CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022510Orig1s000

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

Application Type/Number:	NDA 022510
Through:	Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Kristina A. Toliver, PharmD, Team Leader Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Abstral (Fentanyl Citrate) (b) (4) Tablets 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg
Applicant:	ProStrakan Inc
OSE RCM #:	2010/2596

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

1 INTRODUCTION

This re-assessment of the proprietary name responds to the anticipated approval of NDA 022510 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Abstral, acceptable in OSE Reviews #2009-1587, dated November 19, 2009 and 2009-2773 dated August 6, 2010. The Division of Anesthesia and Analgesia Products did not have any concerns with the proposed name, Abstral, during our initial review. Additionally, the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on November 4, 2009, and May 20, 2010.

2 METHODS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 6) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We use the same search criteria outlined in OSE Review #2009-1587, for the proposed proprietary name, Abstral. None of the product characteristics for Abstral have been altered since our previous review, thus we did not re-evaluate previous names of concern. Additionally, DMEPA searches 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.

3 RESULTS

The safety evaluator searches of the databases listed in Section 5 did not identify any additional names thought to look similar to Abstral 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 December 23, 2010.

4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Abstral, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Abstral, 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 Anesthesia and Analgesia Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

5 REFERENCES

1. Toliver, K. OSE Review #2009-2773: Proprietary Name Review for Abstral. August 6, 2010.

2. Cantin, L. OSE Review #2009-1587: Proprietary Name Review for Abstral. November 19, 2009.

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 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.

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

/s/

DENISE P TOYER on behalf of KRISTINA C ARNWINE
12/29/2010

DENISE P TOYER
12/29/2010

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

Application Type/Number:	NDA 022510
Through:	Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Kristina A. Toliver, PharmD, Team Leader Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Abstral (Fentanyl Citrate) (b) (4) Tablets 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg
Applicant:	ProStrakan Inc
OSE RCM #:	2009-2773

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

1 INTRODUCTION

This re-assessment of the proprietary name responds to the anticipated approval of NDA 022510 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Abstral, acceptable in OSE Review #2009-1587, dated November 19, 2009. The Division of Anesthesia and Analgesia Products did not have any concerns with the proposed name, Abstral, during our initial review. Additionally, the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on November 4, 2009, and May 20, 2010.

2 METHODS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 6) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We use the same search criteria outlined in OSE Review #2009-1587, for the proposed proprietary name, Abstral. None of the product characteristics for Abstral have been altered since our previous review, thus we did not re-evaluate previous names of concern. Additionally, DMEPA searches 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.

3 RESULTS

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of August 4, 2010.

However, the safety evaluator searches of the databases listed in Section 5 identified one additional name, (b) (4) thought to look similar to Abstral and represent a potential source of drug name confusion.

Failure mode and effect analysis (FMEA) was applied to determine if the proposed name could potentially be confused with any of the name and lead to medication errors. This analysis determined that the name similarity between Abstral and (b) (4) was unlikely to result in medication errors for the reasons presented in Appendix A.

4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Abstral, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Abstral, 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.

5 REFERENCES

1. Cantin, L. OSE Review #2009-1587: Proprietary Name Review for Abstral. November 19, 2009.

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 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.

APPENDIX

<u>Appendix A:</u> Proposed proprietary names that have never been marketed.

Proprietary Name	Similarity to Abstral	Reason for Discard
(b) (4)		

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22510	ORIG-1	PROSTRAKAN INC	Abstral (fentanyl citrate) (b) (4) tablets

---

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

/s/

KRISTINA C ARNWINE
08/06/2010

DENISE P TOYER
08/06/2010

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:	November 17, 2009
To:	Bob Rappaport, Director Division of Anesthesia, Analgesia, and Rheumatology 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 (DMEPA)
From:	Lori Cantin, R.Ph., Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Abstral (Fentanyl Citrate) (b) (4) Tablets 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg
Application Type/Number:	NDA 022510
Applicant/Applicant:	ProStraken Inc.
OSE RCM #:	2009-1587

