e. Suprema Powder for Suprema C Powder and Suprema Tablets for Suprema C Tablets) and evaluated Suprema C Powder and Suprema C Tablets.

3.2 LABEL AND LABELING RISK ASSESSMENT

Upon review of the container and carton labeling the Division of Medication Error Prevention and Analysis identified several areas of vulnerability that could lead to medication errors.

3.2.1 Container Label

The label does not indicate that there is one bottle for each dose.

The label does not indicate that further dilution is needed.

The ingredients are not listed with their corresponding strengths.

The primary display panel contains the statement, [REDACTED] ^{(b) (4)} and ‘Rx only’.

3.2.2 Carton Labeling

The instructions on panel 2 do not emphasize using bold letters the first 6 ounce bottle and second 6 ounce bottle.

Instructions for use only include directions for the overnight regimen [REDACTED] (b) (4)

The ingredients are not listed with their corresponding strengths.

[REDACTED] (b) (4)

3.2.3 Package Insert Labeling

Only the volume, and not the actual strength in grams, is included in Dosage Form and Strength section.

3.2.4 Capital Letter ‘P’

The capital letter ‘P’ is arbitrarily used in the ‘SuPrep’ component of the proposed proprietary name, SuPrep Bowel Prep Kit.

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

The applicant submitted the proposed proprietary name, SuPrep Bowel Prep Kit. The applicant has chosen to capitalize the letter ‘P’ in SuPrep. We believe that the capitalization of the letter ‘P’ in the proposed name, SuPrep Bowel Prep Kit, will vary in practice. Of note all participants in the prescription studies failed to capitalize the letter ‘P’ in SuPrep. Phonetically, “SuPrep” is identical to “Suprep”, because of this DMEPA prefers the name to appear in standard case (upper case, lower case) presentation. For these reasons we considered both an uppercase and lowercase presentation of the ‘p’ when evaluating the orthographic and phonetic similarity of name pairs.

We identified a total of 15 names as having some potential similarity to SuPrep Bowel Prep Kit. A Failure Mode and Effects Analysis (FMEA) was then conducted to determine if the proposed name, SuPrep Bowel Prep Kit, could potentially be confused with any of the 15 names and lead to medication error. This analysis determined that the name similarity between SuPrep Bowel Prep Kit and the identified names was unlikely to result in medication errors for the 15 names identified for the reasons described in Appendices C through G.

4.2 LABEL AND LABELING RISK ASSESSMENT

The results of the Label and Labeling Risk Assessment identified the following areas of needed improvement.

4.2.1 Inadequate Instructions for Use

The container labels can be improved to optimize comprehension of the directions for the bowel preparation process. Currently, the container labels do not indicate that two sequential doses are necessary prior to the procedure. The label on each bottle should emphasize that two separate doses are necessary to ensure full gastric emptying. The instructions on the carton label (designated as panel 2) must also highlight that two separate doses are necessary for proper bowel cleansing. This could be conveyed [REDACTED] (b) (4) Patients that are unfamiliar with the bowel preparation process may think that the whole kit should be taken at one time, which may result in inadequate cleansing of the bowel.

Additionally, the container label does not instruct that further dilution is required before consuming the bottle. If the patient were to consume the undiluted liquid, the patient is at increased risk of nausea and vomiting per the package insert. A prominent warning on the label to dilute the concentrated liquid will help the patients avoid unnecessary untoward effects from incorrect administration.

[REDACTED] (b) (4)

[REDACTED] (b) (4)

4.2.2 Lack of Required Information

The container label and carton labeling do not indicate the content in grams or milligrams of each individual active ingredient (sodium sulfate, potassium sulfate and magnesium sulfate) in accordance with 21 CFR 201.57 (c) (4). Additionally, the contents in grams or milligrams should be presented in the Dosage Form and Strength of the Package Insert section in accordance with CFR 21 201.57 (c) (5) (i). Ensuring the practitioners are aware of the actual strength and content of the medication is imperative to understand how the addition of these electrolytes may affect each patient.

4.3.3 Duplicative Information

The container label contains a statement, [REDACTED] (b) (4) as well as the 'Rx Only' statement. Since the product name includes 'Bowel Prep Kit', the [REDACTED] (b) (4) statement is unnecessary. [REDACTED] (b) (4)

4 CONCLUSIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, SuPrep Bowel Prep Kit, is not vulnerable to name confusion that could lead to medication errors. As such, we do not object to the use of the proprietary name, SuPrep Bowel Prep Kit, for this product. Additionally, DDMAC does not object to the proposed name, SuPrep Bowel Prep Kit, from a promotional perspective.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

The Label and Labeling Risk Assessment findings indicate that the presentation of information on the proposed container labels introduces vulnerability to confusion that could lead to medication errors. We believe the risks identified can be addressed and mitigated prior to drug approval, and provide recommendations in Section 5.2 that aim at reducing the risk of medication errors.

5 COMMENTS AND RECOMMENDATIONS

5.1 COMMENTS TO THE DIVISION

We would be willing to meet with the Division for further discussion, if needed. Please copy us on any communication to the applicant with regard to this review. If you have further questions or need clarifications, please contact Cheryle Milburn, project manager, at 301-796-2084.