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

CONTENTS

EXECUTIVE SUMMARY 3
1 BACKGROUND 3
1.1 Introduction 3
1.2 Product Information 3
2 METHODS AND MATERIALS 4
2.1 Search Criteria 4
2.2 FDA Prescription Analysis Studies 5
3 RESULTS 5
3.1 Database and Information Sources 5
3.2 Expert Panel Discussion 6
3.3 FDA Prescription Analysis Studies 6
3.4 Comments from the Division of Anesthesia, Analgesia and Rheumatology Products (DAARP) 6
3.5 Safety Evaluator Risk Assessment 6
4 DISCUSSION 6
5 CONCLUSIONS AND RECOMMENDATIONS 7
6 COMMENTS TO THE APPLICANT 7
6.1 Proposed Proprietary Name 7
7 REFERENCES 8
APPENDICES 10

EXECUTIVE SUMMARY

Abstral is the proposed proprietary name for the currently approved product, Fentanyl Citrate (b) (4) Tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Abstral, acceptable for this product.

The proposed proprietary name must be re-reviewed 90 days before approval of the NDA. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to the August 25, 2009, request from the Applicant, ProStraken Inc., for an assessment of the proposed proprietary name, Abstral, regarding potential name confusion with other proprietary or established drug names. Additionally, the container labels, carton and package insert labeling were submitted for review and comment on August 5, 2009, and will be reviewed under separate cover.

DMEPA notes that the Applicant refers to the dosage form for this product as an (b) (4) and believes that the more accurate dosage form designation for this product is Sublingual Tablet. The Abstral drug product is intended to be placed under the tongue until it is completely dissolved, and its absorption is via the sublingual route, whereas an (b) (4) is typically dissolved on top of the tongue and then swallowed, with absorption occurring in the gastrointestinal tract. This issue was discussed with the ONDQA reviewer and the Labeling and Nomenclature Committee, who also recommended that the dosage form be designated as 'Sublingual Tablet'. A final decision on this issue is pending and will be further addressed in the label and labeling review for this product.

1.2 PRODUCT INFORMATION

ABSTRAL PRODUCT INFORMATION	
Mechanism of Action	μ-Opioid Agonist
Indication for Use	Management of breakthrough pain in cancer patients who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain.
Usual Dose	• All patients should start therapy with a single 100 microgram tablet. ➢ If adequate analgesia is obtained within 30 minutes of administration of the 100 microgram tablet, patients should continue to treat subsequent episodes of breakthrough pain with this dose. ➢ If adequate analgesia is not obtained within 30 minutes of administration of the first dose, a supplemental (second) dose of the same strength tablet (i.e. 100 micrograms in this case) may be administered. No more than one supplemental dose may be taken for a particular breakthrough episode.

ABSTRAL PRODUCT INFORMATION	
	➢ Patients should wait at least 2 hours before treating another episode of breakthrough pain with ABSTRAL • If adequate analgesia was not obtained with the first 100 microgram dose, the next episode should be treated with a 200 microgram dose. If adequate analgesia is not obtained within 30 minutes of this new dose, a supplemental dose of the same strength (in this case 200 microgram) can again be administered and an increase in dose to the next highest tablet strength should be considered for the next episode of breakthrough pain (refer to figure below). • Dose escalation should continue in a stepwise manner over consecutive breakthrough episodes until adequate analgesia is achieved. • The dose strength for the supplemental (second) sublingual tablet should be equivalent to the initial dose taken for a particular episode.
Dosage Form	(b) (4) Tablet (see Section 1.1 for additional information related to the dosage form designation).
Product Strengths	100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg
Route of Administration	Sublingual
Frequency of Administration	Every 2 hours as needed
Storage Requirements	Store at 20 to 25°C (68 to 77°F); excursions permitted between 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].
How Supplied	Tablets in individually sealed child-resistant blister cards containing 4 tablets, in pack sizes of 12 (100 mcg, 200 mcg, 300 mcg, and 400 mcg strengths), and 32 (all strengths)

2 METHODS AND MATERIALS

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

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'A' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Abstral the DMEPA staff also consider the other orthographic appearance of the name on lined and unlined orders. Specific attributes taken into

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

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

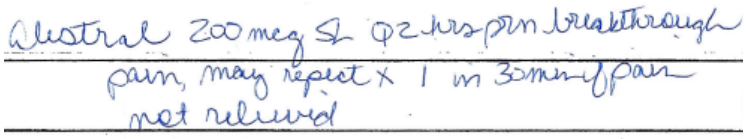
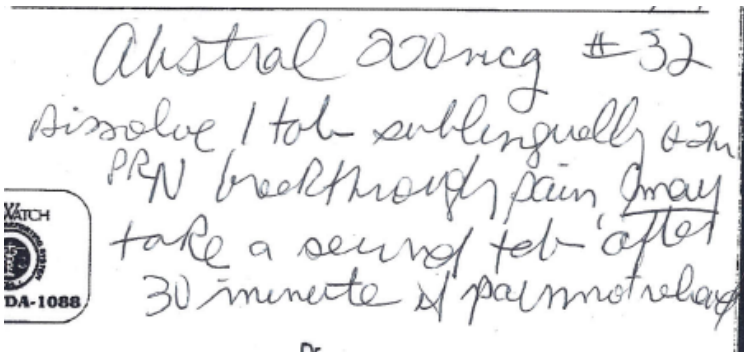
consideration include the length of the name (seven letters), upstrokes (four, 'A', 'b', 't' and 'l'), down-strokes (none), cross-strokes (one, 't'), and dotted letters (none). Additionally, several letters in Abstral may be vulnerable to ambiguity when scripted (see Appendix C). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Abstral.

When searching to identify potential names that may sound similar to Abstral, the DMEPA staff search for names with similar number of syllables (two), stresses (AB-stral, ab-STRAL), and placement of vowel and consonant sounds. The DMEPA staff also considers that pronunciation of parts of the name can vary such as "-stral" may sound like "-strol". Additionally, several letters in Abstral may be subject to interpretation when spoken (see Appendix B). The Applicant's intended pronunciation of the proprietary name was not provided with the proposed name submission, thus it could not be considered in this review.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

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

Figure 1. Abstral Study 0914 (conducted on September 14, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order: 	Abstral 100 mcg #32 Dissolve 1 tablet SL q2hrs PRN UD
Outpatient Medication Order: 	

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of twelve (12) names as having some similarity to the name Abstral.

Eleven (11) of the names were thought to look like Abstral. These names are: Atralin, Colestid, Allerhist, Abelcet, Ala-hist, Habitrol, Acetasol, Acthrel, Statrol, (b) (4) and Avastin.

One (1) name was thought to look and sound similar to Abstral. This name is: Abstral.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of September 23, 2009.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Abstral. DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 21 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. A total of 12 participants (11 from the outpatient prescription study) interpreted the name correctly as "Abstral." The remainder of the participants misinterpreted the drug name. All four (4) practitioners who responded to the inpatient prescription study misinterpreted the name incorrectly as 'Alestral'. The other five (5) misinterpretations occurred in the verbal prescription study, where the responses differed from Abstral by only 1 or 2 letters (n=9). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 COMMENTS FROM THE DIVISION OF ANESTHESIA, ANALGESIA AND RHEUMATOLOGY PRODUCTS (DAARP)

In response to the OSE September 9, 2009, e-mail, DAARP did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

DMEPA notified DAARP, via e-mail, that we had no objections to the proposed proprietary name, Abstral, on September 25, 2009. Per e-mail correspondence from the Division on October 21, 2009 they indicated they concur with our assessment of the proposed proprietary name, Abstral.

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified two (2) additional names which were thought to look or sound similar to Abstral and represent a potential source of drug name confusion. The two names, Sectral and Cartrol, were thought to look similar to Abstral. One (1) additional name, Actiq, was evaluated due to similar product characteristics shared with Abstral.

4 DISCUSSION

DDMAC had no concerns with the proposed name and neither did the Division of Anesthesia, Analgesia, and Rheumatology Products.

DMEPA did not identify aspects of the name that would render it unacceptable other than names with similar appearances and sound to Abstral. In total, DMEPA identified and evaluated fifteen (15) names for their potential similarity to the proposed name, Abstral. One (1) name, Abstral, was identified as the same drug product that is currently marketed in several countries, including the United Kingdom, Spain, Germany and France, by the same sponsor for this NDA, ProStraken Inc., and thus was not evaluated further. Two (2) names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix D). One (1) name was for a discontinued drug product that does not have an available generic equivalent and was not evaluated further (see Appendix E).

Failure mode and effect analysis (FMEA) was then applied to determine if the potential name could potentially be confused with the remaining eleven (11) names and lead to medication errors. This analysis determined that the name similarity between Abstral was unlikely to result in medication errors with any of the 11 products for the reasons presented in Appendices F through H.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Abstral, does not contribute to medication errors, nor is it promotional. Thus, the Division of Medication Error Prevention and Analysis has no objection to the proposed proprietary name, Abstral, for this product.