5.2 COMMENTS TO THE APPLICANT

5.2.1. *Proprietary Name*

We have completed our review of the proposed proprietary name, SuPrep Bowel Prep Kit, and have concluded that it is acceptable. However, SuPrep Bowel Prep Kit will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you. If any of the proposed product characteristics are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

5.2.2 *Labels and Labeling*

Based upon our assessment of the labels and labeling, we have identified the following areas of needed improvement:

1. Container Label
 - a. The proprietary name submitted contains a capitalized 'P' in the middle of the name. We believe that the capitalization of the letter 'P' in the proposed name, SuPrep Bowel Prep Kit, will vary in practice. Thus, we request the name be revised so that the 'p' is in lower case.
 - b. Each bottle should emphasize that two separate doses are necessary for treatment. This could be conveyed (b) (4)
 - c. The label should indicate that further dilution is required prior to ingesting the liquid.
 - d. The container label should indicate the corresponding strengths of each ingredient (i.e. Sodium sulfate, Potassium sulfate, and Magnesium sulfate for Oral Solution, 17.5 g/3.13 g/1.6 g) in accordance with CFR 21 201.57 (c) (4).
 - e. Remove the statement, (b) (4)
2. Carton Labeling
 - a. (b) (4)
 - b. Include instructions for (b) (4) the overnight regimen (b) (4)
 - c. The carton labeling should indicate the corresponding strengths of each ingredient (i.e. Sodium sulfate, Potassium sulfate, and Magnesium sulfate for Oral Solution, 17.5 g/3.13 g/1.6 g) in accordance with CFR 21 201.57 (c) (4).

3. Package Insert

Ensure that the strength of each ingredient in the SuPrep Bowel Prep Kit is included in the Dosage Form and Strength section to be in accordance with Physician Labeling Requirements (PLR) 21CFR 201.57(c)(4)(i).

6 REFERENCES

1. ***Micromedex Integrated Index*** (<http://weblern/>)

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. This is a database which was created for The Division of Medication Error Prevention, FDA.

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

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

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

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

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

This is a list of proposed and pending names that is generated by the Division 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](#) and [generic drugs](#) and [therapeutic biological products](#); [prescription](#) and [over-the-counter](#) human drugs and [therapeutic biologicals](#), [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

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

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

8. ***United States Patent and Trademark Office*** <http://www.uspto.gov>.

Provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online*** (<http://weblern/>)

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

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

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

11. Natural Medicines Comprehensive Databases (<http://weblern/>)

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

12. Stat!Ref (<http://weblern/>)

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

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

List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

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

However, because the Applicant has little control over how the name will be spoken in practice, we also consider a variety of pronunciations that could occur in the English language.

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

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

Appendix B: FDA Prescription Study Responses- SuPrep Study 1010

Inpatient Medication Order	Voice Prescription	Outpatient Medication Order
Suprep	Suprep	Syprep Bowel Prep
Suprep Bowel Prep Kit	Food Prep bowel prep kit	Suprep Bowel Prep Kit
Suprep bowel prep kit	Suprep Bowel Prep Kit 24	Syprep Bowl Prep
Suprep Bowel prep kit	Suprep Bowel Prep Kit	Suprep Bowel Prep Kit
Suprep Bowel Prep Kit	Suprep	Supres Bowel Prep Kit
Suprep Bowel Prep Kit	Suprep Bowel Prep Kit	Suprep Bowel Prep
Suprex	Suprep	Syprep
Suprep	Fuprep Bowel Prep Kit	Suprep Bowel Prep Kit
Suprep Bowel Prep Kit	Suprep Bowel Prep Kit	
	Suprep Bowel Prep Kit	
	Suprep bowel prep kit	
	Fluprep-bowel prep kit	

Appendix C: Foreign Drugs Identified As Look-Alike and/or Sound-Alike

Drug Name	Similarity to SuPrep Bowel Prep Kit	Country
Supressin (Doxazosin)	Sound-Alike	Austria
Supresol (Methylprednisolone)	Sound-Alike	Italy
Supres Hydralazine hydrochloride Methyldopa/Chlorothiazide	Look-Alike and Sound-Alike	Australia-no longer actively marketed (Hydralazine) Canada-no longer actively marketed (Methyldopa/ Chlorothiazide)
Suprex (Co-trimaxazole)	Look-Alike and Sound-Alike	Phillipines

Appendix D: Similar name patented by Braintree Laboratories (Applicant for SuPrep Bowel Prep Kit)

Name reported in EPD	Source
Suprep	SAEGIS

Appendix E: Expired tradename found in USPTO, no drug associated with name

Name reported in EPD	Date expired
(b) (4)	

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

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
<p>SuPrep Bowel Prep Kit (Sodium sulfate, Potassium sulfate and magnesium sulfate for Oral Solution)</p>		<p>17.5 g/3.13 g/1.6 g per six ounce bottle</p>	<p>Overnight Preparation: One six ounce bottle mixed with 16 ounce of water one day prior to colonoscopy, 10 to 12 hours after first dose, follow with another six ounce bottle mixed with 16 ounce of water.</p> <p>(b) (4)</p>
<p>Supprelin (Histrelin acetate)</p> <p>(Withdrawn by Commissioner 9/17/2003)</p> <p>Now available as Vantas</p>	<p>Look</p>	<p>0.2 mg/mL, 0.5 mg/mL, 1 mg/mL injection</p>	<p>Vantas—50 mg Histrelin implant inserted once every 12 months in the inner aspect of the upper arm</p>
<p>Dulcolax Bowel Prep Kit (Bisacodyl)</p>	<p>Look</p>	<p>(Four) 5 mg oral tablets and (one) 10 mg rectal suppository</p>	<p>Take tablets orally the evening before procedure and insert the suppository rectally 1 to 2 hours before procedure.</p>
<p>Halflytely & Bisacodyl Bowel Prep Kit (PEG-3350, Sodium chloride, Sodium bicarbonate, Potassium chloride oral solution and bisacodyl delayed release tablet</p>	<p>Look</p>	<p>Two liters of liquid, (two) 5 mg bidacodyl oral tablets</p>	<p>Dose: 1 day prior to colonoscopy take two tablets orally followed by 2 liters of Halflytely solution, taken as 8 ounces every 10 minutes</p>

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
SuPrep Bowel Prep Kit (Sodium sulfate, Potassium sulfate and magnesium sulfate for Oral Solution)		17.5 g/3.13 g/1.6 g per six ounce bottle	Overnight Preparation: One six ounce bottle mixed with 16 ounce of water one day prior to colonoscopy, 10 to 12 hours after first dose, follow with another six ounce bottle mixed with 16 ounce of water. <div style="background-color: #cccccc; padding: 5px; margin-top: 10px;">(b) (4)</div>
Suprax (Cefixime)	Look and Sound	200 mg, 400 mg oral tablet 100 mg/5 mL, 200 mg/5 mL oral suspension	Acute exacerbation of COPD: (adult) 400 mg orally per day given once or twice daily, (pediatric) 8 mg/kg/day orally given once or twice daily Acute Bronchitis: (adult) 400 mg orally per day given once or twice daily, (pediatric) 8 mg/kg/day orally given once or twice daily Uncomplicated Gonorrhea: (adult) Single oral dose of 400 mg or 800 mg Pharyngitis, Tonsillitis, Uncomplicated urinary tract infection: 400 mg orally per day given once or twice daily
Subutex (Buprenorphine hydrochloride)	Sound	2 mg, 8 mg sublingual tablet	12 mg to 16 mg sublingually as a single daily dose
Suprema C (Vitamin C, Selenium, Bioflavonoids)	Sound	2500 mg Vitamin C, 65 mcg Selenium, 150 mg Bioflavonoids/5mL oral powder 500 mg Vitamin C, 6 mcg Selenium, 10 mg Bioflavonoids per oral tablet	1 tablet or teaspoonful as needed for vitamin deficiency

Appendix G: Names of products with only one strength but differentiating product characteristic(s)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Other differentiating product characteristics
<p>SuPrep Bowel Prep Kit (Sodium sulfate, Potassium sulfate and magnesium sulfate for Oral Solution)</p>		<p>17.5 g/3.13 g/1.6 g per six ounce bottle</p>	<p>Overnight Preparation: One six ounce bottle mixed with 16 ounce of water one day prior to colonoscopy, 10 to 12 hours after first dose, follow with another six ounce bottle mixed with 16 ounce of water.</p> <p>(b) (4)</p>	
<p>Supprelin LA</p>	<p>Sound</p>	<p>50 mg subcutaneous implant</p>	<p>One 50 mg implant every 12 months placed subcutaneously</p>	<p>Route of administration (oral vs. subcutaneous)</p> <p>Dosage form (liquid concentrate vs. implant, which must be implanted by a health care provider)</p> <p>Dose (six ounce bottles vs. 50 mg)</p>
<p>Suprane (Desflurane)</p>	<p>Sound</p>	<p>99.9 %; 240 mL vial, liquid for inhalation</p>	<p>Dose delivered via vaporizer specifically designed for desfluarne. Dose depends on age and whether given with a benzodiazepine or opiate. Minimum alveolar concentration (MAC) of 2.3 to 6.9</p>	<p>Route of administration (oral vs. inhalation via vaporizer)</p> <p>Dose (six ounce bottles vs. based on minimum alveolar concentration (MAC))</p> <p>Suprane requires a vaporizer specifically designed for Desflurane</p>

Appendix H: Container and Carton Label

(b) (4)



8 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page.

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this page is the manifestation of the electronic signature.**

/s/

Anne Crandall
4/16/2009 10:42:36 AM
DRUG SAFETY OFFICE REVIEWER

Kristina Arnwine
4/16/2009 11:47:26 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
4/16/2009 12:40:04 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
4/16/2009 04:48:54 PM
DRUG SAFETY OFFICE REVIEWER