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.

If you have further questions or need clarifications, please contact Abolade Adeolu, Safety Regulatory Project Manager, at 301-796-4264.

6 COMMENTS TO THE APPLICANT

6.1 PROPOSED PROPRIETARY NAME

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

Abstral 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.

7 REFERENCES

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

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

2. Phonetic and Orthographic Computer Analysis (POCA)

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

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

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

4. AMF Decision Support System [DSS]

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

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

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

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

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

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

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

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[5] DMEPA provides the product characteristics considered for this review in section one. Additionally, in this review, DMEPA considered the fact that the Applicant refers to the dosage form for this drug product as an (b) (4) when the more accurate dosage form designation for this product is 'Sublingual Tablet'. Both dosage form designations were considered when evaluating the proposed proprietary name, as a final determination regarding the dosage form designation for this product was pending at the time of this review.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products

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

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

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

because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name similarity	*Attributes examined to identify similar drug names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-stokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

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

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

3. FDA Prescription Analysis Studies

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

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

4. Comments from the OND review Division or Generic drugs

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

The OND or 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 concur/not concur with DMEPA's final decision.

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, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[6] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses 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

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

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.

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

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

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant 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. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, 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 approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate

the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. (See Section 4 for limitations of the process).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name: Abstral	**Scripted may appear as**	**Spoken may be interpreted as**
Upper case 'A'	S, Ce, Ci	O
Lower case 'b'	le, h, k	v
Lower case 's'	r,	z
Lower case 't'	x, f	
Lower case 'r'	n, v, u;	
Lower case 'a'	e, o, u	o
Lower case 'l'	'al' may appear as 'd'	

Appendix C: FDA Prescription Study Responses

Inpatient Medication Order	**Outpatient Medication Order**	**Voice Prescription**
Alestral	Abstral	Absrol
Alestral	Abstral	Abstral
Alestral	Abstral	Abstrol
Alestral	Abstral	Abstrall
	Abstral	Abstrol
	Abstral	Abstrol
	Abstral	
	Abstral	
	Abstral	
	Abstral	
	Abstral	

Appendix D: Names Lacking Orthographic and/or Phonetic Similarity to Abstral

Name	Similarity to Abstral
Allerhist	Look
Acetasol	Look

Appendix E: Drug products that are discontinued and no generic equivalent is available

Proprietary Name	Similarity to Abstral	Status and Date
Statrol (Neomycin sulfate and Polymixin B sulfate)	Look	Discontinued per Orange Book: NDA 50344 (ophthalmic ointment) NDA 50456 (ophthalmic solution) NDA 62339 (ophthalmic solution) No generic ophthalmic preparations containing only neomycin and polymixin B are available

Appendix F: Products with no numerical overlap in strength, dose and/or route of administration

Abstral **(Fentanyl citrate)** (b) (4)	**N/A**	**100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg**	**Starting dose is 100 mcg, may repeat 100 mcg dose in 30 min if adequate analgesia not achieved; must wait at least 2 hours before treating another episode of breakthrough pain; dose escalation in a stepwise manner for pain not relieved by 100 mcg dose.** **Sig: Dissolve (XXX mg) sublingually every 2 hours as needed for breakthrough pain. (XXX mg) may be repeated in 30 minutes for pain not relieved by first dose**
Product name with potential for confusion	**Similarity to Proposed Proprietary Name**	**Strength**	**Usual Dose** **(if applicable)**
Atralin (Tretinoin) Topical Gel Rx	Look	0.5%	Apply a thin layer to the affected area(s) topically once daily at bedtime

Appendix F: Products with no numerical overlap in strength, dose and/or route of administration

Abstral **(Fentanyl citrate)** (b) (4) [redacted]	**N/A**	**100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg**	**Starting dose is 100 mcg, may repeat 100 mcg dose in 30 min if adequate analgesia not achieved; must wait at least 2 hours before treating another episode of breakthrough pain; dose escalation in a stepwise manner for pain not relieved by 100 mcg dose.** **Sig: Dissolve (XXX mg) sublingually every 2 hours as needed for breakthrough pain. (XXX mg) may be repeated in 30 minutes for pain not relieved by first dose**
Product name with potential for confusion	**Similarity to Proposed Proprietary Name**	**Strength**	**Usual Dose** **(if applicable)**
Ala-hist (Brompheniramine and Diphenhydramine) Tablet, Extended-Release Rx	Look	Single-strength product: 6 mg/25 mg per Tablet	1 to 2 tablets orally every 12 hours* (Note: not found in Facts and Comparisons, Clinical Pharmacology Online, Drugs@FDA, 2009 Red Book or LexiComp Online) Unapproved, marketed product *Dosage and Administration information obtained from medscape.com
Habitrol (Nicotine) Transdermal Patch	Look	7 mg/24 hour, 14 mg/24 hour and 21 mg/24 hour	Apply one patch to intact skin once daily. Remove and replace patch every 24 hours.
(b) (4) [redacted]			
Cartrol (Carteolol hydrochloride) Tablets Rx	Look	2.5 mg and 5 mg	2.5 mg to 5 mg orally once daily

Appendix G: Products with overlap in strength, dose or achievable dose with multiple differentiating product characteristics

Product name with potential for confusion	**Similarity to Abstral**	**Strength**	**Usual Dose (if applicable)**	**Differentiating Product Characteristics (Abstral vs. Product)**
Abstral		**100 mcg 200 mcg 300 mcg 400 mcg 600 mcg 800 mcg**	**Dissolve (XXX mg) sublingually every 2 hours as needed for breakthrough pain. (XXX mg) may be repeated in 30 minutes for pain not relieved by first dose**	
Abelcet (Amphotericin B) Rx	Look	100 mg/20 mL vial Overlap in strength	3 to 6 mg/kg/day* intravenously at a rate not greater than 2.5 mg/kg/hour *Weight-based doses of Abelcet may overlap with Abstral 100 mcg, 200 mcg, 300 mcg, and 400 mcg doses	***Route of Administration:*** sublingual vs. intravenous ***Frequency:*** Every 2 hours as needed vs. once daily
Acthrel (Corticorelin ovine triflutate) Rx	Look	100 mcg/vial Overlap in strength	Single dose of 1 mcg/kg infused intravenously over 30 to 60 seconds	***Route of Administration:*** sublingual vs. intravenous ***Frequency:*** Every 2 hours as needed vs. one-time single dose
Avastin (Bevacizumab) Injection Rx	Look	25 mg/mL Available in 100 mg/4 mL and 400 mg/16 mL vials	5 mg/kg* or 10 mg/kg* intravenously every 14 days *Weight-based doses of Avastin may overlap with some doses of Abstral	***Route of Administration:*** sublingual vs. intravenous ***Frequency:*** Every 2 hours as needed vs. once every 14 days

Appendix G: Products with overlap in strength, dose or achievable dose with multiple differentiating product characteristics

Product name with potential for confusion	**Similarity to Abstral**	**Strength**	**Usual Dose (if applicable)**	**Differentiating Product Characteristics (Abstral vs. Product)**
Abstral		**100 mcg 200 mcg 300 mcg 400 mcg 600 mcg 800 mcg**	**Dissolve (XXX mg) sublingually every 2 hours as needed for breakthrough pain. (XXX mg) may be repeated in 30 minutes for pain not relieved by first dose**	
Colestid (Colestipol hydrochloride) Tablet Granules: available in packets or in a bottle with a scoop	Look	1 g Tablet* 5 g Packets 5 g per one level scoop	2 to 16 grams per day orally, divided once or twice daily 1 to 6 packets or level scoopfuls per day, divided once or twice daily *Dose similarity between 1 g tablet (1,000 mg) and 100 mcg dose of Abstral, however, it is expected that the strength/dose of Colestid would be written in grams	***Strength:*** 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg vs. 1 g or 5 g ***Frequency:*** Every 2 hours as needed vs. once or twice daily ***Units:*** mcg vs. grams/packets/scoopfuls

Appendix H: Potential confusing name with numerical similarity in strength or dose		
Abstral **(Fentanyl citrate)** (b) (4)	**100 mcg, 200 mcg, 300 mcg** **400 mcg, 600 mcg, 800 mcg**	**Dissolve (XXX mg) sublingually every 2 hours as needed for breakthrough pain. (XXX mg) may be repeated in 30 minutes for pain not relieved by first dose**
Failure Mode: Name confusion	**Causes** **(could be multiple)**	**Rationale**
Sectral (Acebutolol hydrochloride) 200 mg to 1,200 mg per day, divided once daily or twice daily (for doses greater than 400 mg)	**Orthographic similarities:** Similar name length (7 letters vs. 7 letters) 'A' can look like 'S' Both names end in with the same suffix 'tral' No downstrokes in either name No dotted letters in either name **Phonetic similarities:** The suffix "tral" is the same for both names Same number of syllables in both names **Product characteristic similarities:** *Strength Overlap:* 200 mcg vs. 200 mg *Dosage Overlap:* 200 mcg, 400 mcg, 600 mcg, 800 mcg vs. 200 mg, 400 mg, 600 mg, and 800 mg	Orthographic differences and phonetic differences in the names, in conjunction with differentiating product characteristics, minimize the likelihood of medication error due to name confusion in the usual practice setting. ***Rationale:*** **Orthographic Differences:** Abstral has 4 upstrokes, Sectral has 3 upstrokes The prefix 'Abs' does not look like the prefix 'Sec' **Phonetic Differences:** The prefixes "Abs" and "Sec" do not sound alike **Product Characteristic Differences:** *Frequency of Administration:* Dissolve (XXX mg) sublingually every 2 hours as needed for breakthrough pain. (XXX mg) may be repeated in 30 minutes for pain not relieved by first dose vs. once or twice daily Abstral is intended for "as needed" use for breakthrough pain in cancer patients and is not to be indicated for scheduled "around-the-clock" use, while Sectral us an antihypertensive/anti-arrhythmic that is administered on a regular once or twice daily schedule.

Appendix H: Potential confusing name with numerical similarity in strength or dose		
Abstral **(Fentanyl citrate)** (b) (4)	**100 mcg, 200 mcg, 300 mcg 400 mcg, 600 mcg, 800 mcg**	**Dissolve (XXX mg) sublingually every 2 hours as needed for breakthrough pain. (XXX mg) may be repeated in 30 minutes for pain not relieved by first dose**
Failure Mode: Name confusion	**Causes** **(could be multiple)**	**Rationale**
Actiq (Fentanyl Citrate) Lozenge for Oral and Transmucosal use Initial dose of Actiq for breakthrough pain is 200 mcg; dosage may be repeated in 30 minutes; dosage is titrated until adequate analgesia is achieved Available in: 200 mcg 400 mcg 600 mcg 800 mcg 1200 mcg 1600 mcg	**Orthographic similarities:** Both names begin with the letter 'A' Each name has 1 cross-stroke ('t') **Phonetic similarities:** Both names begin with the letter "A" Each name has two syllables **Product characteristic similarities:** *Strength overlap in the following strengths:* 200 mcg, 400 mcg, 600 mcg, 800 mcg *Achievable dose potential:* 1200 mcg and 1600 mcg doses are achievable with the available strengths of Abstral. *Active Ingredient:* Both products contain Fentanyl Citrate *Route of administration:* Both products are administered via the oral cavity *Frequency of use:* Same for both products *Indication for use:* Same for both products *DEA Schedule:* Both are Class II controlled substances	Orthographic differences and phonetic differences in the names minimize the likelihood of medication error due to name confusion in the usual practice setting. ***Rationale:*** **Orthographic Differences:** Abstral has 4 upstrokes, Actiq has 2 upstrokes Abstral has no downstrokes, Actiq has 1 downstroke ('q') Abstral has no dotted letters, Actiq has 1 dotted letter ('i') Abstral ends in an upstroke ('l'), Actiq ends in a downstroke ('q') Abstral contains 7 letters and Actiq contains 5 letters, thus Abstral appears longer when scripted With the exception of the first letter 'A', the names do not look similar when scripted **Phonetic Differences:** The prefixes "Ab-" and "Ac-" do not sound similar The suffixes "-stral" and "-tiq" do not sound similar

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22510	ORIG-1	PROSTRAKAN INC	FENTANYL CITRATE (b) (4)

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

/s/

LORI G CANTIN
11/17/2009

KRISTINA C ARNWINE
11/17/2009

DENISE P TOYER
11/19/2009

CAROL A HOLQUIST
11/19/2009